Mary Masters
P. O. Box 82043
San Diego, California 92138

Rec'd 7/13/01
1b

By Federal Express

June 8, 2001

Document Control Center
Secretary of U. S. Food and Drug Administration
1390 Piccard Drive, Room 26
Rockville, Maryland 20850

Dear Sir/Madam;

On behalf of myself, the claimant, I hereby submit (2) copies of my Petition for Declaration Under Title 21; Section 1604, Paragraph 2 (B)

Please return a date-stamped copy of this letter at the time of delivery.

If you have any questions, please do not hesitate to call.

Sincerely

Mary Masters

01P-0303

CP1

DEPARTMENT OF HEALTH AND HUMAN SERVICES
U.S. FOOD AND DRUG ADMINISTRATION

PETITION FOR DECLARATION UNDER TITLE 21; SECTION 1604 PARAGRAPH 2 (B)

Submitted by:
Mary Masters, Claimant
P. O. Box 82043
San Diego, California 92138

01P-0323

CP1

Appendix

1. Attachment 1: Letter to Dr. Barry Sands FDA: from Calcitek Dated 9/20/89

2. Attachment 2 Petition For Reclassification of a Medical Device Under Section 513 (e) Endosseous Dental Implants for Prosthetic Attachment

3. Attachment 3: Letter from FDA to Calcitek (Riichard LaRiviere) dated August 31, 1989.

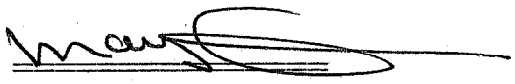
4. Attachment 4 Deposition of Richard LaRiviere Dated July 10, 1998 page 115-120

5. Attachment 5 Advertisement of "Biointegration" Verifying Calcitek trademark "Integral".

6. Stay Pending Petition for Declaration. Title 21; Section 1604 (3) (d)

I declare under penalty of perjury of the laws of the State of California that the foregoing attachments are true and correct copies.

June 8, 2001



Mary Masters

PETITION FOR DECLARATION

MARY MASTERS,
Petitioner - Claimant

CALCITEK, INC.
Manufacturer - Biomaterials Supplier

TO THE SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES U.S. FOOD AND DRUG ADMINISTRATION;

Pursuant to U. S. Code as of 01/05/99

Title 21, Chapter 21, Section 1604, Liability of biomaterials suppliers

(a) In general
Except as provided in section 1606 of this title, a biomaterials supplier shall not be liable for harm to a claimant caused by an implant unless such supplier is liable -

(1) as a manufacturer of the implant, as provided in subsection (b) of this section;

(2) as a seller of the implant, as provided in subsection (c) of this section; or
(3) for furnishing raw materials or component parts for the implant that failed to meet applicable contractural requirements or specification, as provided in subsection (d) of this section.

(b) Liability of manufacturer
(1) In general

A biomaterials supplier may,to the extent required and permitted by any other applicable law be liable for harm to a claimant by an implant if the biomaterials supplier is the manufacturer of the implant.

(2) Grounds for liability.

The biomaterial supplier may be considered the manufacturer of the implant that allegedly caused harm to a claimant only if the biomaterial supplier-

(a) (i) registered or was required to register with the Secretary pursuant to section 360 (j) of this title and the regulations issued are under such section; (B) is the subject of a declaration issued by the Secretary pursuant to paragraph (3) that states that the supplier, with respect to the implant that allegedly caused harm to the claimant, was required to -

(i) register with the Secretary under section 360 of this title, and the regulations issued under such section, but failed to do so; or (ii) include the implant on a list od devices filed with the Secretary pursuant to section 360 (j) of this title and the regulations issued under such section, but failed to do so; Calcitek, Inc. was required to register and Calcitek, Inc's registration number is 2023141, Letter from Calcitek, Inc. to Dr. Barry Sands dated September 20, 1989. (Attachment 1). Calcitek, Inc. was required to register pursuant to paragraph 2 (b), (A) (i) as evidenced by Petition For Reclassification of a Medical Device Under 513 (e) Endoseous Dental Implants for Prosthetic Attachment (Attachment 2)

A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by an implant if the claimant in an action shows, by a preponderance of the evidence, that -

(1) the biomaterials supplier supplied raw materials or component parts for sein the implant that either - (A) did not constitute the product described in the contract between the biomaterials supplier and the person who contracted

Grounds for liability: The biomaterials supplier may be considered the manufacturer of the implant that allegedly caused harm to a claimant only if the biomaterials supplier -

(A) (i) registered or was required to register with the Secretary pursuant to section 360 of this title and the regulations issued under such section; and

(ii) included or was required to include the implant on a list of devices filed with the Secretary pursuant to section 360 (i) of this title and the regulations issued under such section;

The manufacturer Calcitek, Inc. received a letter dated August 31, 1989 from William Damaska, Director , Division of Compliance Operations, Office of Compliance and Surveillance, Center For Devices and Radiological Health.

On page 1, paragraph 7, Mr. Damaska :

" that the purpose of this letter is to inform you that under Section 510 (k) of the Federal Food, Drug, and CosmeticAct (the Act) 21 U.S.C. 360 (k) changes or modifications that could significantly affect the safety or effectiveness of the device require a notification to the Food and Drug Admin istration (FDA) at least (90) days prior to introduction of the changed or modified device in commercial distribution in the United States. This requirement is accomplished by the submission of a Premarket Notification- 510 - (k). The information necessary to comply with the Premarket notification(510 (k)) requirement is found in 21 CFR Part 807, Subpart E - Premarket Notification (copy enclosed). "

On page 1, paragraph 8, Mr. Damaska:

"We would appreciate a response within 30 days describing action you have taken to achieve compliance with the Act or providing information which you believe substantiates your decision that a 510 (k) is not required." (Attachment 3)

On July 10, 1998, Mr. Richard LaRiviere was deposed for the State of California County of Range, California, Case No. 747549 entitled Connie Bentele vs. Calcitek, Inc. Mr. LaRiviere was asked the question page 115 paragraph 2: line 7-11

Q "Is your understanding that if a product is marketed with claims that are determined to not be substantially equivalent, then a product is misbranded."

page 115, line 21-25. page 116, lines 1-3.

A "Back in 1983-1985, when this product was first introduced, you simply had to have the evidence on file. Not until 1989, when the claims were challanged, did we realize or did we find out that the claims were not considered substantially equivalent, or substantiated. We believed we were in compliance."

page 116, lines 3-4

Q Despite your belief that you were in compliance, the FDA determined otherwise; correct?

Page 116: line 5

A Yes

page 116: lines 18-20

Q However, based on the FDA's ultimate determination, is it your understanding that what was on file ultimately was determined to not be adequate?

page 117: lines 11-21

Q You testified that Calcitek had placed certain information on file with

the FDA with regards to the claims that were placed on the brochures.

A Yes

Q You testified that Calcitek was under the impression that those claims were sufficient,

A Yes

Q The FDA ultimately determined that they were insufficient; correct?

A Correct.

The foregoing evidence is Attachment 4.

Title 21; Chapter 21; Section 1604; paragraph 3 (A) Administrative Procedures

(A) In general
The Secretary may issue a declaration described in paragraph (2) (B) on the motion of the Secretary or any petition by any person.

Claimant is filing this petition pursuant to paragraph 3 (A) Administrative Procedures.

(c) Liability of seller

A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable as a seller for harm to a claimant caused by an implant only if -

(A) held title to the implant and then acted as a seller of the implant after its initial sale by the manufacturer; or

Calcitek held title to the Integral implant a tradesman for Calcitek, Inc. See

Biointegration Integral (Attachment 5) It was falsely advertised as being FDA approved.

(2) (B) on the motion of the secretary or on petition by any person, after providing -

(i) notice to the affected persons; and
(ii) an opportunity for an informal hearing.

(B) Docketing and final decision

Immediately upon receipt of a petition filed pursuant to this paragraph, the Secretary shall docket the petition. Not later than 120 days after the petition is filed, the Secretary shall issue a final decision on the petition.

(C) Applicability of statute of limitations

Any applicable statute of limitations shall toll during the period from the time a claimant files a petition with the Secretary under this paragraph until such time as either (i) the Secretary issues a final decision on the petition, or (ii) the petition is withdrawn.

(D) Stay pending petition for declaration

If a claimant has filed a petition for a declaration with respect to a defendant, and the Secretary Has not issued a final decision on the petition, the court shall stay all proceedings with respect to that defendant until such time as the Secretary has issued a final decision on the petition.

(c) Liability as seller

A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable as a seller for harm to a claimant caused by an implant only if-

(1) the biomaterials supplier-

(A) held title to the implant and then acted as a seller of the implant after its initial sale by the manufacturer; or

(B) acted under contract as a seller to arrange for the transfer of the implant directly to the claimant after the initial sale by the manufacturer of the implant; or

(2) the biomaterials supplier is related by common ownership or control to a person meeting all of the requirements described in paragraph (1), if a court deciding a motion to dismiss in accordance with section 1605 (c) (3) (B) (ii) of this title finds on the basis of affidavits submitted in accordance with Section 1605 of this title, that it is necessary to impose liability on the biomaterials supplier as a seller because the related seller meeting the requirements of paragraph (1) lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail.

(d) liability for failure to meet applicable contractual requirements or

specifications A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by an implant if the claimant in an action shows, by a preponderance of the evidence, that -

(1) that the biomaterial supplier supplied raw materials or component parts for use in the implant that either -

(A) Did not constitute the product described in the contract between the biomaterial supplier and the person who contracted for the supplying of the product; or

(B) failed to meet any specifications that were-

(i) accepted, pursuant to applicable law, by the biomaterials supplier;

(ii) published by the biomaterials supplier;

(iii) provided by the biomaterials supplier to the person who contracted for such products;

(iv) contained in a master file that was submitted by the biomaterials supplier to the Secretary and that is currently maintained by the biomaterial supplier for purposed of premarklet approval of medical devices; or

(v) included in the submissions for purposes of premarket approval or review by the Secretary under section 360, 360c, 360e, or 360j of this title, and received clearance from the Secretary if such specifications were accepted, pursuant to applicable law, by the biomaterial supplier; and

(2) Such failure to meet applicable contractural requirements or specifications was an actual and proximate cause of the harm to the claimant.

Claimant has sustained severe bodily injuries, past, present and future, and to date has had 11 surgeries through March, 1999, resulting from injuries received from the Calcitek biomaterials. Present need for more surgeries at an additional expense of $45,000. Claimant is filing this Petition for Declaration as her expenses for surgeries are $107,000. Calcitek has denied liability and falsely told the court that their products are FDA approved; the contrary is true as evidenced by the proponderance of evidence in the enclosed attachments.

Dated: June 6, 2001 Respectively submitted,

Mary Masters - Claimant

PROOF OF SERVICE

I, Mary Masters declare, that I am over the age of eighteen years and that I am a party to this action. I served the following documernts on June 8, 2001 on the following parties:
DC. No. CV-99-02215-JNK No. 00-55904

Petition for Declaration: Request for Stay; Under Title 21, Section 1064 Paragraph 2 (B);Paragraph 360 (j)

Secretary of U. S. Food and Drug Administration original & 3 copies
1390 Piccard Drive, Room 26, Rockville, Maryland 20850

To The Clerk of the Court
Unitet States Court of Appeals
For the Ninth Circuit
95 Seventh Street
San Francisco, California 94103

Same day Service FED EX
06/10/01

Hugh Mc Cabe, Esq.
Thomas Dymott, Esq.
Neil, Dymott, Perkins, Brown & Frank
1010 Second Avenue, Suite 2500
San Diego, California 92101
(Attorneys for Calcitek)

Hand Carried: 6/10/01

Brian Rawers
Medill & Rawers
110 West C Street, Suite 1515
San Diego, Ca. 92101

Hand Carried: 6/10/01

I declare un the penalty of perjury, in the laws of the Stare of California, the foregoing is true and correct.

Dated: 06/102001_

Mary Masters Plaintiff- Appellee
P. O. Box 82043
San Diego, California 92138

Appendix

1. Attachment 1: Letter to Dr. Barry Sands FDA: from Calcitek Dated 9/20/89

2. Attachment 2 Petition For Reclassification of a Medical Device Under Section 513 (e) Endosseous Dental Implants for Prosthetic Attachment

3. Attachment 3: Letter from FDA to Calcitek (Riichard LaRiviere) dated August 31, 1989.

4. Attachment 4 Deposition of Richard LaRiviere Dated July 10, 1998 page 115-120

5. Attachment 5 Advertisement of "Biointegration" Verifying Calcitek trademark "Integral".

6. Stay Pending Petition for Declaration. Title 21; Section 1604 (3) (d)

I declare under penalty of perjury of the laws of the State of California that the foregoing attachments are true and correct copies.

June 8, 2001

Mary Masters

CALCITEK INC.

Calcitek, Inc.
[illegible]
[illegible] 92009
619 [illegible]-9515
[illegible] 91-775 CALCITEK SDG

September 20, 1989

REGISTERED MAIL

Mr. Barry Sands
Scientific Reviewer
Division of Obstetrics/Gynecology,
Ear, Nose, Throat and Dental Devices
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20857

RE: Integral (August 31, 1989 compliance letter)

Dear Mr. Sands:

In response to the above referenced compliance letter, Calcitek Inc., registration number 2023141, requests that the clinical information submitted to you during our September 19, 1989 meeting be accepted as a supplement to the above referenced 510(k). As we discussed in the meeting, we believe the data contained within that package substantiates the claims in question. As we agreed, pending review of the supplement, all distribution of the offending literature has ceased and journal ads not already printed have been pulled. Any interim use of literature making the claims in question will be done with the words "INVESTIGATIONAL CLAIMS UNDER REGULATORY REVIEW" clearly printed on the document.

I would like to extend my sincere gratitude to you and Mr. Uldriks for agreeing to see us on such short notice and look forward to swift resolution of this matter.

Please feel free to call me if I can be of further assisance.

Sincerely,

Richard Lariviere
Director Quality Assurance and Regulatory Affairs
(619)431-9515

cc: Mr. Casper Uldriks, Acting Deputy Chief,
Regulatory Compliance
Mr. James Fraser
Mr. Floyd Larson

Plaintiff's EXHIBIT 2
FOR IDENTIFICATION
SYLVIE HANKS, CSR# 5618
7-10 19 91
WIT: LARIVIERE

Exhibit 1

Department of Health and Human Services
U.S. Food and Drug Administration

Petition for Reclassification of a Medical Device Under Section 513(e)

Endosseous Dental Implants for Prosthetic Attachment

Submitted by
The Dental Implant Manufacturers Association
2000 M Street, N.W., Suite 700
Washington, D.C. 20036
202/463-0800

FDA DENIED Petition

EXHIBIT 2

Dr. M. O. Brose (6) reports a study conducted at Ohio State University to evaluate and compare the longevity of this implant system in healed and immediate extraction sites in the maxilla and mandible. The 33 patients in the study ranged from 21 to 72 years of age. Fifty-two implant placements were attempted, 40 of which were placed in healed sites, 12 in immediate (fresh) extraction sites. Of the total, 18 devices were placed in the maxilla and 34 in the mandible.

Patients were recalled at six month intervals, following restoration, at which time periodontal probe depths and mobility values were recorded and a PAF radiograph or panoral film was made. Two surgical failures and one unknown failure are recorded. One of the surgical failures was replaced and is now in function. Four implants were lost due to excessive loading forces, and two of these failures are the result of the operation of the dental school's undergraduate clinic and are not related to the implant design or the type of prosthesis placed upon the implant.

The study concluded that there is no difference in the success rates of implants placed in healed or fresh extraction sites and no difference in bone loss between sites in the maxilla and mandible. There is more bone loss at 6 (45% more) and 18 months (30% more) with implants retaining removable prostheses than those retaining fixed protheses and a subsequent lesser success rate at 18 months for those implants retaining removable prostheses (85%) than fixed single tooth protheses (96.0%).

7. Summary of Safety and Effectiveness of a 3-Year Clinical Investigation of Integral® HA-Coated Titanium Cylinder Implants (Calcitek Device)

Design shape:	**Cylinder**
Length:	**8 mm – 15 mm**
Diameter:	**4.0 mm**
Materials:	**Ti–6Al–4V**
Coatings:	**Hydroxylapatite**
Placement:	**Mandible and maxilla**
Applications:	**Partially and totally edentulous jaws**
Success Rate:	**98.5% over 6 months to 3 years**

Exhibit 2

GRAHAM & JAMES
ATTORNEYS AT LAW
2000 H STREET, N.W., SUITE 700
WASHINGTON, D.C. 20036
TELEPHONE (202) 463-0800

TELEX
90-4103 CHALGRAY WSH
TELECOPIER
(202) 463-0823
CABLE
CHALGRAY, WASHINGTON.

OTHER OFFICES
SAN FRANCISCO, CA
PALO ALTO, CA
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LONG BEACH, CA
NEWPORT BEACH, CA
NEW YORK, NY
RALEIGH, NC
MILAN
HONG KONG
BEIJING
TOKYO

AFFILIATED OFFICES
KUWAIT
JEDDAH
RIYADH
BAHRAIN

BY HAND

December 11, 1989

Document Control Center
U.S. Food and Drug Administration
1390 Piccard Drive, Room 26
Rockville, Maryland 20850

Dear Sir/Madam:

On behalf of the Dental Implant Manufacturers Association (DIMA), we hereby submit four (4) copies of DIMA's six (6) volume Petition for Reclassification for a Medical Device Under Section 513(e): Endosseous Dental Implants for Prosthetic Attachment. The unbound copy is for the Dockets Management Branch in the form they requested.

Five additional copies are being delivered today to the Dental Devices Division office as requested by staff.

Please return a date-stamped copy of this letter to our messenger at the time of delivery.

If you have any questions, please do not hesitate to call.

Sincerely,

Daniel J. Manelli

Emalee G. Murphy

Enclosures

Exhibit 2

Food and Drug Administration
Rockville MD 20857

January 22, 1990

FILE COPY

Daniel J. Manelli
Graham & James
2000 M Street, N.W.
Suite 700
Washington, D.C. 20036

Dear Mr. Manelli:

Your petition requesting the Food and Drug Administration to reclassify root and blade form endosseous dental implants for prosthetic attachment composed of biocompatible materials from class III to class II was received by this office on 01/22/90. It was assigned docket number 88N-0244/CP1 and it was filed on 12/12/89. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that accepting the petition for filing is a procedural matter in that it in no way reflects an Agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Dockets Management Branch

EXHIBIT 2

Attachment to Berry's

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 31 1989

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Mr. Richard Loriviere
Calcitek, Inc.
2320 Faraday Avenue
Carlsbad, California 92008

Re: Integral®

Dear Mr. Loriviere:

It has come to our attention that you have made or are considering making changes or modifications to the above referenced device.

We understand that the modifications consist of changes in the labeling claims which include the following:

"~~This coating~~ permits bone to actually bond with the implant surface."

"Histological studies demonstrate why Calcitite-coated implants may perform better than uncoated implants."

"...Calcitite-coated implants,...covers a greater percentage of the implant surface. Plus there are virtually no fibrous tissue elements between the bone and the implant."

Based on the information we have reviewed, we believe that the above described modifications may constitute significant changes, as described i 21 CFR Section 807.81(b), in the referenced medical devices.

The purpose of this letter is to inform you that under Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360(k)) changes or modifications that could significantly affect the safety or effectiveness of the device require a notification to the Food and Drug Administration (FDA) at least ninety (90) days prior to introduction of th changed or modified device in commercial distribution in the United State This requirement is accomplished by the submission of a Premarket Notification - (510(k)). The information necessary to comply with the Premarket Notification (510(k)) requirement is found in 21 CFR Part 807, Subpart E - Premarket Notification Procedures (copy enclosed).

We would appreciate a response within 30 days describing the action you have taken to achieve compliance with the Act or providing information which you believe substantiates your decision that a 510(k)) is not required.

Plaintiff's EXHIBIT 1
FOR IDENTIFICATION
SYLVIE HANKS, CSR# 9618
7-10 1998
WIT: LARIVIERE

Exhibit 3

Should you have any further questions regarding the submission of a Premarket Notification (510(k)), I suggest you contact Lillian Yin, Ph.D. of the Division of Obstetrics/Gynecology, Ear, Nose, Throat, and Dental Devices at (301) 427-7555.

Sincerely yours,

William H. Damaska
Director
Division of Compliance Operations
Office of Compliance
and Surveillance
Center for Devices and
Radiological Health

Enclosure: As Stated

Prep:CEUldriks:2/24/89
T/D:JABryant:2/27/89
Edit:RCox:2/27/89
Init:CEUldriks:2/28/89
Revised:DASegerson:3/14/89
Revised:JGovernale for KSS:6/19/89
Revised:CEUldriks:6/26/89
Redraft:JABryant:6/29/89
Edit:RCox:6/30/89
Init:CEUldriks:6/30/89
Redraft:JABryant:7/3/89
Revised:CEUldriks:7/3/89
Final:JABryant:8/28/89

cc: HFZ-323 (CEU, 18676, r/f, 510(k))
HFZ-320 (WHD/Board)
HFZ-300
HFA-224

1989 CAP 8.34

Exhibit 3

IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ORANGE

CONNIE BENTELE,

Plaintiff,

vs.

CALCITEK, INC., et al.,

Defendants.

No. 747549

Deposition of RICHARD LARIVIERE, taken on behalf of Plaintiff Connie Bentele, at 200 North Main Street, Second Floor, Santa Ana, California, beginning at 11:20 a.m. and ending at 3:20 p.m. on Friday, July 10, 1998, before SYLVIE HANKS, Certified Shorthand Reporter No. 9618.

Exhibit 4

APPEARANCES:

For Plaintiff Connie Bentele:

HORTON BARBARO & REILLY
BY: KIM VALENTINE-SIBERT
Attorney at Law
200 North Main Street, Second Floor
Santa Ana, California 92701
(714) 835-2122

For Defendant Calcitek, Inc., and Deponent Richard Lariviere:

HAIGHT, BROWN & BONESTEEL, L.L.P.
BY: BRUCE CLEELAND
Attorney at Law
5 Hutton Centre Drive, Suite 900
Santa Ana, California 92707-0510
(714) 754-1100

HAIGHT, BROWN & BONESTEEL, L.L.P.
BY: SHANNA R. DAVIS
Attorney at Law
1620 26th Street, Suite 4000 North
Santa Monica, California 90406
(310) 449-6000

Exhibit 4

Claims Under Regulatory Review" provision?

A Correct.

Q Is it your understanding that if a product is marketed with claims that are determined to not be substantially equivalent, then a product is misbranded?

MR. CLEELAND: Insofar as it asks for a legal conclusion, I will object as it lacks foundation. Insofar as it asks for the witness's understanding, it is therefore irrelevant and inadmissible, and I will object on that basis.

Go ahead if you have an answer, sir.

THE WITNESS: I believe once the claim's determined to be unsubstantiated, to continue to market the product would be misbranded.

BY MS. VALENTINE-SIBERT:

Q So the fact that the product has been marketed with those claims and the claims are never determined to be substantially equivalent is of no consequence?

A Back in 1984-1985, when this product was first introduced, you simply had to have the evidence on file to support the claims. We had the evidence on file. Not until 1989, when the claims were challenged, did we realize or did we find out that the

claims were not considered substantially equivalent, or substantiated. We believed we were in compliance.

Q Despite your belief that you were in compliance, the FDA determined otherwise; correct?

A Yes.

Q You said that in 1984 and 1985, you had the information on file.

A I'm speculating that that's the time frame.

Q Okay.

A I don't know when these claims were originally made.

Q But what information would have been on file?

A I believe the reports that were cited.

Q To substantiate those claims?

A Yes.

Q However, based on the FDA's ultimate determination, is it your understanding that what was on file ultimately was determined to not be adequate?

MR. CLEELAND: Can I have that back, please.

(Record read.)

MR. CLEELAND: I've got to hear that one more time. I'm sorry.

(Record read.)

Exhibit 4

MR. CLEELAND: Yeah, I have multiple concerns over that question, including vague and ambiguous as to what ultimate determination and who made that determination and who determined it was not adequate. The witness testified that the company believed that it was adequate. He submitted documentation in support. So I think it becomes a little convoluted.

BY MS. VALENTINE-SIBERT:

Q Did you understand the question?

A Not anymore.

Q You testified that Calcitek had placed certain information on file with the FDA with regards to the claims that were placed on the brochures.

A Yes.

Q You testified that Calcitek was under the impression that those claims were sufficient.

A Yes.

Q The FDA ultimately determined that they were insufficient; correct?

A Correct.

Q Now, that worked really well because I have no idea where I was going with that now.

MR. CLEELAND: It happens.

BY MS. VALENTINE-SIBERT:

Q I assume that Mr. Cleeland and Ms. Davis

Exhibit 4

represent you for the purposes of this deposition; is that correct?

A Yes.

Q Other than the conversations that you've had with them pertaining to this particular lawsuit, have you had conversations with anyone else pertaining to this lawsuit?

A No.

Q Prior to our attempts to contact you with respect to testifying in this lawsuit, were you aware of this lawsuit at all?

A No.

MS. VALENTINE-SIBERT: Okay. I don't have any further questions.

MR. CLEELAND: Okay. Thanks.

MS. VALENTINE-SIBERT: Okay. I propose that we relieve the court reporter of her duties under the Code and that the original of the deposition be forwarded to your office, I presume?

MS. DAVIS: That's fine.

MR. CLEELAND: That would be fine.

MS. DAVIS: The Santa Monica office is fine.

MR. CLEELAND: Send it to her address.

MS. VALENTINE-SIBERT: Okay. Then you'll go ahead and send it to Mr. Lariviere and have him make

Exhibit 4

corrections and provide us with copies of those corrections within 20 days after he makes the corrections?

MS. DAVIS: That would be fine.

MS. VALENTINE-SIBERT: And that if the original transcript is lost or stolen or misplaced, that a certified copy can be utilized as an original?

MS. DAVIS: That's fine.

MS. VALENTINE-SIBERT: That's it. Thank you.

//

//

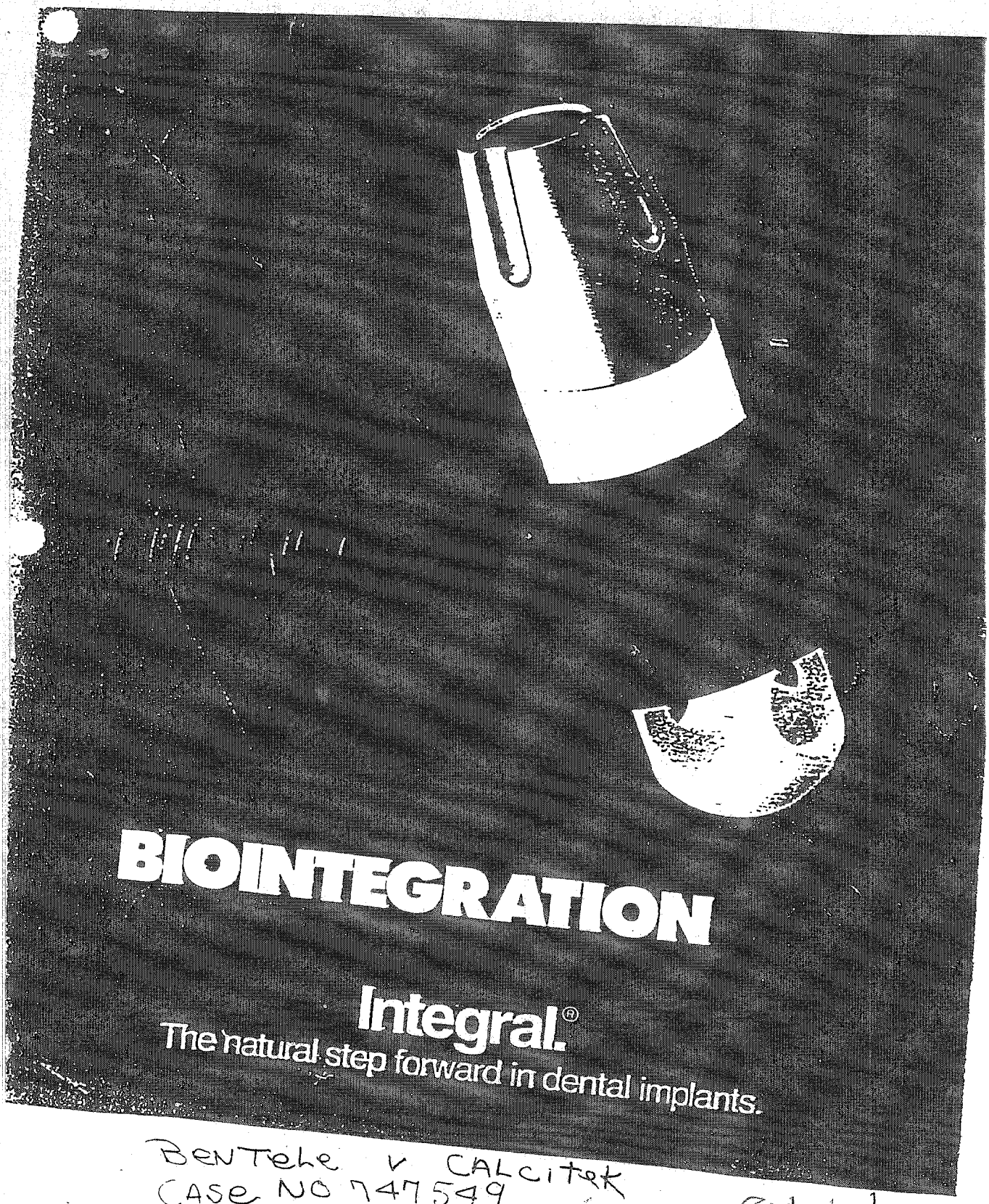
Exhibit 4

I, RICHARD LARIVIERE, do hereby declare under penalty of perjury that I have read the foregoing transcript; that I have made such corrections as noted herein, in ink, initialed by me, or attached hereto; that my testimony as contained herein, as corrected, is true and correct.

EXECUTED this _____ day of _____, 19___, at _____, _____.
(City) (State)

_____
RICHARD LARIVIERE

Exhibit 4



BENTELE v CALCITEK
CASE NO 747549
FALSE ADVERTISEMENT

EXHIBIT 5

INTEGRAL® COMBINES BIOINTEGRATION** AND OS

F. D. A. SAID FALSE

The Integral Advantage

The Integral biointegrated dental implant system goes one step beyond conventional osseointegrated dental implant systems. Like other contemporary endosseous implants, Integral uses a "gentle" two-stage implantation procedure to ensure complete fixation prior to loading.

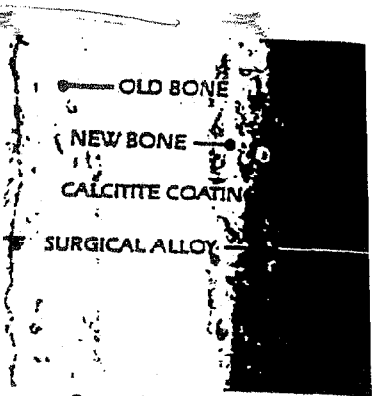
But to achieve *true biointegration*, the titanium Integral implant receives our unique Calcitite* (brand of hydroxylapatite) coating. This coating permits bone to actually bond with the implant surface.[1,2]

The Superiority of Calcitite Coating

Numerous in-vivo studies have confirmed the superior biocompatability and bone-bonding characteristics of hydroxylapatite materials.

Biomechanical tests on both loaded and unloaded implants dramatically reveal the superiority of Calcitite-coated implants in both degree and rate of fixation in bone.[2,3]

Additionally, the presence of more supporting bone on the Calcitite-coated implant surfaces (versus uncoated implants) may contribute to continued implant success.[3]

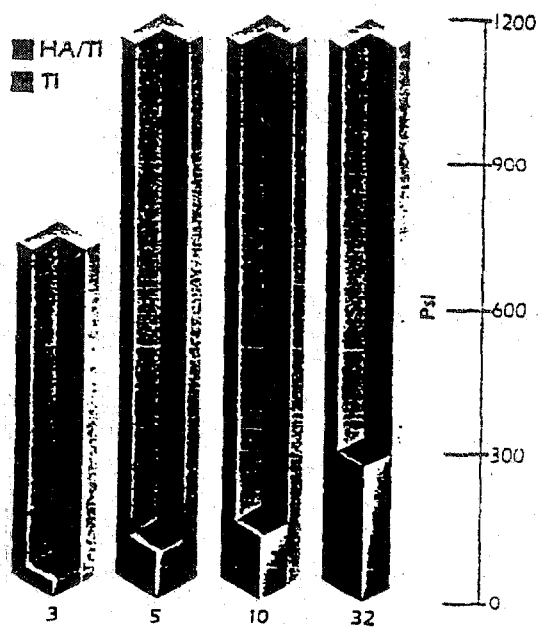


Ground histologic section of Calcitite-coat surgical alloy 3 weeks post-implantation in canine femur. New bone has been deposit on both the coating and the surface of the bone implant site.

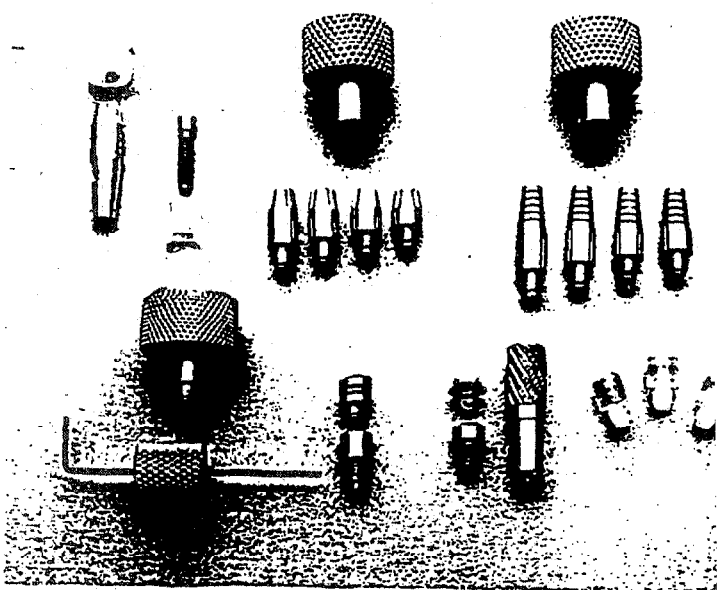
The unique bone response to HA coated titanium has led several investigators to conclude that Calcitite-coate implants may not be as susceptible to installation variables as uncoated metal implants.[3]

Calcitite-Coated Implants Bond Better

Histological studies demonstrate why Calcitite-coated implants may perform better than uncoated implants. With uncoated titanium implants, new bone grows up to and then adapts to their surface. Frequently, intervening fibrous tissue elements are present between the implant and bone, thereby possibly weakening support.



Attachment strength of titanium and HA-coated titanium transcortical implant plugs in dogs.



A wide selection of threaded attachments allow for maximum flexibility of prosthetic restoration.

Exhibit 5

...grated Dental Implant System.

PRODUCT DESCRIPTION

The Integral™ System is a clinically proven two-stage system, consisting of a Calcitite® coated, biocompatible, titanium implant body and a selection of threaded abutments and attachments which allow for a wide variety of fixed or removable prosthetic applications.

The Calcitite brand of dense hydroxylapatite (HA) coating is applied and bonded to the implant surface using a modified plasma spray process. It is a unique coating that creates a *dramatic biochemical bond between the implant and natural bone*, not just a mechanical fixation as observed in other osseointegrated implants. The Integral system combines contemporary implant research and the most advanced principles of biomaterials engineering.

PRODUCT USAGE

The Integral brand implant is indicated for fully or partially edentulous patients where fixed or removable appliances are the restoration of choice.

PRODUCT ADVANTAGES

The Integral system demonstrates many significant advantages:

- The exclusive Calcitite coating on the Integral implant has demonstrated its ability to enhance osseointegration because it biologically bonds to natural bone. Deposition of new bone occurs not just at the old bone site, but also on the hydroxylapatite coating itself, resulting in a significant increase in the rate at which the surgical site heals. Evidence of an attachment of gingival epithelium to hydroxylapatite implants has been shown by previous researchers. This seal is seen as essential for reducing the risk of infection and implant failure.
- Integral implants are provided sterile and are protected by a special double wrapped holding-vial transfer system for easy delivery to a sterile field.
- A simplified surgical procedure not only minimizes chairside time, but greatly reduces the risk of bone trauma. Bone is cooled during the staged drilling procedure by internal irrigation while the unique design of the drill simultaneously removes the cutting debris.
- Integral implant bodies are available in four lengths to accommodate individual anatomic requirements. Their design and the Calcitite coating create rapid initial stabilization of the implant.
- A wide selection of threaded attachments are available, allowing maximum flexibility in the choice of prosthetic restorations. The system incorporates fixed and removable abutment designs. Integral implants accept time-proven systems such as the Zest® Anchor, an o-ring attachment, various bar attachments and magnetic retention systems. And, should the patient's prosthetic needs change, requiring a different restorative solution, our threaded abutments, in most case will allow for a complete change of restoration type, without disrupting the integrity of the implant itself.

PACKAGING

The Integral system is available in a surgical kit which provides all necessary placement instrumentation and eight implants. Abutments and other attachments may be selected on an individual basis. A complete listing of prosthetic attachment options can be found in our price list.

PERSONAL, TECHNICAL SERVICE

Your orders are handled by technical representatives with significant product knowledge. They can answer your questions about the Integral System and hydroxylapatite technology. Product literature, technical papers, video instructional materials and patient education literature are available upon request.

ORDERING INFORMATION

Orders may be placed direct by calling toll-free (800) 854-7019 or (800) 542-6019, in CA.

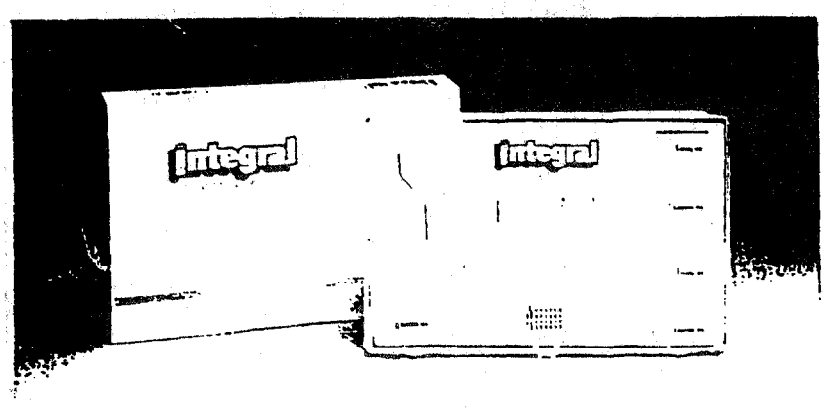
SHIPPING

All shipments are subject to a $3.00 freight and handling fee which will be included on each invoice. Shipments are sent 2nd Day Federal Express, unless otherwise specified.

TERMS

2% 10 days: net 30 days. Prices, policies and terms are subject to change without notice.

No product will be accepted for return without prior authorization. Merchandise authorized for return will be subject to a restocking charge. All freight must be prepaid on returned merchandise.



Integral® Surgical Kit.

Calcitek, Inc.

The Recognized Leader in Hydroxylapatite Technology

2320 Faraday, Carlsbad, CA 92008

7208 4/88

Exhibit 5

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

MARY MASTERS,

Plaintiff-Appellant

v.

SULZER CALCITEK, INC; et al.,
Defendants-Appellees,

No. 00-55904

D.C. No. CV-99-02215-JNK

REQUEST FOR STAY
PENDING PETITION
FOR DECLARATION
TITLE 21; SECTION 1604

Appeal from the United States District Court
for the Southern District of California
Judith N. Keep, Chief District Judge, Presiding

TO THE COURT; Request is made for stay pending Petition for Declaration under Title 21, Chapter 21, Section 1604 (3) (d): Administrative Procedures. If a claimant has filed a Petition For Declaration with respect to a defendant, and the Secretary has not issued a final decision on the petition, the court shall stay all proceedings with respect to that defendant until such time as the Secretary has issued a final decision on the petition.

Dated: June 8, 2001

Respectively submitted

Mary Masters

Exhibit 6

ROUTING SLIP
GENERATED BY: HF-40
DATE: JUL 16, 2001

FDA CONTROL NUMBER: 01 3549 **TRACER #:** **OS #:** 0711010053

DATE OF CORRESPONDENCE: 07/01/01 **DATE INTO FDA:** 07/16/01

TO: TOMMY THOMPSON, DEPARTMENT OF HEALTH AND HUMAN SERVICES

FROM: MARY MASTERS

SYNOPSIS: FORWARDS "PETITION FOR DECLARATION" - FILER CLAIMS WAS INJURED BY UNAPPROVED DENTAL DEVICES

LEAD OFFICE: HF-40 **HOME OFFICE:** HF-40

CONTACT/PHONE#: MIKELE A BRYANT 301-827-4450

COPIES:

COORDINATION: HFA-305
HFZ-1

SIGNATURE REQUIRED:

REFERRALS FROM HF-40

ASSIGNED TO	ACTION	DUE DATE
HF-40	PREPARE DIRECT REPLY	07/25/01

Secretary's Correspondence

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE SECRETARY
EXECUTIVE SECRETARIAT

From:	**Mary Masters**	*OS#:*	**071120010053**
Organization:	**P.O. Box 82043**	*Date on Letter:*	
City/State:	**San Diego CA**	*Date Received:*	**7/11/01**
On Behalf Of:		*Type:*	**General Public**

Subject: **Forwards 'Petition For Declaration' on issues relating to non-FDA approved materials for dental prostetics**

Assigned to:	**FDA**	*Dep.ES:*	**Dick Eisinger**
PC:	**Tom Kuchenberg**	*Date Assigned:*	**7/11/01**
Action Required:	**Direct Reply**	*Date Reassigned:*	
		Reply Due Date:	**7/25/01**

Info Copies To:

Interim (Y/N):	**No**	*Date Interim Sent:*	

Comments: **writer has called and will be calling again.**

File Index:	**PO-4-10**	*CCC:*	**Elaine Gross**

3549

July 1, 2001

Mr. Tommy Thompson
Secretary of
Department of Health & Human Services
200 Independence Avenue SW
Washington, D. D. 20201

Dear Secretary:

Attached is my Petition For Declaration pursuant to Title 21, Chapter 21, Section 1604.

Please docket this petition (A) (B)

> "Immediately upon receipt of a petition filed pursuant to this paragraph, the Secretary shall docket the Petition. Not later than 120 days after the petition is filed, the Secretary shall issue a final decision on the petition."

I have requested the court to stay all proceedings with respect to the defendants until such time as the Secretary has issued a final decision on the petition.

Thank you for your assistance. I am enclosing one copy to be returned to me in a postage paid envelope after docketing.

Claimant,

Mary Masters
P. O. Box 82043
San Diego, California 92138
Telephone: 619-462-1464

MR. TOMMY THOMPSON
SECRETARY OF
DEPARTMENT OF HEALTH & HUMAN SERVICES
200 INDEPENDENCE AVENUE SW
WASHINGTON, D. C. 20201

PETITION FOR DECLARATION
PURSUANT TO TITLE 21, SEC TION 1604

Submitted by Claimant:
Mary Masters
P. O. Box 82043
San Diego, California 92138
Telephone: 619-462-1464

PETITION FOR DECLARATION

MARY MASTERS
Petitioner - Claimant

CALCITEK, INC.

Manufacturer - Biomaterials Supplier

RONALD W. EVASIC, D. D. S.
President of Scripps Implant Dentistry Education & Research Foundation
Biomaterials Supplier

TO THE SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Pursuant to U.S. Code as of 01/05/99

Title 21, Chapter 21, Section 1604,
Liability of biomaterials supplier

paragraph 3 (A) Administrative Procedures.

(2) (B)

TABLE OF CONTENTS

ADMINISTRATIVE PROCEDURES

(A) In general Administrative Procedures

The Secretary may issue a declaration described in paragraph (2) (B) on the motion of the Secretary or any petition by any person.

(2) (B) on the motion of the secretary or on petition by any person, after providing -

(i) notice to the affected persons; and
(II) an opportunity for an informal hearing.

(B) Docketing and final decision
Immediately upon receipt of a petition filed pursuant to this paragraph, the Secretary shall docket the petition. Not later than 120 days after the petition is filed, the Secretary shall issue a final decision on the petition.

Petition for Declaration is being requested from the Secretary of Health & Human Resources, under Title 21, Chapter 21, Section 1604, Liability of biomaterials suppliers.

INTRODUCTION

During the period of time from October, 1985 through July, 1990, Claimant was sold Calcitek biomaterials which were only allowed to be used in animal studies and limited human investigative studies. The products are:

a) The Biolite (trademark) Carbon Coated Metal Dental Implant: Sold: October, 1985; K840750. This blade caused severe infection and corrosion of adjacent teeth. (Attachment 15) 2) HA blocks implanted without consent: Oct., 1989: Barry Sands memorandum to Calcitek, (Attachment 1) supports the fact that this "HA" was investigative. c) Integrals, K895680/B Sold: June- July 1990: proof this product was investigative Sept. 22, 1989, (Attachment 7); Dec. 3, 1990 Integral was seized from market: (Attachment 11); HA coated castable abutments Sold: Oct., 1989 to June, 1990: Were not approved when sold: K900694. O ring: Sold October, 1989: Not approved when sold: K900545. Calcitek "crystals" and "granules" were implanted without permission.

Claimant has sustained severe bodily injuries, past, present and future, and to date has had 11surgeries through March, 1999, resulting from injuries received from Calcitek biomaterials. Present need for more surgeries at an additional expense of $45,000. Claimant is filing this Petition for Declaration for federal question. Expenses for surgeries are $107,000. . The products were represented to be FDA approved. Calcitek has denied liability for the Claimant's injuries and has falsely told the court that the products are FDA approved, (Attachment 16) The contrary is true. The attachments prove, by a preponderance of evidence, that the products were either seized or never filed with the FDA prior to being sold to the Claimant.

Calcitek was required to register pursuant to paragraph 2 (b), (A), (i) as evidenced by Petition For Reclassification of a Medical Device Under 513 (e) Endosseous Dental Implants For Prosthetic Attachment (Attachment 2). Calcitek's registration number 2023141

Title 21 - Food and Drugs
Chapter 21 - BIOMATERIALS ACCESS ASSURANCE
Section 1604 Liability of biomaterials suppliers

STATUTE

(a) In general:

Except as provided in section 1606 of this title, a biomaterials supplier shall not be liable for harm to a claimant caused by an implant unless such supplier is liable -

(1) as a manufacture of the implant, as provided in subsection (b) of this section;

(2) as a seller of the implant, as provided in subsection (c) of this section; or

(3) for furnishing raw materials or component parts for the implant that failed to meet applicable contractual requirements or specifications, as provided in subsection (d) of this section.

(b) Liability as manufacturer

(1) In general

A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by an implant if the biomaterials supplier is the manufacturer of the implant,

(2) Grounds for liability

The biomaterials supplier may be considered the manufacturer of the implant that allegedly caused harm to a claimant only if the biomaterials supplier -

(A) (i) registered or was required to register with the Secretary pursuant to section 360 of this title and the regulations issued under such section; and

(ii) Included or was required to include the implant on a list of devices filed with the Secretary pursuant to section 360 (j) of this title and the regulations issued under such section;

(B) is the subject of a declaration issued by the Secretary pursuant to paragraph (3) that states that the supplier, with respect to the implant that allegedly caused harm to the claimant, was required to -
(i) register with the Secretary under 360 of this title, and the regulations issued under such section, but failed to do so; or
(ii) include the implant on a list of devices filed with the Secretary pursuant to section 360 (j) of this title and the regulations issued under such section, but failed to do so; or

(C) is related by common ownership or control to a person meeting all the requirements described in subparagraphs (A) or (B), if the court deciding a motion to dismiss in accordance with section 1605 (c) (3) (B) (i) of this title finds, on the basis of affidavits submitted in accordance with section 1605 of this title, that it is necessary to impose liability on the biomaterials supplier as a manufacturer because the related manufacturer meeting the requirements of subparagraph (A) or (B) lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail.

(3) Administrative procedures

(A) In general

The Secretary may issue a declaration described in paragraph (2) (B) on the motion of the Secretary or on petition by any person, after providing -

(i) notice to the affected persons; and

(ii) an opportunity for an informal hearing.

(B) Docketing and final decision.

Immediately upon receipt of a petition filed pursuant to this paragraph, the Secretary shall docket the petition. Not later than 120 days after the petition is filed, the Secretary shall issue a final decision on the petition.

(C) Applicability of statute of limitations

Any applicable statute of limitations shall toll during the period from the time a claimant files a petition with the Secretary under this paragraph until such time as either (i) the Secretary issues a final decision on the petition, or (ii) the petition is withdrawn.

(D) Stay pending petition for declaration

If a claimant has filed a petition for a declaration with respect to a defendant, and the Secretary has not issued a final decision on the petition, the court shall stay all proceedings with respect to that defendant until such time as the Secretary has issued a final decision on the petition,

(c) Liability as seller.

A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable as a seller for harm to a claimant caused by an implant only if -

(i) the biomaterials supplier -

(A) held title to the implant and then acted as a seller of the implant after its initial sale by the manufacturer; or

(B) acted under contract as a seller to arrange for the transfer of the implant directly to the claimant after the initial sale by the manufacturer of the implant; or

(2) the biomaterials supplier is related by common ownership or control to a person meeting all the requirements described in paragraph (1), if a court deciding a motion to dismiss in accordance with section 1605 (c) (3) (B) (ii) of this title finds, on the basis of affidavits submitted in accordance with section 1605 of this title , that it is necessary to impose liability on the biomaterials supplier as a seller because the related seller meeting the requirements of paragraph (1) lacks sufficient financial resourses to satisfy any judgment that the court feels it is likely to enter should the claimant prevail.

(d) Liability for failure to meet applicable contractual requirements or specifications.

A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by an implant if the claimant in an action shows, by a preponderance of the evidence that -

(1) the biomaterials supplier supplied raw materials or component parts for use in the implant that either -
(A) did not constitute the product described in the contract between the biomaterials supplier and the person who contracted for the supplying of the product; or
(B) failed to meet any specifications that were -
(i) accepted pursuant to applicable law, by the biomaterials supplier;

(ii) published by the biomaterials supplier;

(iii) provided by the biomaterials supplier to the person who contracted for such product;

(iv) contained in a master file that was submitted by the biomaterials supplier to the Secretary and that is currently maintained by the biomaterials supplier for purpose of premarket approval of medical of medical devices; or

(v)included in the submissions for purposes of premarket approval or review by the Secretary under section 360, 360c, 360e, or 360j of this title, and received dived clearance from the Secretary if such applications were accepted, pursuant to applicable law, by the biomaterials supplier; and

(2) such failure to meet applicable contractual requirements or specifications was an actual and proximate cause of the harm to the claimant.

Calcitek was required to register pursuant to paragraph 2 (b), (A), (i) as evidenced by Petition For Reclassification of a Medical Device Under 513 (e) Endosseous Dental Implants For Prosthetic Attachment (Attachment 2).

(A) (i) registered or was required to required to register with the Secretary pursuant to section 360 of this title and the regulations issued under such section; and

(ii) included or was required to include the implant on a list of devices filed with the Secretary pursuant to section 360 (i) of this title and the regulations issued under such section:

The manufacturer Calcitek, Inc. received a letter dated August 31, 1989 from William Damaska, Director, Division of Compliance Operationd, Office of Compliance and Surveillance, Center For Devices and Radiologic Health.

On page 1, paragraph 7, Mr. Damaska:

"that the purpose of this letter is to inform you that under Section 510 (k) of the Federal Food, Drug, and Cosmetic Act (the Act) 21 U S C 360 (k) changes or modifications that could significantly affect the safety or effectiveness of the device require a notification to the Food and Drug Administration (FDA) at least (90) days prior to introduction of the changed or modified device in commercial distribution in the United States. This requirement is accimplished by the submission of a Premarket Notification - 510 - (k). The information necessary to comply with the Premarket Notification 510 - (k). The information necessary to comply with the Premarket Notification 510 (k)) requirement is found in 21 CFR Part 807, Subpart E. Premarket Notification (copy enclosed).

On page 1, paragraph 8, Mr. Damaska:

"We would appreciate a response within 30 days describing action you have taken to achieve compliance with the Act or providing information which you believe substantiates your decision that a 510 (k) is not required." (Attachment 3)

On July 10, 1998, Mr. Richard LaRiviere was deposed for the State of California County of Range, California, Case No. 747549 entitled Connie Bentele vs. Calcitek, Inc. Mr. LaRiviere was asked the question page 115 paragraph 2: line 7-11

Q "Is your understanding that if a product is marketed with claims that

A "Back in 1983-1985, when this product was first introduced, you simply had to have the evidence on file. Not until 1989, when the claims were challanged, did we realize or did we find out that the claims were not considered substantially equivalent, or substantiated. We believed we were in compliance."

page 116, lines 3-4

Q Despite your belief that you were in compliance, the FDA determined otherwise; correct?

Page 116: line 5

A Yes

page 116: lines 18-20

Q However, based on the FDA's ultimate determination, is it your understanding that what was on file ultimately was determined to not be adequate?

page 117: lines 11-21

Q You testified that Calcitek had placed certain information on file with the FDA with regards to the claims that were placed on the brochures.

A Yes

Q You testified that Calcitek was under the impression that those claims were sufficient,

A Yes

Q The FDA ultimately determined that they were insufficient; correct?

A Correct.

The foregoing evidence is Attachment 4.

Title 21; Chapter 21; Section 1604; paragraph 3 (A) Administrative Procedures

(A) In general
The Secretary may issue a declaration described in paragraph (2) (B) on the motion of the Secretary or any petition by any person.

Claimant is filing this petition pursuant to paragraph 3 (A) Administrative Procedures.

(c) Liability of seller

A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable as a seller for harm to a claimant caused by an implant only if -

(A) held title to the implant and then acted as a seller of the implant after its initial sale by the manufacturer; or

Calcitek held title to the Integral implant a tradesman for Calcitek, Inc. See

Biointegration Integral (Attachment 5) It was falsely advertised as being FDA approved.

(2) (B) on the motion of the secretary or on petition by any person, after providing -

(i) notice to the affected persons; and
(ii) an opportunity for an informal hearing.

(B) Docketing and final decision

Immediately upon receipt of a petition filed pursuant to this paragraph, the Secretary shall docket the petition. Not later than 120 days after the petition is filed, the Secretary shall issue a final decision on the petition.

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(1) the biomaterials supplier-

(A) held title to the implant and then acted as a seller of the implant after its initial sale by the manufacturer; or

(B) acted under contract as a seller to arrange for the transfer of the implant directly to the claimant after the initial sale by the manufacturer of the implant; or

(2) the biomaterials supplier is related by common ownership or control to a person meeting all of the requirements described in paragraph (1), if a court

HISTORY

In 1976, P.A. 442 as amended, the Department of Justice filed suit against Dr. Evasic in the State of Michigan. Consent Order dated January 17, 1983; Stipulation dated: November, 30, 1982, First Amended Complaint, Dated March 4, 1982 and Complaint Dated October 27, 1977.

In 1987,Dr Ronald W. Evasic formed a nonprofit California corporation entitled The Scripps Implant Dentistry Education and Research Foundation (SIDERC)., located at Scripps Torrey Pines Campus, La Jolla, California. (Exhibit 1) At that time Dr. Evasic was not a California dentist, as he did not receive his California dental license until August 3, 1990 and the license is no longer valid in the State of California License No. 38676.

The corporation President and Director was Dr.Ronald W. Evasic who at that time was licensed by the State of Michigan License No. -29-01-008170, Expired 8/31/93 and the State of Oklahoma. Dr. Evasic conducted dental implant training courses through his corporation in California and Oklahoma. . At that time, Dr. Evasic resided at 2419 Foilage Drive, Ada, Oklahoma, 94820. The dentists who enrolled in the courses were told to mail their checks to Dr. Evasic's residence in Oklahoma; however, they were not told that they were mailing their checks to Dr. Evasic's residence, they were told that they were mailing their checks to Scripps Implant Dentistry Center. Each dentist mailed a check for $7,500.00.(Exhibit 2).

In 1988, Dr. Evasic hired Dr. Thomas Golec, a California dentist to teach subperiosteal dental implant training through Dr. Evasic's corporation. Dr Golec was in private group practice and he was also a research dentist for Calcitek, Inc.

The materials used in the dental implant courses were Calcitek, Inc. products which were mailed to the dentists from Texas and from Calcitek, Inc.in Carlsbad, California.

In 1988, Calcitek Inc. was a California corporation owned by InterMedica, Inc. a California corporation, who then became a Texas corporation.

In August, 1989, Calcitek, Inc. was purchased by Sulzer medica, Inc. of Winterhur, Switzerland. At a later date Sulzer medica, Inc. moved from Switzerland to the State of Texas.

Plaintiff was used in Dr. Evasic's dental implant training courses without her consent; subsequently Dr. Evasic treated the plaintiff from 1992-1995 and

CONCLUSION

Claimant is requesting Petition for Declaration for federal question.

dated - 07.01.01 claimant

Mary Mosley

ATTACHMENTS

1.. A copy of memorandum dated: April 11, 1989: To: Calcitek, Inc. From: Biomedical Engineer, ENT & Dental Device: Barry Sands, Biomedical Engineer Subject: Unapproved Indications for use of Calcitek Hydrpxylapatite

2. A copy of Petition For Reclassification of a Medical Device Under Section 513 (e) Endosseous Dental Implants for Prosthetic Attachments. (FDA denied petition)

3. A copy of letter dated August 31, 1989: To: Richard Loriviere, Calcitek, Inc. 2320 Faraday Avenue, Carlsbad, California 92008 From: William H. Damaska, Director, Division of Compliance Operations, Office of Compliance and Surveillance, Center for Devices and Radiologic Health Re: Integral (trademark)

5. Deposition of Richard LaRiviere: Dated July 10, 1998 to Page 117.

6. Advertisement of "Biointegration" Verifying Calcitek trademark Integral. (The FDA deemed this false advertising.

7. A copy letter dated September 22, 1989. To: Calcitek, Inc.: Attention Richard L. Lariviere, 2320 Faraday Avenue, Carlsbad, California 92008. From: Robert I. Chiseler, Premarket Notification Coordinator, Office of Device Evaluatiob, Center for Devices and Radiological Health, Department of Health & Human Services. Re: D.C. Number: K895680: Received: 09/20/89: 90th. Day: 12/19/89. Product: Integral.

8... A copy of memorandum dated: March 10, 1990: To Jim Fraser, President of Calcitek, Inc: From Rick Lariviere, Subject: Year End Complaint: Summary for 1989.

9.. A copy of a letter dated: September 20, 1989: To: Calcitek, Inc. From: Barry Sands, Scientific Reviewer. Division of Obstetrics/ Gynecologym Ear, Nose, Throat and Dental Devices. Food and Drug Administration 139 Piccard Drive Rockville, MD 20857 Re: August 21, 1989 compliance letter

10... A copy of letter to Ms. Kimberly M. Carlson Manager, Regulatory Affairs, Calcitek Inc. 2320 Faraday Avenue, Carlsbad, California 92008, dated May 30, 1990 from Dr. Lillian Yin, Director of Division of OB-GYN, ENT, and dental Device Devices; Center For Devices and radiological Health, Department of Health & Human Services. Re: K895680/A Integrral: Dated: March 15 and March 27, 1990: Received: March 16 and April 24, 1990.

11. A copy of letter dated December 3, 1990, to Richard LaRiviere , Calcitek, Inc., 2320 Faraday Avenue, Carlsbad, California 92008 from David West, Ph.D., Deputy Director, Office of Device Evaluation Center For Devices and Radiological Health. Re: K895680/A Regulatory Class III Dated: August 11, 1990: Received: September 4, 1990.

12. A copy of warning letter to James S. Fraser, Calcitek, Inc. Dated May 15, 1992 from Department of Health & Human Services , Dr. Thomas Sawyer, Director, Compliance Branch, U.S. Food and Drug Administration 1521 West Pico Blvd., Los Angeles, Calif.

13.. A copy of a letter to Mr. James A. Fraser, Calcitek, Inc. Dated: February 3, 1992 from Thonas L. Sawyer, Director of Compliance Branch, Los Angeles District,

14. A copy of American Society for Testing & Materials, 1916 Race Street, Philadelphia, Pa. 19103, Standard Specification for Composition of Ceramic Hydroxylapaite for Surgical implants. Designation: F 1184-88

15. A copy of Biolite (trademark) Carbon Coated Metal Dental Implant.

16. A copy of Robert L. Riley's testimony . Testimony from earlier court case.

Attachment 4
Barry's review

DATE: 4/11/89

FROM: Biomedical Engineer, ENT & Dental Devices

SUBJECT: Unapproved Indications for Use of Calcitek Hydroxylapatite

TO: Director, Division of Product Surveillance (HFZ-340)
Through: Director, Division of OB-GYN, ENT and Dental Devices (HFZ-470) _____
Chief, ENT and Dental Device Branch (HFZ-470) _____

Calcitek is presently marketing an endosseous implant for bone filling and augmentation with the indication for use with dental implants (see attachment). This indication for use has never been reviewed by DOED. In addition, we would find that this indication for use would warrant animal and clinical trials to determine its safety and effectiveness. We ask that the Office of Compliance inform Calcitek of its potential violations of the Medical Device Amendments. Thank you.

S

Barry E. Sands
Biomedical Engineer

Attachment 1

Should you have any further questions regarding the submission of a Premarket Notification (510(k)), I suggest you contact Lillian Yin, Ph.D. of the Division of Obstetrics/Gynecology, Ear, Nose, Throat, and Dental Devices at (301) 427-7555.

Sincerely yours,

William H. Damaska
Director
Division of Compliance Operations
Office of Compliance
and Surveillance
Center for Devices and
Radiological Health

Enclosure: As Stated

Prep:CEUldriks:2/24/89
T/D:JABryant:2/27/89
Edit:RCox:2/27/89
Init:CEUldriks:2/28/89
Revised:DASegerson:3/14/89
Revised:JGovernale for KSS:6/19/89
Revised:CEUldriks:6/26/89
Redraft:JABryant:6/29/89
Edit:RCox:6/30/89
Init:CEUldriks:6/30/89
Redraft:JABryant:7/3/89
Revised:CEUldriks:7/3/89
Final:JABryant:8/28/89

cc: HFZ-323 (CEU, 18676, r/f, 510(k))
HFZ-320 (WHD/Board)
HFZ-300
HFA-224

1989 CAP 8.34

Page 2 :
attachment 3

Department of Health and Human Services
U.S. Food and Drug Administration

Petition for Reclassification of a Medical Device Under Section 513(e)

Endosseous Dental Implants for Prosthetic Attachment

THIS PETITION WAS NOT APPROVED BY FDA

Attachment 2

Submitted by
The Dental Implant Manufacturers Association
2000 M Street, N.W., Suite 700
Washington, D.C. 20036
202/463-0800

Attachment 4 Comp.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Admini-
Rockville MD 20857

AUG 31 1989

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Mr. Richard Loriviere
Calcitek, Inc.
2320 Faraday Avenue
Carlsbad, California 92008

Re: Integral®

Dear Mr. Loriviere:

It has come to our attention that you have made or are considering making changes or modifications to the above referenced device.

We understand that the modifications consist of changes in the labeling claims which include the following:

"This coating permits bone to actually bond with the implant surface."

"Histological studies demonstrate why Calcitite-coated implants may perform better than uncoated implants."

"...Calcitite-coated implants,...covers a greater percentage of the implant surface. Plus there are virtually no fibrous tissue elements between the bone and the implant."

Based on the information we have reviewed, we believe that the above described modifications may constitute significant changes, as described 21 CFR Section 807.81(b), in the referenced medical devices.

The purpose of this letter is to inform you that under Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360(k)) changes or modifications that could significantly affect the safety or effectiveness of the device require a notification to the Food and Drug Administration (FDA) at least ninety (90) days prior to introduction of changed or modified device in commercial distribution in the United Sta This requirement is accomplished by the submission of a Premarket Notification - (510(k)). The information necessary to comply with the Premarket Notification (510(k)) requirement is found in 21 CFR Part 807 Subpart E - Premarket Notification Procedures (copy enclosed).

We would appreciate a response within 30 days describing the action you have taken to achieve compliance with the Act or providing information which you believe substantiates your decision that a 510(k)) is not required.

Plaintiff's EXHIBIT 1
FOR IDENTIFICATION
SYLVIE HANKS, CSR# 9618
7-10 19 98
WIT: LARIVIERE

Attachment 3

Attachment 4
Barry review

TO: Dave Segerson, Deputy Director, DOED

FROM: Biomedical Engineer, DOED

SUBJECT: Calcitek Meeting - Unsubstantiated Product Claims

A meeting was held on September 19, 1989, at the request of Calcitek. The request came as a result of a letter from the Office of Compliance. This letter informed Calcitek that their endosseous implant was being marketed with claims that were not included in 510(k) K840750. The following individuals were in attendance:

Floyd Larson ---------- Calcitek

Richard Lariviere ----- Calcitek

Casper Uldriks -------- OCS/DCO

Barry Sands ----------- ODE/DOED

The representatives of Calcitek displayed a document containing evidence that they felt demonstrated that the claims in question were accurate. Barry Sands informed Calcitek that the evidence may be sufficient to prove the claims but that this was not the primary issue. Mr. Sands explained that the 510(k) on file did not contain these claims and that it was necessary to submit a new 510(k) so that the claims could be reviewed.

Calcitek then asked Mr. Uldriks what Calcitek could do to resolve this matter. Mr. Uldriks explained that at present the device in question, "Integral" was considered misbranded and adulterated and was subject to seizure. Calcitek stated that they had stopped distribution of all mailings that contained these claims and that published advertisements with these claims would no longer be used.
At present, Calcitek was intending to display products at several conferences in the near future. Mr. Uldriks explained that their both or literature distributed at the conference could either not contain these claims or labeling would have to be included describing these claims as investigational.

It was at this point that Calcitek formally submitted the document containing the evidence as a 510(k) submission. In addition, Calcitek presented a document containing advertisements from their competitors that they felt were misleading and in violation with FDA regulations. Barry Sands received both documents.

Attachment 4
WIT: LARIVIERE 19 10 1989

IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ORANGE

CONNIE BENTELE, Plaintiff, vs. CALCITEK, INC., et al., Defendants.	)	No. 747549

CERTIFIED COPY

DEPOSITION OF RICHARD LARIVIERE

Santa Ana, California

Friday, July 10, 1998

Attachment 5

Reported by:
SYLVIE HANKS
CSR No. 9618
JOB No. 512595

IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ORANGE

CONNIE BENTELE, Plaintiff, vs. CALCITEK, INC., et al., Defendants.	No. 747549

Deposition of RICHARD LARIVIERE, taken on behalf of Plaintiff Connie Bentele, at 200 North Main Street, Second Floor, Santa Ana, California, beginning at 11:20 a.m. and ending at 3:20 p.m. on Friday, July 10, 1998, before SYLVIE HANKS, Certified Shorthand Reporter No. 9618.

Attachment 5

specifically regarding the approval process of a 510(k), I believe that document would stay within the 510(k) file.

Q And where would the 510(k) file be?

A Again, with the master product file.

Q At some point in time during your employment with Calcitek, did you specifically respond to the FDA regarding the 510(k) of the Integral implant?

A If I understand your question correctly, yes.

Q Do you recall when that would have been?

A No. I'm really bad with dates.

Q That's okay. Would it have normally been your custom and practice, if you were going to respond to the FDA with respect to a particular 510(k), to have reviewed that specific 510(k)?

A Maybe the aspect of the 510(k) that was being challenged, but not necessarily the entire 510(k).

Q Okay. You would have, however, had access to all of the original 510(k) paperwork, though?

A Yes.

Q I believe you testified earlier that you

MR. CLEELAND: Thank you.

MS. VALENTINE-SIBERT: I'll show you a document. We're going to mark it as Exhibit 1. I'm going to go ahead and give you this copy. It's a letter the FDA directed to you of August 31, 1989.

(Plaintiff's Exhibit 1 marked.)

THE WITNESS: Okay.

BY MS. VALENTINE-SIBERT:

Q Do you recall having seen that document before?

A Yes.

Q Is it as a result of that document that you requested a meeting with the FDA?

A I believe so.

Q Okay. As I understand it, you testified that the reason for your meeting with the FDA was an attempt to provide evidence to substantiate the claims that are listed in that letter; is that correct?

A Yes.

Q And what was the result of that meeting?

A We were unable to prove to FDA's level of satisfaction to substantiate these claims.

Q So what was then determined to be the next step?

A We deleted all of these statements from

our labeling.

Q And do you know when that took place

A Immediately following the meeting with FDA. I don't remember the dates.

Q Okay. If you can flip that over to the front page --

A I'm sorry.

Q That appears to be a memo that was generated by the FDA, and the subject is your meeting. And I believe it says that the meeting was September 19, 1989. Does that sound about right to you?

A Yes.

Q How long would it have taken for Calcitek to have deleted those claims on their labels?

A I don't recall the start-stop time line. But we went through a process of working with the agency to try to substantiate the claims where I believe they allowed us to continue making the claims during the review period. And then once we had the final decision from the FDA, we destroyed the product that was in inventory.

Q So you didn't immediately after having that meeting with the FDA go back and delete the claims right then and there on the spot?

A Not as I recall.

Q Okay. Do you recall receiving any written documentation from the FDA that authorized you to continue using those claims while your investigation continued?

MR. CLEELAND: That assumes facts not in evidence.

THE WITNESS: I'm sorry?

MR. CLEELAND: Objection. Assumes facts not in evidence.

We're just preparing the transcript in case this issue ultimately comes before a judge. If you can answer that question, you're certainly welcome to do so.

THE WITNESS: There was a period of time, I believe, where we were allowed to put a disclaimer on the labeling that claims were under regulatory review or something to that effect.

BY MS. VALENTINE-SIBERT:

Q Was that something that was determined as a result of that meeting?

A It probably came from this meeting. I don't know if it was exactly this meeting, but as a result of the dialogue that we opened.

Q Okay. I'm going to show you another

me the purpose of the supporting documentation

MR. CLEELAND: I don't know that I understand what you mean, "purpose of the supporting documentation."

MS. VALENTINE-SIBERT: Well, as I understand it, he provided that letter as well as the supporting documentation to the FDA, and I was asking him what was the purpose of providing them with that supporting documentation.

MR. CLEELAND: What was his intent for providing that material?

MS. VALENTINE-SIBERT: Okay.

MR. CLEELAND: I mean it could be lots of different things. I'm just concerned about "purpose."

BY MS. VALENTINE-SIBERT:

Q Okay. What was your intent?

A This was a further continued effort to provide enough data to FDA to support the claim that HA bonds to bone.

Q Is the data that is attached to that letter additional data that you did not provide to Barry Sands at the original meeting of September 19?

A Oh, I don't recall that.

Q Okay. Do you recall if you provided him

letter, there is a statement made that says, "You are required to wait ninety days after the received date shown above or until receipt of a 'substantially equivalent' letter before placing the product into commercial distribution." Correct?

A Yes.

Q So that letter appears to be inconsistent with your --

MR. CLEELAND: Go ahead.

BY MS. VALENTINE-SIBERT:

Q Okay. With your letter of September 20, 1989, does it not?

MR. CLEELAND: Well, you're asking him to speculate on the word "inconsistent." Do you have a specific reference that might be more appropriate?

BY MS. VALENTINE-SIBERT:

Q Do you understand my question?

A I think you have two different issues here.

Q Okay. Can you explain to me why they are two different issues?

A I believe this is a completely separate submission. The name may have been reused, but I don't believe it's that product that this is referring to. But I don't recall.

Q Is there more than one Integral implant?

A I think we used the name for varying sizes of Integral implants. I don't recall what this 510(k) is for.

Q So you're indicating that there could be two totally different 510(k)'s for two different Integral implants?

A You have to define the term "different." "Integral" is simply a name. It's a brand. I don't recall what this 510(k) was for.

Q So there's more than one type of an implant that would be labeled as an Integral implant?

A There may be more than one 510(k) for the product line called Integral would be a better description.

Q Okay. What is an Integral implant?

A Integral was the brand name that was assigned to the original product line, which was a 4-millimeter-diameter implant in varying lengths. And it was coated with hydroxylapatite. Later on we came out with a smaller diameter, a larger diameter, different-sized attachments, different tools. Those may have had their own separate 510(k)'s but carried the same brand name.

Q So are you saying that if the size of an

Integral implant changes, it requires a separate 510(k)?

A It may be.

Q What would be the determining factor as to whether it would or would not require a separate 510(k)?

A What the original clearance was issued for.

Q Would changing the labeling on an Integral implant require a separate 510(k)?

A In some cases.

Q If labeling was at some point determined to not be substantially equivalent under an already-approved 510(k), would it then be appropriate to file a separate 510(k)?

MR. CLEELAND: You're asking for this person's apparent expertise, actions that occurred after the date of the event on which your client is basing their claim. He's been produced here, we believe, as a percipient witness to the action of the corporation that had to deal with your case. It appears to be getting perhaps into his area of expertise, and he might be entitled to compensation for that.

MS. VALENTINE-SIBERT: Well, I'm simply asking him what he knows with respect to the 510(k) process,

and the 510(k) that we're discussing originated prior to our client being implanted with the Integral implant.

MR. CLEELAND: And all these discussions are after the fact. My concern is --

MS. VALENTINE-SIBERT: The question --

MR. CLEELAND: Hang on a second. My concern is this witness has offered to come here, and you now appear to be asking him for expert testimony, his interpretation on how the FDA regulations work, function, and perform and what he would do. I'd be happy to go within reason, but it appears to be getting a little far afield. Unless I'm wrong.

MS. VALENTINE-SIBERT: Well, I think that in light of the position that he held, I'm asking him what he did and what he knew at the time he held this position with Calcitek.

MR. CLEELAND: That's not what you asked. You asked him to speculate to something. Now, if you ask what he did, I think that's fine. Even though it's after the date and I don't think it has anything to do with your case, we'll certainly cooperate. But you're asking him what would he do under a given scenario, and there's no evidence that that existed or occurred. So I'm a little concerned we're getting

into hypotheticals with what was represented to be a percipient witness.

BY MS. VALENTINE-SIBERT:

Q Okay. Do you know what the original clearance was for the original 510(k) that was approved in 1984 for the Integral implant?

A Do I know what the original clearance was?

Q Right.

A It's a pretty broad question.

Q Okay. You indicated that the only way you can tell whether or not a different 510(k) would be required is based on what the original clearance was; is that correct?

A That's one of the guidelines.

Q So in order for you to determine whether or not an additional 510(k) was necessary for the Integral implant, would you then need to know what the original clearance was for the originating 510(k)?

MR. CLEELAND: I think your question just went full circle. You've asked a nonsensical question.

BY MS. VALENTINE-SIBERT:

Q Do you understand the question?

A Yeah. I still -- I still find it very broad. If you could be more specific, sizes of

implants, for example.

Q Okay. I apologize, but actually what you're testifying to is kind of different than what I've heard before in this case; so it's kind of requiring that I change my line of questioning.

Let's take a break for a second. Okay?

MR. CLEELAND: Sure.

(Recess.)

BY MS. VALENTINE-SIBERT:

Q Okay. So back to the separate 510(k). As I understood your testimony, you do not know why a separate 510(k) would have been filed on the Integral implant?

A I don't recall exactly what this one's for.

Q Okay. Who would have made the decision to file a separate 510(k)?

A It was pretty much an understanding. I don't know if it was any individual person back at that time.

Q Well, it would seem that someone would have to make a decision that a 510(k) would have to be filed.

MR. CLEELAND: There is no question.

BY MS. VALENTINE-SIBERT:

Q Correct?

A Yeah, I guess there was just such an overwhelming understanding amongst the management team of "Here's a new product. If this is what this is, we need to submit."

Q But you don't know if this is a new product?

A I don't recall exactly what this one was.

Q Was part of your job duties in 1989 to prepare 510(k)'s to be sent to the FDA?

A That was within regulatory, yes.

Q In 1989, in September of 1989, would you personally have been the person to prepare the 510(k)?

A Again, I can't recall when Kim started, but this is addressed to me. It would appear as though I signed the 510(k). And I probably had a lot of involvement.

Q Okay. Other than yourself and Kim Carlson, is there anyone else at Calcitek who would have been involved in the decision to file a separate 510(k)?

A The decision to submit basically starts with regulatory opinion -- regulatory opinion and then

probably management discussion. But it might be R and D, it might be sales and marketing, regulatory, all of us getting together to understand what the product was, what the product was already cleared for, and whether or not this fell within the currently cleared indications or the currently cleared limitations.

Q You testified earlier that you recall receiving a letter from the FDA indicating that certain labeling claims with respect to the original Integral implant's 510(k) were questionable as to whether or not they were substantially equivalent; correct?

A Yes.

Q Would you at that time have suggested that a separate 510(k) be filed as a result of those indications from the FDA?

MR. CLEELAND: Are you asking whether he did, or are you asking him to speculate?

MS. VALENTINE-SIBERT: Well, obviously he doesn't know if he did.

MR. CLEELAND: Okay. My concern is your comment, "Would you have." It implies some level of guessing or speculation. I don't mind you going along with the line of questioning. I have some concern

that you imply either action or inaction or recollection or failure of recollection to a specific task.

BY MS. VALENTINE-SIBERT:

Q So in this particular case, you do not recall having suggested that this particular 510(k) be initiated, this being the new --

MR. CLEELAND: Well, that being the September 22, 1989, letter that he testified he doesn't know what that is?

MS. VALENTINE-SIBERT: No. That's not what I'm asking him.

MR. CLEELAND: Okay.

MS. VALENTINE-SIBERT: I'm asking him if -- he indicated that this letter leads him to believe that a separate 510(k) had been filed.

MR. CLEELAND: On a different product; although he does not know what. Correct? My concern is he said he doesn't know what that was for; so it would make it difficult for him to give a response to you that is meaningful as to a specific item or product. He doesn't know what that correlates to.

BY MS. VALENTINE-SIBERT:

Q Were you ever aware of a situation where two different 510(k)'s were filed on the same

product?

A Again I have to ask for clarification. Same product or same brand name?

Q Same product.

A Two 510(k)'s on the same product? I honestly don't recall.

Q Is the brand name something that is usually identified in the 510(k)?

A Not customarily.

MS. VALENTINE-SIBERT: I'm going to mark this as Exhibit 3.

MR. CLEELAND: This has two pages to it?

MS. VALENTINE-SIBERT: Yes, it does.

MR. CLEELAND: Did you intend to have both pages?

MS. VALENTINE-SIBERT: Yes.

MR. CLEELAND: Page 2 actually refers to page 3, and it has a different person's name on it. Did you intend those to be the same?

MS. VALENTINE-SIBERT: That's definitely not good. Actually, you know what? Maybe this is actually only one page. I don't know what this second page goes to, but it doesn't go to this letter.

MR. CLEELAND: Okay.

MS. VALENTINE-SIBERT: So it's actually only

one page.

MR. CLEELAND: Thanks.

MS. VALENTINE-SIBERT: Thanks for clarifying that.

(Plaintiff's Exhibit 3 marked.)

BY MS. VALENTINE-SIBERT:

Q Do you recall ever suggesting that an amendment be made to the original 510(k) for the Integral implant?

A An amendment? In regards to anything specific?

Q I'm sorry?

A In regards to anything specific?

Q Okay. Let me ask you another question. Do you recall the FDA ever indicating to you that there was a question as to the definition of the term "endosteous implant"?

A I don't remember there being a question with regards to that term of "endosseous implant."

Q Okay. I'm going to show you another document. It's dated July 10, 1990.

A January 10?

Q January. Did I say July? January 10, 1990.

MR. CLEELAND: We can fix that.

THE WITNESS: Okay.

BY MS. VALENTINE-SIBERT:

Q Have you seen that document before? Do you recall?

A I believe so.

Q Do you recall whether you made the suggestion to make that 510(k) amendment?

A I don't believing that that was our decision. I believe the agency required it.

Q The agency being the FDA?

A FDA.

Q And do you recall why they required it?

A I believe it's because they felt as though the abutments needed to be a part of the submission, which they weren't originally. So we were following through at their request to give them the documentation they were looking for.

Q Did that amendment have anything to do with the definition of an "endosteous implant"?

A I think in the context that you're using it now, it may have broadened the definition to include the abutments. Is that what you're referring to?

Q Okay. As part of the continuing effort to satisfy the FDA with respect to the labeling

claims, would that have been something that was done with respect to the original 510(k)?

A Yes, I believe so.

Q Okay. And were there any meetings that you had requested or initiated in-house to discuss those labeling claims?

A Yes.

Q Who would have been in attendance at that meeting, those meetings?

Let me just ask this. Was there more than one?

A I don't recall the number of meetings, but we would have certainly discussed the outcome of our FDA meeting.

Q Okay. So you would think it would be more than one?

A Possibly, probably. I'm not sure.

Q Okay. Who would you have requested attend the meeting?

A Off the top of my head, I would think the department heads, the president, myself, and Kim.

Q Okay. And the department heads would be like the -- for which departments?

A Marketing and sales, research, development, manufacturing.

Q And during that time that you were employed with Calcitek, did the same people hold those titles?

A There were some changes.

Q Okay. Do you recall who was specifically at the meetings that the discussion took place with regards to the labeling claims?

A Not really.

Q Okay. Who would have made the decision to place the questioned labeling claims on the product?

A Those labels were from the original founders of the company. Those claims dated back to the initial release of the product.

Q So that would have been back in 1984?

A Whenever we released the product. I don't know that it was 1984.

Q Would there have been a committee or an individual, if you know, that would have been responsible for labeling claims?

MR. CLEELAND: Back in 1984?

BY MS. VALENTINE-SIBERT:

Q Well, if you know.

MS. DAVIS: Ever?

THE WITNESS: I don't know.

BY MS. VALENTINE-SIBERT:

Q Okay. Were you ever told who was responsible for placing those particular claims on the labels of the Integral implant?

A No.

Q Okay. When you had your meetings with respect to those labeling claims, what was the course of action that was discussed?

A Well, as I recall and as these memos indicate, we continued to work with the agency to try to present enough data to satisfy their -- satisfy them with regards to the claims being accurate.

Q Okay. Did the FDA inform you that if the claims were ultimately determined to render the product not substantially equivalent, that by continuing to label them during the interim period of time with those claims, that Calcitek ran the risk of marketing a misbranded product?

A As I recall, the addition of the "Investigational Claims Under Regulatory Review" statement originated from our meeting with FDA and that that was the agreement, that we would put that stipulation on all existing labeling while we continued our dialogue with FDA.

Q And that labeling claim of

MR. CLEELAND: Are you talking about in reference to the representation the labels -- we have not looked at the label. We have not discussed warnings regarding the application and use. I assume your question is related to the same line of questioning we just had?

MS. VALENTINE-SIBERT: That's correct.

MR. CLEELAND: Thank you very much. I apologize.

MS. VALENTINE-SIBERT: That's okay.

Q So yourself and Kim Carlson had -- let me ask you this. Did you initiate any additional studies to be completed as a result of the FDA's concerns of the labeling claims?

A I don't recall if we initiated new studies or if we tried to gain more information that was available. I honestly don't recall. But we did try to present scientific evidence to support the claims.

Q But you don't recall whether that scientific data was something that was already in existence or something that you had just requested to be compiled?

A The claims were based on existing scientific evidence, as I recall. And we may have

tried to augment that with additional studies or with additional data that we had developed. Animal studies, for example. It's hard to get humans to volunteer samples for testing. But I don't know if we specifically went out to start a study to satisfy FDA during this whole process. I don't think that it allowed for that kind of timing.

Q Okay. Ultimately the claims were determined by the FDA to be not substantially equivalent; correct?

A Correct.

Q And what was the basis for --

(Interruption in the proceedings.)

(Recess.)

(Record read.)

BY MS. VALENTINE-SIBERT:

Q What was the basis for that determination?

MR. CLEELAND: In other words, what was the representation to the witness by the FDA?

MS. VALENTINE-SIBERT: Correct.

MR. CLEELAND: Thank you.

THE WITNESS: The data that we were able to present did in fact indicate that hydroxylapatite bonds to bone. As I recall, the Doremus paper that I

think you have here, as I recall, it was an n of 1; in other words, only one example of HA bonding to bone, which they didn't feel satisfied the requirements to make a broad claim that HA bonds to bone.

BY MS. VALENTINE-SIBERT:

Q I'm showing you a letter dated March 15, 1990, to Calcitek authored by Kim Carlson. And under the number 1, it has, "Questioned Labeling Claims." And as I understand it, the claim was that the coating permits bone to actually bond with the implant surface.

A Okay.

Q Does that refresh your recollection as to what in fact the FDA was concerned with? You testified that there was a problem with the claim that the HA bonded to bone. As I understand this statement, the issue is whether or not the coating, the HA coating, bonds with the implant surface.

MR. CLEELAND: There's no question.

BY MS. VALENTINE-SIBERT:

Q Upon review of this letter, does this refresh your recollection as to what in fact the FDA's concern or stated concern was?

A I still read this as HA bonding to bone.

Q So the statement the coating permits the bone to actually bond with the implant surface -- okay. I understand what you're saying now. Okay. Okay. I understand what you're saying.

Okay. So the FDA ultimately determined that Calcitek was unable to provide them with enough information to continue to make those claims?

A Correct.

Q And at that time did Calcitek make a determination as to what to do next?

A Yes.

Q And who within Calcitek made that determination?

A Possibly the president of the company.

Q Did you make recommendations to the president with respect to the nonequivalency or not substantial equivalency of those claims, as to how to now rectify the situation?

MS. DAVIS: At what point in time?

MR. CLEELAND: Rectify what situation?

MS. VALENTINE-SIBERT: The fact that there's claims on the product that was deemed to be not substantially equivalent.

MR. CLEELAND: Well, we've gone from the FDA saying something, and you're asking for the company's

response --

MS. VALENTINE-SIBERT: I asked if he gave the president input as to what Calcitek's response should be.

MR. CLEELAND: After the FDA offered the conclusion they did not believe the statements could be substantiated?

MS. VALENTINE-SIBERT: Yes.

MR. CLEELAND: Thank you.

THE WITNESS: Yes. I'm sure I did.

BY MS. VALENTINE-SIBERT:

Q Do you have a specific recollection of that?

A I think there are only two choices, or actually maybe three: take the product off the market, discontinue the claims, or challenge FDA in court.

Q Do you have a specific recollection as to what your suggestion was, if any, to the president?

A I recall that we discontinued the claims. We threw away every piece of literature that had the claims on it that we could find.

Q And was that your recommendation?

A Yes.

Q Do you recall what time frame that would have been completed in, throwing away all those labels

"Investigational Claims Under Regulatory Review" was placed on every label between the time that that was authorized up until the time that the product was deemed not substantially equivalent?

A That was the plan. And I believe that to have been the case. Every label that carried those claims was -- every piece of literature that carried those claims was overlabeled with that statement.

Q So you're not aware of any labels that were marketed without that claim? During --

A During the period that we were working with FDA, we were very diligent to make sure that we stayed within compliance, within their good graces. We honestly felt as though we had a legitimate claim, and we thought we had enough evidence to support that. And we tried to work with FDA, and we tried to do that by accommodating this proposal.

Q So you're not aware of any labels that were put into the stream of commerce during that time frame that did not have that statement on it?

A During that time frame, no.

Q Okay. Prior to your meeting with the FDA, obviously the labels didn't have any type of a warning or caveat, if you will, on them; correct?

A Correct.

A When I saw something beyond the scope of previous experience, absolutely.

Q And who would that have been?

A Tom Golec was one clinical adviser. We had -- we had a few people. I'm trying to remember the names.

Tom was the clinical guy. It might come to me.

Q Okay. You testified earlier that you were also the individual in charge of the quality control -- quality assurance for Calcitek at the beginning of your employment, and then you became the vice president; correct?

A Yes.

Q At some point in time during your employment, the FDA indicated that they had a problem with the quality assurance with respect to the HA coating; is that correct?

A I think that's too broad a statement. They had a concern with which -- with regards to the controls that we had in place or lack of controls that they thought were appropriate.

Q And what specifically did they feel needed to be in place that was not?

A To my recollection they wanted to track

don't know if I saw this when I was actually at Calcitek or if I actually got a copy of this independently of Calcitek. But I think I was there. I should have checked my resume.

BY MS. VALENTINE-SIBERT:

Q I was trying to see if you authored any letters that might help you, but unfortunately you didn't; so that won't help.

A Well, I believe I was there.

Q Okay. So did you or did you not say that you saw that while you were still employed?

A Yes.

Q Okay.

A I believe I did.

Q Okay. Really quick I'm just going to show you this December 3, 1990, letter.

A Yes.

Q And as I understand it, that was the letter that notified Calcitek that they had finally determined the product was not substantially equivalent. Is that your understanding?

A Yes.

Q Okay. So it would have been shortly after this December 3, 1990, date that Calcitek would have made its decision, as you testified earlier, to

remove the labeling claims?

A Yes.

Q Okay. The letter that you have in front of you discusses a couple of concerns that the FDA had, one of which was the specific labeling claims. And as I understand the letter, the FDA did an audit or an inspection at Calcitek and found some product with the labeling claims still attached to them.

A Yes.

Q Do you have an understanding as to why Calcitek would still have product with those claims on it as late as 1992?

A No. This was a tremendous surprise.

MS. DAVIS: Can I just state for the record that the front page of that letter says when the inspection was done, and the inspection was not done in 1992; that the inspection was done --

MS. VALENTINE-SIBERT: October of '91.

MS. DAVIS: Correct.

THE WITNESS: No, this was quite a surprise. We had revised all of our labeling. We had deleted the comments. We had reprinted the labeling. What we believe happened was that there was an ordering error. But we have never been able -- we were never able to trace back how that happened.

failure mode of an HA implant is to have the HA come off. There are many reasons why that can happen.

Q Okay. So would it be fair to say that that is a risk that is associated with having an HA-coated implant?

A I would say that's correct.

Q And you testified earlier when I showed you a letter that indicated customer complaints of HA coming off of an implant, you indicated that that was not a unique complaint?

MR. CLEELAND: Actually, that wasn't what he said.

But if you understand the question she's about to ask you, you can answer it. She hasn't asked it yet.

BY MS. VALENTINE-SIBERT:

Q Is that correct?

A Well, yeah. What I intended to say, what I meant to say, was that a letter stating that HA came off of the implant associated with the complaint, it's not unusual. That is a failure mode of an HA-coated implant.

Q Are you aware of any labeling or advertisements or brochures that warned the consumers of that failure mode?

A I'm not aware of consumer-targeted labeling, at least not immediately. Most of our labeling, most of our literature, was targeted at our customers, which would be surgeons, the prosthodontists.

Q Are you aware of any labeling or brochures or advertisement that would have been presented to the customers that evidenced the failure mode of HA coming off of the coating? I mean off of the implant?

A I don't recall any literature targeted to a customer. We may have done it, but I don't recall it.

Q So are you aware of any labeling, advertisements, or brochures or any other documents, for that matter, that would have warned anyone who was purchasing or ultimately consuming or being the consumer of that product that there in fact was a potential risk of the HA coming off of the implant?

A Again, it seems like the same question. I don't recall any literature for a consumer.

Q Okay. Well, I'm just making sure that I'm, like, covering all my bases on that.

A All right.

Q Because really all I'm trying to

Claims Under Regulatory Review" provision?

A Correct.

Q Is it your understanding that if a product is marketed with claims that are determined to not be substantially equivalent, then a product is misbranded?

MR. CLEELAND: Insofar as it asks for a legal conclusion, I will object as it lacks foundation. Insofar as it asks for the witness's understanding, it is therefore irrelevant and inadmissible, and I will object on that basis.

Go ahead if you have an answer, sir.

THE WITNESS: I believe once the claim's determined to be unsubstantiated, to continue to market the product would be misbranded.

BY MS. VALENTINE-SIBERT:

Q So the fact that the product has been marketed with those claims and the claims are never determined to be substantially equivalent is of no consequence?

A Back in 1984-1985, when this product was first introduced, you simply had to have the evidence on file to support the claims. We had the evidence on file. Not until 1989, when the claims were challenged, did we realize or did we find out that the

claims were not considered substantially equivalent, or substantiated. We believed we were in compliance.

Q Despite your belief that you were in compliance, the FDA determined otherwise; correct?

A Yes.

Q You said that in 1984 and 1985, you had the information on file.

A I'm speculating that that's the time frame.

Q Okay.

A I don't know when these claims were originally made.

Q But what information would have been on file?

A I believe the reports that were cited.

Q To substantiate those claims?

A Yes.

Q However, based on the FDA's ultimate determination, is it your understanding that what was on file ultimately was determined to not be adequate?

MR. CLEELAND: Can I have that back, please.

(Record read.)

MR. CLEELAND: I've got to hear that one more time. I'm sorry.

(Record read.)

Exhibit 4

MR. CLEELAND: Yeah, I have multiple concerns over that question, including vague and ambiguous as to what ultimate determination and who made that determination and who determined it was not adequate. The witness testified that the company believed that it was adequate. He submitted documentation in support. So I think it becomes a little convoluted.

BY MS. VALENTINE-SIBERT:

Q Did you understand the question?

A Not anymore.

Q You testified that Calcitek had placed certain information on file with the FDA with regards to the claims that were placed on the brochures.

A Yes.

Q You testified that Calcitek was under the impression that those claims were sufficient.

A Yes.

Q The FDA ultimately determined that they were insufficient; correct?

A Correct.

Q Now, that worked really well because I have no idea where I was going with that now.

MR. CLEELAND: It happens.

BY MS. VALENTINE-SIBERT:

Q I assume that Mr. Cleeland and Ms. Davis

Exhibit 4

represent you for the purposes of this deposition; is that correct?

A Yes.

Q Other than the conversations that you've had with them pertaining to this particular lawsuit, have you had conversations with anyone else pertaining to this lawsuit?

A No.

Q Prior to our attempts to contact you with respect to testifying in this lawsuit, were you aware of this lawsuit at all?

A No.

MS. VALENTINE-SIBERT: Okay. I don't have any further questions.

MR. CLEELAND: Okay. Thanks.

MS. VALENTINE-SIBERT: Okay. I propose that we relieve the court reporter of her duties under the Code and that the original of the deposition be forwarded to your office, I presume?

MS. DAVIS: That's fine.

MR. CLEELAND: That would be fine.

MS. DAVIS: The Santa Monica office is fine.

MR. CLEELAND: Send it to her address.

MS. VALENTINE-SIBERT: Okay. Then you'll go ahead and send it to Mr. Lariviere and have him make

Exhibit 4

corrections and provide us with copies of those corrections within 20 days after he makes the corrections?

MS. DAVIS: That would be fine.

MS. VALENTINE-SIBERT: And that if the original transcript is lost or stolen or misplaced, that a certified copy can be utilized as an original?

MS. DAVIS: That's fine.

MS. VALENTINE-SIBERT: That's it. Thank you.

//

//

Exhibit 4

I, RICHARD LARIVIERE, do hereby declare under penalty of perjury that I have read the foregoing transcript; that I have made such corrections as noted herein, in ink, initialed by me, or attached hereto; that my testimony as contained herein, as corrected, is true and correct.

EXECUTED this _____ day of _____, 19___, at _____ (City), _____ (State).

_____
RICHARD LARIVIERE

Exhibit 4

STATE OF CALIFORNIA)
: ss
COUNTY OF ORANGE)

I, the undersigned, a Certified Shorthand Reporter of the State of California, do hereby certify:

That the foregoing proceedings were taken before me at the time and place herein set forth; that any witnesses in the foregoing proceedings, prior to testifying, were placed under oath; that a verbatim record of the proceedings was made by me using machine shorthand which was thereafter transcribed under my direction; further, that the foregoing is an accurate transcription thereof.

I further certify that I am neither financially interested in the action nor a relative or employee of any attorney of any of the parties.

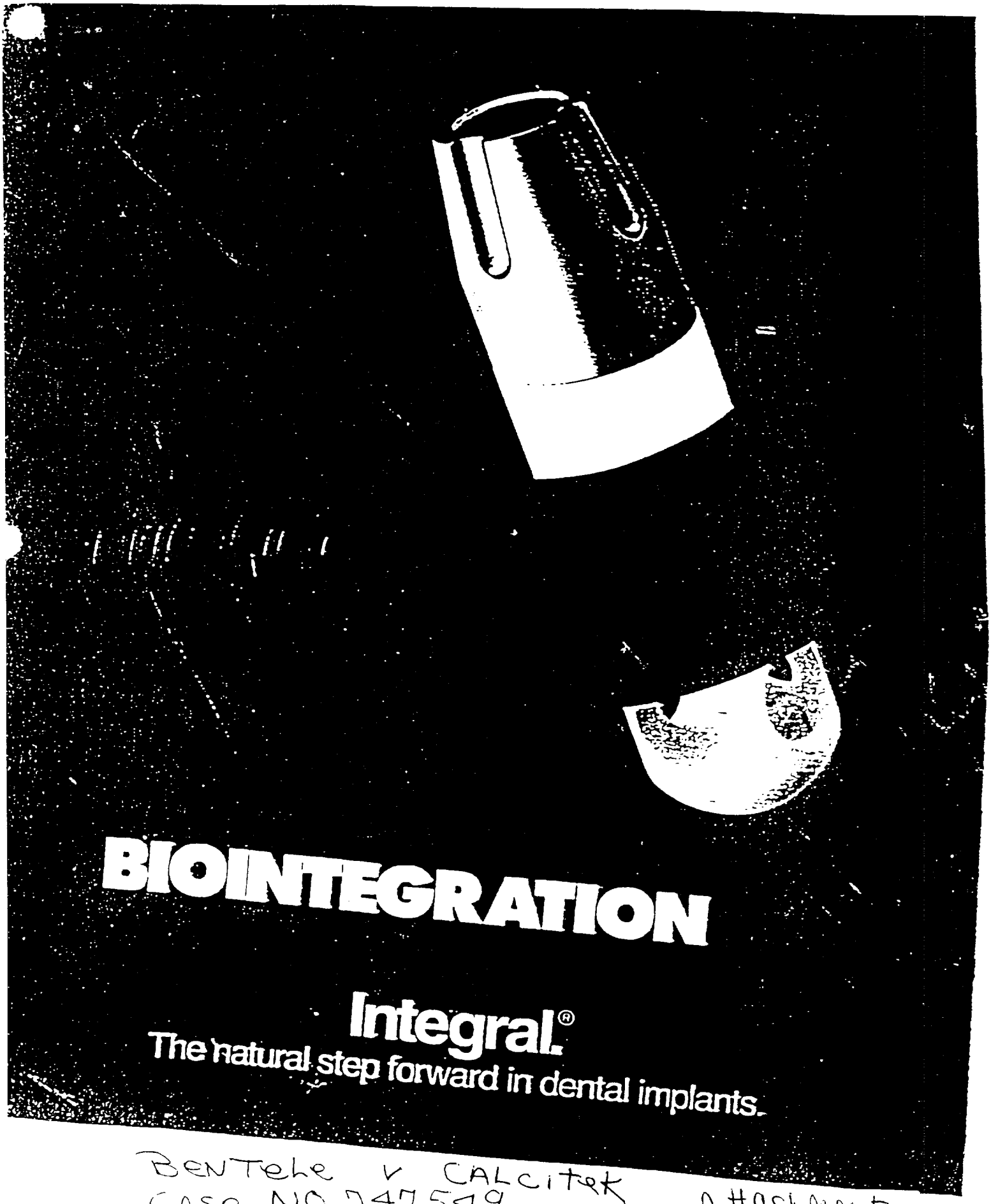
IN WITNESS WHEREOF, I have this date subscribed my name.

Dated: JUL 23 1998

Sylvie Hanks

SYLVIE HANKS
CSR No. 9618

Exhibit 4



BENTeke v CALCITEK
CASE NO 747549
FALSE ADVERTISEMENT
SUBMITTED TO COURT

ATTACHMENT 6

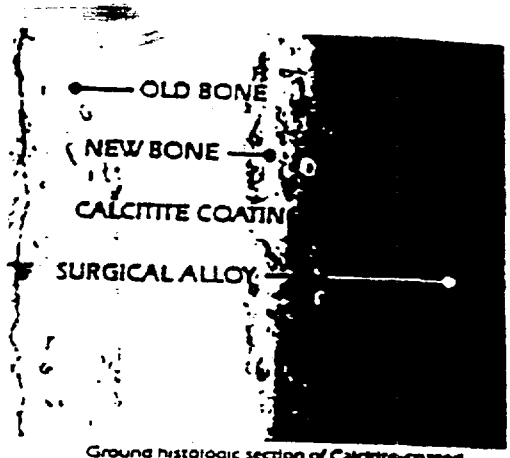
INTEGRAL® COMBINES BIOINTEGRATION™ AND OSSEO

F. D. A. SAID FALSE

The Integral Advantage

The Integral biointegrated dental implant system goes one step beyond conventional osseointegrated dental implant systems. Like other contemporary endosseous implants, Integral uses a "gentle" two-stage implantation procedure to ensure complete fixation prior to loading.

But to achieve *true biointegration*, the titanium Integral implant receives our unique Calcitite® (brand of hydroxylapatite) coating. This coating permits bone to actually bond with the implant surface.[1,2]



Ground histologic section of Calcitite-coated surgical alloy 3 weeks post-implantation in a canine femur. New bone has been deposited on both the coating and the surface of the bone implant site.

The Superiority of Calcitite Coating

Numerous in-vivo studies have confirmed the superior biocompatability and bone-bonding characteristics of hydroxylapatite materials.[3]

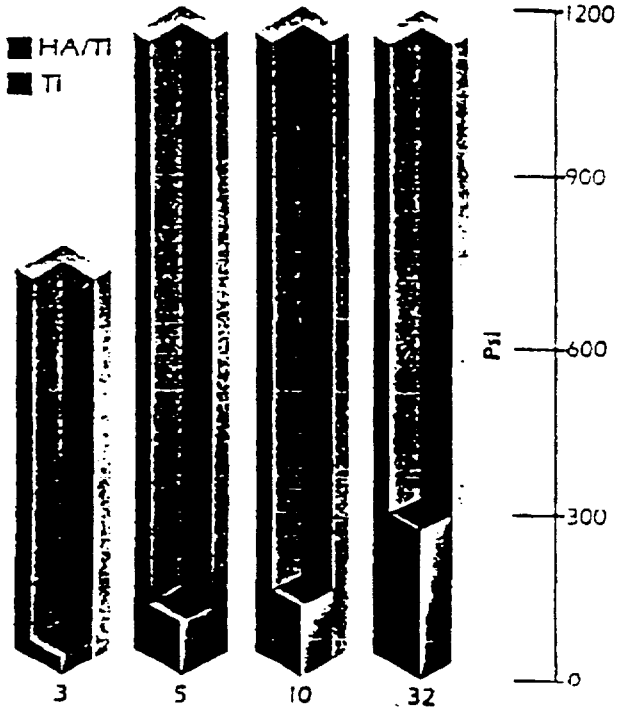
Biomechanical tests on both loaded and unloaded implants dramatically reveal the superiority of Calcitite-coated implants in both degree and rate of fixation in bone.[2,3]

Additionally, the presence of more supporting bone on the Calcitite-coated implant surfaces (versus uncoated implants) may contribute to continued implant success.[3]

The unique bone response to HA coated titanium has led several investigators to conclude that Calcitite-coated implants may not be as susceptible to installation variables as uncoated metal implants.[3]

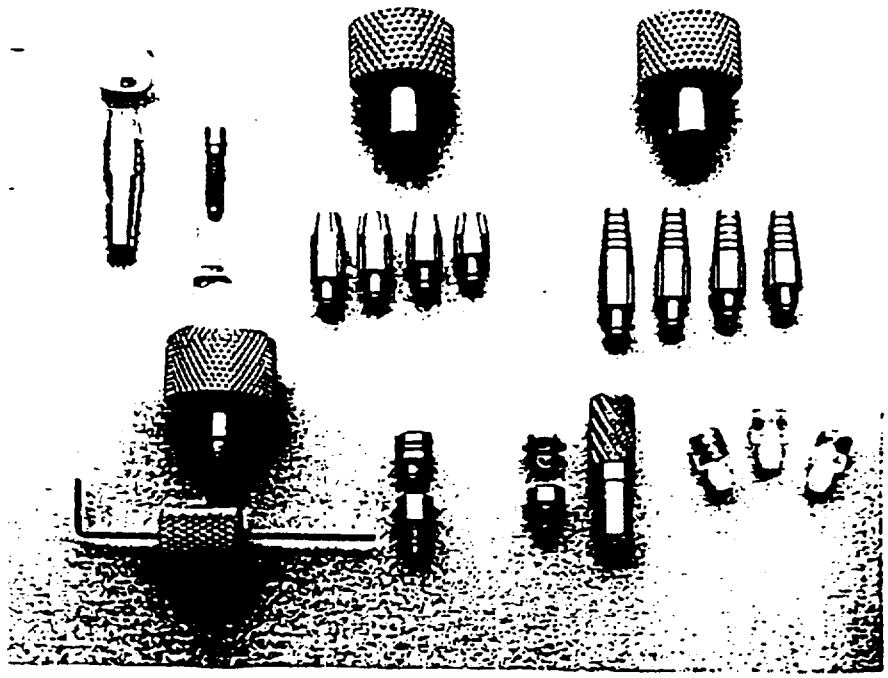
Calcitite-Coated Implants Bond Better

Histological studies demonstrate why Calcitite-coated implants may perform better than uncoated implants. With uncoated titanium implants, new bone grows up to and then adapts to their surface. Frequently, intervening fibrous tissue elements are present between the implant and bone, thereby possibly weakening support.



Weeks Post-Implantation

Attachment strength of titanium and HA-coated titanium transcortical implant plugs in dogs.



A wide selection of threaded attachments allow for maximum flexibility of prosthetic restoration.

Attachment 6
Page 2

PRODUCT DESCRIPTION

The Integral® System is a clinically proven two-stage system, consisting of a Calcitite® coated, biocompatible, titanium implant body and a selection of threaded abutments and attachments which allow for a wide variety of fixed or removable prosthetic applications.

The Calcitite brand of dense hydroxylapatite (HA) coating is applied and bonded to the implant surface using a modified plasma spray process. It is a unique coating that creates a *dramatic biochemical bond between the implant and natural bone*, not just a mechanical fixation as observed in other osseointegrated implants. The Integral system combines contemporary implant research and the most advanced principles of biomaterials engineering.

PRODUCT USAGE

The Integral brand implant is indicated for fully or partially edentulous patients where fixed or removable appliances are the restoration of choice.

PRODUCT ADVANTAGES

The Integral system demonstrates many significant advantages:

- The exclusive Calcitite coating on the Integral implant has demonstrated its ability to enhance osseointegration because it biologically bonds to natural bone. Deposition of new bone occurs not just at the old bone site, but also on the hydroxylapatite coating itself, resulting in a significant increase in the rate at which the surgical site heals. Evidence of an attachment of gingival epithelium to hydroxylapatite implants has been shown by previous researchers. This seal is seen as essential for reducing the risk of infection and implant failure.
- Integral implants are provided sterile and are protected by a special double wrapped holding-vial transfer system for easy delivery to a sterile field.
- A simplified surgical procedure not only minimizes chairside time, but greatly reduces the risk of bone trauma. Bone is cooled during the staged drilling procedure by internal irrigation while the unique design of the drill simultaneously removes the cutting debris.
- Integral implant bodies are available in four lengths to accommodate individual anatomic requirements. Their design and the Calcitite coating create rapid initial stabilization of the implant.
- A wide selection of threaded attachments are available, allowing maximum flexibility in the choice of prosthetic restorations. The system incorporates fixed and removable abutment designs. Integral implants accept time-proven systems such as the Zest® Anchor, an o-ring attachment, various bar attachments and magnetic retention systems. And, should the patient's prosthetic needs change, requiring a different restorative solution, our threaded abutments, in most cases will allow for a complete change of restoration type, without disrupting the integrity of the implant itself.

PACKAGING

The Integral system is available in a surgical kit which provides a necessary placement instrumenta tion and eight implants. Abutments and other attachments ma be selected on an individual basis A complete listing of prosthetic attachment options can be found in our price list.

PERSONAL, TECHNICAL SERVICE

Your orders are handled by technical representatives with signifi cant product knowledge. They ca answer your questions about the Integral System and hydroxylapatite technology. Product litera ture, technical papers, video instructional materials and patie education literature are availabl upon request.

ORDERING INFORMATION

Orders may be placed direct by calling toll-free (800) 854-7019 or (800) 542-6019, in CA.

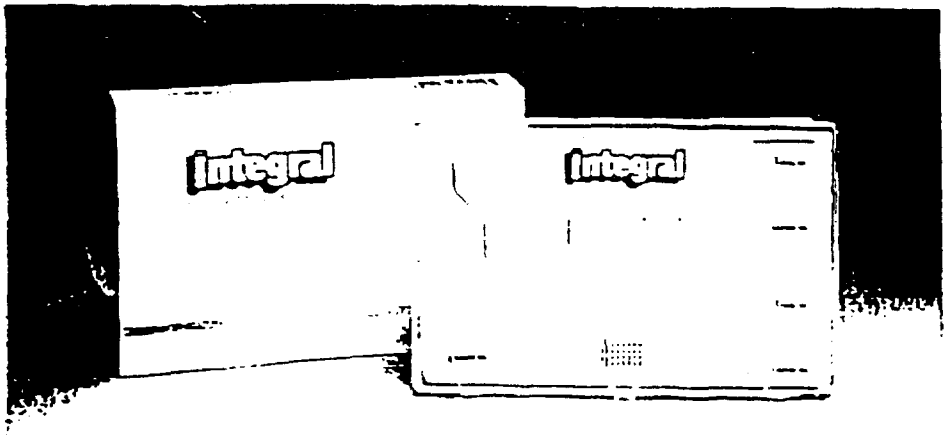
SHIPPING

All shipments are subject to a $3.00 freight and handling fee which will be included on each invoice. Shipments are sent 2nd Day Federal Express, unless otherwise specified.

TERMS

2% 10 days: net 30 days. Prices, policies and terms are subject t change without notice.

No product will be accepted f return without prior authorizati Merchandise authorized for retu will be subject to a restocking charge. All freight must be prepa on returned merchandise.



Integral® Surgical Kit.

Calcitek, Inc.

The Recognized Leader in Hydroxylapatite Tech

2320 Faraday, Carlsbad, CA 920

Caution: Federal law restricts this device to sale by or o order of a licensed dentist or physician. Read accompa instructions prior to use.

7208 4/88

Attachment 6
Page 3

DEPARTMENT OF HEALTH AND HUMAN SERVICES — Public Health S

Food and Drug Adm
Center for Device
Radiological Heal
Office of Device
Document Mail Cen
1390 Piccard Driv
Rockville, Maryla

SEPTEMBER 22, 1989

CALCITEK, INC.
ATTN: RICHARD L. LARIVIERE
2320 FARADAY AVENUE
CARLSBAD, CA 92008

D.C. Number : K895680
Received : 09-20-89
90th Day : 12-19-89
Product : INTEGRAL

The Premarket Notification you have submitted as required under Section 510(k) of the Federal Food, Drug, and Cosmetic Act for the above referenced device has been received and assigned an unique document control number (D.C. Number above). Please cite this D.C. Number in any future correspondence that relates to this submission.

We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. We intend to complete our review expeditiously and within ninety days. Occasionally, however, a submitter will not receive a final decision or a request for additional information until after ninety days has elapsed. Be aware that FDA is able to continue the review of a submission beyond the ninety day period and might conclude that the device is not substantially equivalent. A "not substantially equivalent" device may not be in commercial distribution without an approved premarket approval application or reclassification of the device. We, therefore, recommend that you not market this device before FDA has made a final decision. Thus, if you have not received a decision within ninety days, it would be prudent to check with FDA to determine the status of your submission.

All correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

Plaintiff's EXHIBIT 3
FOR IDENTIFICATION
SYLVIE MARKS, CSR# 0618
7-10 19 98
LARIVIERE

Attachment 7

117

CALCITEK INC.

September 20, 1989

REGISTERED MAIL

Calcitek, Inc.
[illegible]
510 [illegible]

Mr. Barry Sands
Scientific Reviewer
Division of Obstetrics/Gynecology,
Ear, Nose, Throat and Dental Devices
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20857

RE: Integral (August 31, 1989 compliance letter)

Dear Mr. Sands:

In response to the above referenced compliance letter, Calcitek Inc., registration number 2023141, requests that the clinical information submitted to you during our September 19, 1989 meeting be accepted as a supplement to the above referenced 510(k). As we discussed in the meeting, we believe the data contained within that package substantiates the claims in question. As we agreed, pending review of the supplement, all distribution of the offending literature has ceased and journal ads not already printed have been pulled. Any interim use of literature making the claims in question will be done with the words "INVESTIGATIONAL CLAIMS UNDER REGULATORY REVIEW" clearly printed on the document.

I would like to extend my sincere gratitude to you and Mr. Uldriks for agreeing to see us on such short notice and look forward to swift resolution of this matter.

Please feel free to call me if I can be of further assisance.

Sincerely,

Richard Lariviere
Director Quality Assurance and Regulatory Affairs
(619)431-9515

cc: Mr. Casper Uldriks, Acting Deputy Chief, Regulatory Compliance

Mr. James Fraser
Mr. Floyd Larson

Plaintiff's EXHIBIT 2
FOR IDENTIFICATION
SYLVIE HANKS, CSR# 5618
7-10 19 [illegible]
WIT: LARIVIERE

Attachment 9

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health S

Food and Drug
1390 Piccard D
Rockville, MD 2

MAY 30 1990

Ms. Kimberly M. Carlson
Manager, Regulatory Affairs
Calcitek, Inc.
2320 Faraday Avenue
Carlsbad, California 92008

Re: K895680/A
Integral
Dated: March 15, and March 27, 1990
Received: March 16, and April 24, 1990

Dear Ms. Carlson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete the review of your submission, we require the following:

1. Provide original data from all referenced animal and/or human studies to support claims involving bone bonding. The data submitted to date not substantiated the fact that bone and the Calcitek hydroxylapatite coating actually bond. The data has demonstrated that the bond betwe and bone did not have intervening fibrous tissue. However, chemical bonding was not demonstrated. Furthermore, histological data derivec two or three retrieved implants do not establish the fact that bondir occurs on a regular basis. The data presented thus far demonstrates bone can directly oppose the HA coating without intervening fibrous tissue.

   The reference to Impladent's 510(k) K812321 does not establish the f that claims of bone bonding have been found substantially equivalent The references that were made in Impladent's 510(k) were not conside labeling. In addition, Impladent's implant is of a different geomet configuration than that of yours and this could directly affect the ultimate bone/HA interface.

2. The labeling claims based on animal studies may be included if origi data derived from these studies can be supplied to the Food and Drug Administration (FDA) for review and the following statement prefaces claims.

   "A direct analogy between the animal physiological reaction anc human physiological reaction to dental implants cannot be drawr

3. Provide clinical data to demonstrate the relevance of the results fr transcortical implant study to that of a dental implant placed in th mandible or maxilla. This request is made as a result of a label made about mean attachment strength of hydroxylapatite coated r in the canine femur.

We believe that this information is necessary for us to determine whether not this device is substantially equivalent to a pre-Amendments device wi regard to its safety and effectiveness.

You may not market this device until 90 days after you have provided adeq information described above and required by 21 CFR 807.87(f) and(h). If market the device without conforming to these requirements, you will be i violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemptions (IDE) regulations.

If the requested information is not received within 30 days, we will cons: your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 3(days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(is complete.

Please submit the requested information to:

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
1390 Piccard Drive
Rockville, Maryland 20850

If you have any questions concerning the contents of this letter, please contact Mr. Barry E. Sands, at (301) 427-1230. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or (301) 443-6597.

Sincerely yours,

David A. Lippman

for Lillian Yin, Ph.D.
Director, Division OB-GYN, ENT,
and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Attachment 10

DEPARTMENT OF HEAL .I & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

DEC - 3 1990

hard L. Lariviere
citek, Inc.
0 Faraday Avenue
rlsbad, CA 92008

K895680/B
Integral ←
Regulatory Class: III
Dated: August 31, 1990
Received: September 4, 1990

Dear Mr. Lariviere:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We have determined the device is not substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to any device which has been reclassified into class I (General Controls) or class II (Performance Standards). This decision is based on the fact that your device has a new intended use. This decision does not affect the marketing clearance received under K840750. However, the labeling claims outlined below which were not part of K840750, cannot be used.

a. "The coating permits bone to actually bond with implant surface."

b. "Bone-bonding characteristics of hydroxylapatite material."

c. "Biochemical tests on bone loaded and unloaded implants dramatically reveal the superiority of Calcitite-coated implants on both degree and rate of fixation in bone."

d. "Additionally, the presence of more supporting bone on the Calcitite-coated implant surfaces (versus uncoated implants) may contribute to continued implant success."

e. "But with Calcitite-coated implants, bone grows more rapidly on, and covers a greater percentage of, the implant surface. Plus, there are virtually no fibrous tissue elements between the bone and the implant."

f. "Most important of all, this bonds strongly to the Calcitite-coating. This bone-bonding phenomenon mirrors the bone-bonding associated with dense hydroxylapatite."

g. "Histological studies demonstrate why Calcitite-coated implants may perform better than uncoated implants."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

WARNING LETTER

Los Angeles District
1521 West Pico Boulevard
Los Angeles, California 90015-2486
Telephone (213) 252-7583

WL-51-2

May 15, 1992

Mr. James S. Fraser
President
Calcitek, Inc.
2320 Faraday Avenue
Carlsbad, California 92008

Dear Mr. Fraser:

During an inspection of your medical device facility by the Food and Drug Administration (FDA) between October 8 and November 1, 1991, our investigator documented numerous violations associated with your firm's hydroxylapatite (HA) containing products. These products, "Biointegrated Dental Implant Systems" and "Calcitite Nonresorbable Hydroxylapatite Bone Grafting Material," are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The violations included deviations from the Good Manufacturing Practice for Medical Devices (GMP) regulation, Title 21, Code of Federal Regulations (CFR), Part 820, which cause your firm's hydroxylapatite (HA) containing products to be adulterated within the meaning of Section 501(h) of the Act, including the following:

1. Failure to test each lot of finished device for conformance with device specifications prior to release for distribution, as required by 21 CFR 820.160. For example, the hydroxylapatite content or crystallinity is not properly characterized in the coating of each lot of hydroxylapatite coated devices or packaged hydroxylapatite particles, and the pass/fail criteria for the coating allow [redacted] and hydroxylapatite without regard to their relative ratios. In addition, the 11/26/91 study entitled "The Effects of [redacted] Sterilization on HA Particles and HA Coatings" is not sufficient to justify the absence of tests conducted on devices or test strips following [redacted] irradiation prior to release of finished devices for distribution.

2. Failure to assure that all quality assurance checks are adequate and appropriate for their purpose and are performed correctly, as required by 21 CFR 820.20(a)(4). For example, the hydroxylapatite content or crystallinity is not properly characterized in the coating of each lot of hydroxylapatite coated devices or packaged hydroxylapatite particles and the pass/fail criteria for the coating allow [redacted] and hydroxylapatite without regard to their relative ratios and neither devices nor test strips are tested following [redacted] irradiation prior to release for distribution.

3. Failure to control environmental conditions at the manufacturing site to prevent contamination of the device, where environmental conditions could have an adverse effect on the device's fitness for use, as required by 21 CFR 820.46. For example, humidity is not monitored during the hydroxylapatite coating operations in the plasma spray coating room.

4. Failure to examine device labeling materials for identity, as required by 21 CFR 820.120(d). For example, the container package label for catalogue N. 0803, lot 910589, a 13 mm Integral 4.0 Implant was labeled with a container package label that erroneously stated it was an 8 mm implant.

5. Failure to establish procedures for specification control measures to assure that the design basis for the device is correctly translated into approved specifications, as required by 21 CFR 820.100(a)(1). For example, the effect of humidity could not have been part of the validation of the HA coating operation in the plasma spray coating room.

6. Failure of the device master record to include production environment specifications, as required by 21 CFR 820.181(d). There is no specification for humidity in the plasma spray coating room.

7. Failure to dispose of by-products and chemical effluents in a timely, safe, and sanitary manner, as required by 21 CFR 820.56(d). For example, there was a pink-colored material deposited along the seams of a metal plate on the HA processing machine on October 10. 1991.

8. Failure to maintain a device history record to demonstrate that the device is manufactured in accordance with the device master record, as required by 21 CFR 820.184. For example, the [redacted] ROOM cleaning record did not clearly indicate whether the processor was cleaned or whether production was still continuing from the previous day.

During the inspection, FDA investigators collected labeling for your firm's "Calcitite Nonresorbable Hydroxylapatite Bone Grafting Material," which revealed that these devices are misbranded within the meaning of Sections 502(a) and 502(o) of the Act. The labeling for the devices is false or misleading within the meaning of Section 502(a) in that statements such as:

> "Since Calcitite HA is similar to a mineral naturally found in your body, it is completely compatible with your body";
>
> "Since Calcitite is a mineral naturally found in your body, it is completely compatible with your body"; and
>
> "..... eliciting no inflammatory or foreign body response."

represent or suggest that the material is completely biocompatible, representations or suggestions are false or misleading or otherwise contrary to fact because Calcitek grafts are non-autogenous grafts and cannot be completely compatible.

Your firm's "Calcitite Nonresorbable Hydroxylapatite Bone Grafting Material" is misbranded within the meaning of Section 502(o) of the Act, in that a premarket notification submission was not provided as required by Section 510(k) and 21 CFR 807.81(a)(3), and was not found to be substantially equivalent as required by Section 513(i)(1)(A), when significant changes or modifications were made to the device. For example, the statement: "... can retard further progression of gum disease...aiding in preventing its recurrence" constitutes a major change or modification in the intended use of the device CALCITITE 2040 BONE GRAFT MATERIAL, described in K852682, and requires a premarket notification submission.

During the inspection, FDA investigators also collected labeling and promotional material for your firm's "Biointegrated Dental Implant Systems," which revealed that these devices are adulterated within the meaning of Section 501(f)(1)(B) of the Act, in that the devices have been classified in Class III under Section 513(f) of the Act and are required to have in effect an approved application for premarket approval, and no approvals have been granted. In a letter dated December 3, 1990, regarding K895680, a premarket notification submitted for the Integral device, the "Biointegrated Dental Implant System" was classified in Class III when it is labeled with claims, including:

"The coating permits bone to actually bond with the implant surface."

"Bone-bonding characteristics of hydroxylapatite material."

and

"Biochemical tests on both loaded and unloaded implants dramatically reveal the superiority of Calcitite-coated implants on both degree and rate of fixation in bone."

Statements such as:

".... to ensure complete bony fixation ....,"

"Biointegration and implant stability are enhanced by the Calcitite brand of dense hydroxylapatite (HA) coating ...."

and

".... to ensure a stable biocompatible interface with bone ...."

found in labeling and promotional materials for the Integral and Integral Omniloc Biointegrated Dental Implant Systems cause these devices to be unapproved Class III devices.

You firm's Biointegrated Dental Implant Systems are also misbranded within the meaning of Section 502(t)(2) of the Act in that information was not submitted within the reporting time frames to the Food and Drug Administration (FDA) as required by 21 CFR Part 803, the Medical Device Reporting (MDR) regulation. Specifically, you failed to submit a telephone report within five (5) calendar days and a written report within fifteen (15) working days of your initial receipt of information which reasonably suggested that one of your commercially distributed devices caused or contributed to a serious injury. Your firm's retrospective submission in October 1991 of 21 events identified them as malfunctions, however, FDA considers these events to represent serious injuries as defined in the MDR regulation under 21 CFR Part 803.3(h).

The loss of or failure to osseointegrate of an endosseous implant device leaves the patient with a compromised intra-oral structure (i.e., supporting bony tissue damage) which may allow entry of oral fluid and microorganisms into the implant site, infection, and implant mobility; and necessitates medical intervention by a health-care professional to remove the implant, promote healing, and prevent further bone loss, thereby precluding permanent tissue damage.

The failure to osseointegrate or fracture of the implant may also impair the patient's masticatory function, necessitating medical intervention to remove and revise the implant, to preclude permanent impairment of a body function.

Since the failure to osseointegrate will not correct itself, it cannot be viewed as temporary impairment, but must be viewed as permanent impairment. When a firm receives a report that states that there was a failure of the device to osseointegrate and medical intervention was needed, lacking any other information, the incident is reportable as a serious injury that required medical intervention to prevent permanent impairment of a body function or structure.

Your firm is also in error in the definitions used to identify reportable malfunctions. Perforation of the sinus cavity is considered a serious injury as well a recognized complication. Exfoliation or removal of an implant (before or after restoration) and fracturing of the bone are serious injuries which require medical or surgical intervention to preclude permanent impairment of the body structure or function. Fracturing of the blade portion of the drill and mobility of the implant or complete augmentation would also be considered serious injuries unless your firm obtains information and/or a statement from the health-care professional within five (5) calendar days that no medical or surgical intervention was required to remove the fractured blade or correct the reported mobility problem.

FDA also considers outright fractures of the implant to be serious injuries, especially those where the fracture occurs in the bone or soft tissue area, and the definitions should be revised accordingly.

Your firm should revise its MDR reporting procedures to reflect the interpretation provided above. Also, your firm is responsible for the submission within fifteen (15) working days of receipt of this letter, of all other MDR reportable incidents received by your firm within the 2-year period prior to the date of this letter which have not been reported to FDA. If submission of these reports cannot be completed within fifteen (15) working days of receipt of this letter, provide a tabulation of the reports and the time when the reports will be submitted. The MDR reports and tabulation, if necessary, should reference this Warning Letter and be directed to:

Mrs. Victoria A. Schmid
Device Experience Administration and Monitoring Branch (HFZ-343)
Division of Product Surveillance
Office of Compliance and Surveillance
Food and Drug Administration
1390 Piccard Drive
Rockville, Maryland 20850

This letter should not be construed as an all-inclusive list of deviations associated with your facility and your products. It is your responsibility to assure that you comply with all requirements of the Act. Until these violations are corrected, Federal agencies will be informed that the Food and Drug Administration recommends against the award of contracts for affected products.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office, in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the timeframe within which the corrections will be completed. We acknowledge receipt of your letter dated November 27, 1991, which you may wish to reference in your response.

Your response should be directed to:

Mr. Thomas L. Sawyer
Director, Compliance Branch
U.S. Food and Drug Administration
1521 West Pico Boulevard
Los Angeles, California 90015-2486

Sincerely,

George J. Gerstenberg
District Director

Received 2/6/93

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Los Angeles District
1521 West Pico Boulevard
Los Angeles, California 90015-24
Telephone (213) 252-7583

February 3, 1993

Mr. James S. Fraser
President
Calcitek, Inc.
2320 Faraday Avenue
Carlsbad, CA 92008

Dear Mr. Fraser:

We have completed our review of the labeling and Current Good Manufacturing Practice issues (CGMPs) involved in the Warning Letter WL-51-2, dated May 15, 1992 and your response. The response to the Reporting issues (Medical Device Reporting 'MDRs') dated 10/30/92 from your attorney, is still under review. We did encounter significant delays in that your response had to go through multiple levels of review at FDA headquarters, and we apologize for the delay in providing the following:

1. Your response to labeling sections 502(a), 502(o), and 501(f)(1)(B) appears to be adequate. You have agreed to remove all labeling claims identified in the Warning Letter as causing the device to be misbranded within the meaning of these sections.

2. Your response to the Good Manufacturing Practice section 501(h) appears to be adequate, except for the following:

Scientists in the Office of Device Evaluation (ODE) were consulted on the GMP deviation regarding the failure to test each lot for conformance with device specifications; and the failure to assure the adequacy and appropriateness of all quality assurance checks.

The ODE scientists have advised us that the finished device specifications for the hydroxylapatite coating should include infrared spectrophotometry, crystallinity measurements, and a calcium/phosphorus ratio calculation, to provide a complete characterization of the coating. They advised that while it is not necessary to conduct these tests on each lot of finished devices, there should be some mechanism for periodic testing to assure that the finished device continues to meet the parameters set for these specifications.

In addition, they advised that the maximum trace element concentration allowed by their hydroxylapatite powder (550 ppm) is much higher than that given in the ASTM standard (F1185) for hydroxylapatite (50 ppm). While this standard is a voluntary standard, ODE advises that it is the current industry standard for hydroxylapatite and that trace element concentration allowed by Calcitek could arguably be considered a failure to comply with current good manufacturing practices in the industry.

We would encourage Calcitek to comply with the ASTM standard and lower the allowable maximum trace concentration in the hydroxylapatite powder to 50 ppm.

Please respond to the GMP issue regarding lot testing within thirty (30) days, so that we may close this part of the file. Send the response to my attention at the Los Angeles District Office.

Thomas L. Sawyer
Director Compliance Branch
Los Angeles District Office

Designation: F 1185 – 88 (Reapproved 1993)ε1

AMERICAN SOCIETY FOR TESTING AND MATERIALS
1916 Race St. Philadelphia, Pa 19103

Standard Specification for Composition of Ceramic Hydroxylapatite for Surgical Implants[1]

This standard is issued under the fixed designation F 1185; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

ε1 NOTE—Keywords were added and Section 3 editorially corrected in March 1993.

1. Scope

1.1 This specification covers material requirements for ceramic hydroxylapatite intended for surgical implants. For a material to be called ceramic hydroxylapatite, it must conform to this specification. (See Appendix X1.)

1.2 The biological response to ceramic hydroxylapatite in soft tissue and bone has been characterized by a history of clinical use **(1, 2, 3)**[2] and by laboratory studies **(4, 5, 6)**.

1.3 This specification specifically excludes hydroxylapatite coatings, non-ceramic hydroxylapatite, ceramic-glasses, tribasic calcium phosphate, whitlockite, and alpha- and beta-tricalcium phosphate. (See Specification F 1088.)

2. Referenced Documents

2.1 *ASTM Standard:*
F 1088 Specification for Beta-Tricalcium Phosphate for Surgical Implantation[3]
2.2 *Code of Federal Regulations:*[4]
Title 21, Part 820.
2.3 *National Formulary:*[5]
Tribasic Calcium Phosphate
2.4 *United States Pharmacopeia:*[6]
Identification Tests for Calcium and Phosphate <191>
Lead <251>
Mercury <261>
Arsenic <211>
Heavy Metals <231> Method 1
2.5 *U. S. Geological Survey Method:*[7]
Cadmium

3. Terminology

3.1 *Descriptions of Terms Specific to This Standard:*

3.1.1 *calcining*—the heat treatment of a ceramic precursor for the purpose of eliminating volatile constituents. Calcining is also accompanied by some surface area and bulk volume reductions. Increases in mechanical properties are not usually significant.

3.1.2 *ceramic hydroxylapatite*—hydroxylapatite which has been fired at sintering temperatures. Firing time is mass dependent, and should be sufficiently long to cause significant densification and formation of a biologically stable form.

3.1.3 *hydroxylapatite*—the chemical substance having the empirical formula $Ca_5(PO_4)_3OH$.[8]

3.1.4 *sintering*—an integration of time and temperature of a ceramic precursor which develops a coherent body with useful properties. Sintering is a non-melting process accompanied by significant surface area and bulk volume reductions (densification), grain growth, and increases in mechanical properties.

4. Chemical Requirements

4.1 Elemental analysis for calcium and phosphorus will be consistent with the expected stoichiometry of hydroxylapatite.

4.2 A quantitative X-ray diffraction analysis shall indicate a minimum hydroxylapatite content of 95 % (7). Analysis of relative peak intensities shall be consistent with published data.[9]

4.3 The concentration of trace elements in the hydroxylapatite shall be limited as follows:

Element	ppm, max
As	3
Cd	5
Hg	5
Pb	30
total heavy metals (as lead)	50

For referee purposes, methods in 2.4 and 2.5 shall be used.

4.4 The maximum allowable limit of all heavy metals determined as lead will be 50 ppm as described in 2.4 or

[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.13 on Ceramic Materials.

Current edition approved Oct. 31, 1988. Published December 1988.

[2] The boldface numbers in parentheses refer to the list of references at the end of this specification.

[3] *Annual Book of ASTM Standards*, Vol 13.01.

[4] Available from U.S. Government Printing Office, Washington, DC 20402.

[5] National Formulary XVI. Available from U.S. Pharmacopeia Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852.

[6] United States Pharmacopeia XXI. Available from U.S. Pharmacopeia Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852.

[7] Crock, J. G., Felichte, F. E., and Briggs, P. H., "Determination of Elements in National Bureau of Standards Geological Reference Materials SRM 278 Obsidian and SRM 688 Basalt by Inductively Coupled Argon Plasma—Atomic Emission Spectrometry," *Geostandards Newsletter*, Vol 7, 1983, pp. 335-340.

[8] Chemical Abstracts Service Registry Number [1306-06-5].

[9] The Joint Committee on Powdered Diffraction Standards has established a Powder Diffraction File. The Committee operates on an international basis and cooperates closely with the Data Commission of the International Union of Crystallography and ASTM (American Society for Testing and Materials). Hydroxylapatite data can be found on file card number 9-432 and is available from the Joint Committee on Powder Diffraction Standards, 1600 Park Lane, Swarthmore, PA 19081.

...ITE" POST
...xylapatite Coated Dental Implant

CALCITITE"

...e: Replace "Pyrolite" with "Calcitite"
...erever it appears in following text]

INSTRUCTIONS FOR USE
PYROLITE® POST
Carbon Coated Dental Implant

INDICATIONS: Pyrolite Post dental implants can be used in selected patients to serve as artificial tooth roots to support teeth or bridgework.

WARNINGS: Surgical techniques required to place dental implants are highly specialized and complex procedures. Specialized training is strongly recommended. Practitioners should attend courses of study to prepare them in oral implantology. Improper technique can cause implant failure and loss of bone. Pyrolite Post implants are intended to be used *only* with the specially-designed bone drills supplied with the kit.

PRECAUTIONS: Adequate radiographs, palpation, and direct visual inspection are often necessary to determine the anatomy of available bone. The location of anatomical features to be avoided (such as the inferior alveolar canal, mental foramen, maxillary sinuses, nasal cavity, adjacent teeth, etc.) should be established prior to the use of Pyrolite Post implants.

SURGICAL QUALIFICATIONS: Proper diagnosis, treatment planning, surgical techniques, and post-surgical management are important aspects of implant technology. It is recommended that professionals obtain the expertise required to place implants before attempting the procedure.

CAUTION: Federal law restricts this device to sale by or on the order of a licensed dentist.

Manufactured for:

Calcitek, Inc.™
A Subsidiary of Intermedics Inc
San Diego, CA 92121

2070-1-0 8-83

1.0 INTRODUCTION

The Pyrolite® Post implant is designed for use in either the mandible or maxilla as a free standing single tooth replacement, or as a distal or intermediary abutment for a fixed bridge.

2.0 PATIENT SELECTION

2.1 Preliminary Consideration

The evaluation of a patient as a possible recipient of a Pyrolite Post implant is extremely important. The potential benefit to a patient must be weighed against the risk of receiving an implant. This includes determination of general health, oral hygiene habits and status, motivation toward good dental care, and anatomical acceptability.

The preliminary interview should determine whether the patient is psychologically adapted and motivated to maintain good dental care in the implant area. Severe emotional disorders, deficient mental capabilities, excessive use of tobacco, alcohol, or drugs may be contraindications. If the assessment is positive, the patient's general health and oral condition must be evaluated. The A.D.A. Patient Medical History (long form) may be useful for this purpose.

2.2 Contraindications

Systemic: The following systemic disorders may contraindicate the use of the Pyrolite Post implant:

1. Uncontrolled diabetes mellitus
2. Compromised cardiovascular status
3. Compromised pulmonary status
4. History of cerebral vascular accidents
5. Uncontrolled hypertension
6. All forms of blood dyscrasias
7. All forms of active collagen or granulomatous disease.
8. All other forms of cardiovascular.

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Page 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 13 1984

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

Mr. Richard Hunter
Manager, Regulatory Affairs
Calcitek, Inc.
4125-B Sorrento Valley Boulevard
San Diego, California 92121

Re: K840750
Hydroxylapatite Coated Endosseous
Dental Implants

Dated: February 16, 1984
Received: February 23, 1984

Dear Mr. Hunter:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either class II (Performance Standards) or class III (Premarket Approval), it would be subject to additional controls.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act. In the future, the scope of general controls may be broadened to include additional regulations.

All regulations and information on meetings of the device advisory committees, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so you can convey your views to FDA if you desire and be notified of any additional requirements imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HFZ-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

Robert G. Britain

Robert G. Britain
Acting Director
Office of Device Evaluation
National Center for Devices
and Radiological Health

Attachment
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Appendix A

Blade and Post-Type Dental Endosseous Implants

1. Pyrolite® Post Carbon Coated Dental Implants
   Calcitek, Inc.

2. The Synthodont™ Implant System
   Miter

3. Endosteal Blade Implants
   Implants International

4. Titanium Intraosseous Blades
   Park Dental Research Corp.

5. Flexicut™ Titanium Implants
   Implacent

Attachment 15
Page 3

THE BIOLITE™ CARBON COATED METAL DENTAL IMPLANT — Changed to: THE CALCITITE™ HYDROXYLAPATITE COATED DENTAL IMPLANT

BLADE TYPE

INSTRUCTIONS FOR USE

1.0 IMPLANT SITE

The Biolite™ Carbon coated metal blade is designed for use as a terminal abutment in the mandible and maxilla to support a fixed bridge. The site, a healed edentulous region, requires that a groove be prepared for it using methods similar to those used in placing standard metal blades. — Calcitite™ hydroxylapatite

[Note: Replace Biolite™ Carbon with "Calcitite hydroxylapatite" wherever it appears in following text]

2.0 PATIENT SELECTION

2.1 Preliminary Consideration

The evaluation of a patient as a possible recipient of a Biolite™ Carbon coated metal abutment is extremely important. The potential benefit to the patient must be weighed against the risk of receiving an implant; a determination of general health, hygenic habits, motivation, and acceptable anatomy must also be made.

The preliminary interview should determine whether the patient is psychologically acceptable and motivated to maintain an implant hygenically. Severe emotional disorders, deficient mental capabilities, excessive use of tobacco, alcohol, or drugs are contraindications. If the assessment is positive, the patients general health and oral condition must be evaluated.

2.2 Contraindication--Systemic

The following systemic disorders contraindicate the use of Biolite™ Carbon coated metal abutments:

1. Uncontrolled diabetes mellitus
2. Compromised cardiovascular status
3. Compromised pulmonary states
4. History of cerebral vascular accidents
5. Uncontrolled hypertension
6. All forms of blood dyscrasias
7. All forms of active collagen or granulomatous disease
8. All other forms of cardiovascular, endocrine, nervous allergic, muscular skeletal cutaneous, genitourinary, and pulmonary disease which may compromise the use of an endosseous implant that protrudes into the oral cavity.

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Page 4

Thomas M. Dymott, Esq. (CSB#61015)
NEIL, DYMOTT, PERKINS, BROWN & FRANK
1010 Second Avenue, Suite 2500
San Diego, California 92101-4959
Telephone: (619) 238-1712
Facsimile: (619) 238-1562

Attorneys for Defendant,
CALCITEK, INC.

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF SAN DIEGO

MARY MASTERS, Plaintiff, vs. CALCITEC, INC., IAN AIRES, D.D.S., ESTATE OF THOMAS GOLEC, D.D.S., ESTATE OF ROBERT JAMES, D.D.S., RALPH MAW, (DECEASED) D.D.S., INC., Defendants.	CASE NO. 689884 DECLARATION OF ROBERT L. IN SUPPORT OF CALCITEK, MOTION FOR SUMMARY JUDGM ADJUDICATION OF ISSUES Date: September 20, 199 Time: 1:30 p.m. Dept: 43 I/C Judge Arthur W. Jones [TELEPHONIC RULING -- 53 NO APPEARANCE REQUIRED]

I, Robert L. Riley declare:

1. I am the Director of Technical Services for Calcitek I have personal knowledge of the facts contained within declaration and could and would competently testify there called to do so at trial.

2. I have been involved with Calcitek, Inc.'s line of implants since their inception. I have worked with the engin department in the creation of implant designs, pros components, and ancillary materials. I have published s

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articles on dental implantology, and sit on the Editorial Re
Board for the Journal of Dental Technology magazine. I have
than twenty-five years experience in the field of dentistry. I
been working with dental implants since 1974.

3. Hydroxylapatite is a mineral constituent of bone
teeth. Hydroxylapatite is present in each person's bone and tee
and is the substance which makes bones rigid. The hydroxylapat
manufactured by Calcitek, Inc. is a synthetic material manufactu
to mirror the substance already contained within each person's bo
Human bone recognizes the synthetically-made hydroxylapatite so t
they grow together. Hydroxylapatite is radio-opaque, and is read
visible on x-rays.

4. Calcitek's hydroxylapatite was originally cleared
market by the Food & Drug Administration in the early 1980s.
HA particles sold by Calcitek were cleared to market by the Fooc
Drug Administration by the process of 510(k). A submission was ma
to the Food & Drug Administration claiming equivalency to
predicate device. The predicate device to which Calcitek's HA w
compared was freeze-dried bone. Each subsequent reconfiguratio
and additional product containing hydroxylapatite has been clear
to market by the Food & Drug Administration prior to its sale to t
public. Calcitek's blade implants have never been subject to
recall of any nature.

5. Prior to 1988, Calcitek, Inc. was wholly owned b
Intermedics, a company publicly traded on the New York Stoc
Exchange. Subsequent to 1988, Intermedics was purchased by Sulzer
a Swiss company which now wholly owns Calcitek, Inc. Dr. Thoma
Golec to the best of my knowledge, never owned stock in eithe

Intermedics or Sulzer. Dr. Thomas Golec was never a major shareholder of Calcitek, Inc.

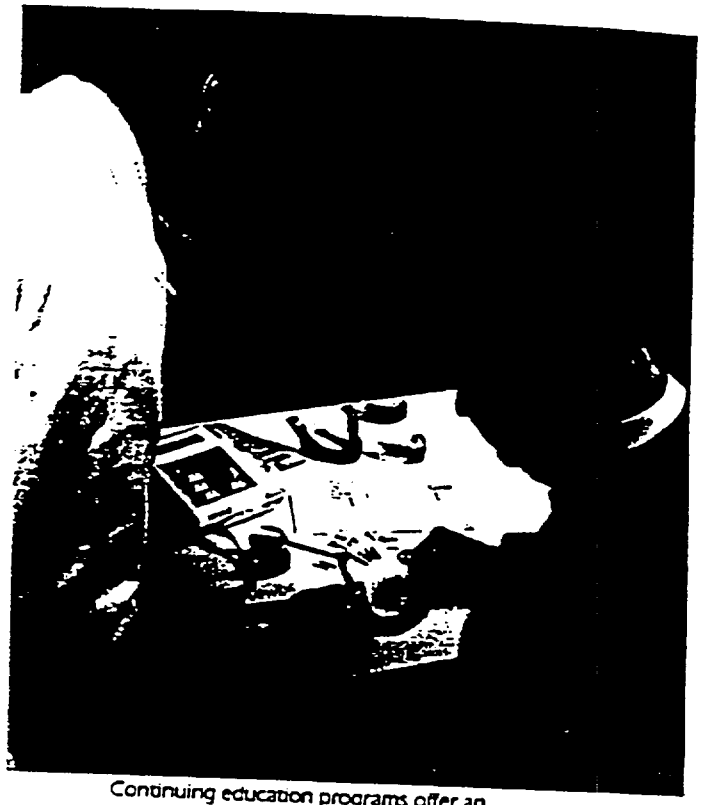
I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed this 22nd day of August, 1996, at Carlsbad, California.

Robert L. Riley

Continuing Education Opportunities

Dentists who incorporate dental implants into their practice can offer their patients more contemporary alternatives to traditional prosthetic procedures. However, surgical techniques required to place dental implants are highly specialized and complex procedures; specialized training is strongly recommended.

Introductory lectures and comprehensive one and two-day continuing education programs are offered at numerous locations throughout the country. Program schedules, including dates and locations, can be obtained by calling Calcitek Customer Service.



Continuing education programs offer an opportunity for specialized training.

Personal, Technical Service

Your orders are handled by technical representatives with significant product knowledge. They can answer your questions about the Integral System and hydroxylapatite technology.

In addition, Calcitek's technical staff is available for telephone consultation to answer case design and prosthesis construction questions, a service which is extremely helpful to restorative dentists and laboratory personnel.

Product literature, technical papers, video instruction materials, patient education literature and demonstration models are available upon request.

Ordering Information

Orders may be placed direct by calling toll-free, 800-854-7019. In California, call 800-542-6019. Customer Service staff are available from 7 a.m. to 5 p.m. Pacific time.

Calcitek, Inc.®

4125 Sorrento Valley Blvd.
San Diego, California 92121
(800) 854-7019
In California, (800) 542-6019

Caution: Federal law restricts this device to sale by or on the order of a licensed dentist. Specialized surgical techniques are required for placement of dental implants. Read instructions prior to use. It is recommended that practitioners attend courses of study to prepare them in established techniques of oral implantology.