K082749

II. 510(k) SUMMARY

DEC 0 4 2008

1. SUBMITTER INFORMATION

A. Company Name: B.A.S.I.C. Dental Implant Systems, Inc.
B. Company Address: 3321 Columbia NE
Albuquerque, NM 87107
USA
C. Company Phone: (505)881-1376
D. Company Facsimile: (505)884-1923
E. Company Contact: Dan Blacklock – Vice President

2. DEVICE IDENTIFICATION

A. Device Trade Name: B.A.S.I.C. Dental Implant System
B. Device Common Name: Dental Implant
C. Classification Name: Endosseous Dental Implant, root-form
D. Device Class: Class II
E. Device Code: DZE

3. MODIFIED FROM DEVICE

Trade Name: B.A.S.I.C. Dental Implant System
510(k) Number: K072595

4. DEVICE DESCRIPTION & SUMMARY OF DEVICE MODIFICATION

The modification is to be able to use stronger titanium because of situations in which this could be beneficial. Since B.A.S.I.C. Dental has been approved as a system using CP Titanium, which is the weakest of the standard titanium available, we would like to be able to use stronger titanium to increase the overall strength of the implant. By using stronger titanium there should be no need for further testing, however the following tests were performed to compile with design controls. The testing revealed as expected that implants produced with stronger titanium had better shear/lateral forces, with no lateral constraints.

Per FDA-CDRH criteria for a Special 510(k), the modification does not affect the intended use or alter the fundamental scientific technology of the device and the modification to the device falls within the design controls of the device.

5. INTENDED USE

The intended use is identical to the predicate device. For reference the intended use is listed below.

The implant for dental purposes, used to replace missing dental organs (teeth). The implant is self-tapping (threads) and is screwed into a pilot bore formed in the jawbone. Upon healing, the implant receives a post, which has a stem, and is adapted to carry dental supra-structures (false teeth).

6. COMPARISON TO PREDICATE DEVICE (UN-MODIFIED DEVICE)

The B.A.S.I.C. Dental Implant is substantially equivalent in the following ways to the identified predicate device;

- Identical dimensional characteristics of implants
- Identical Indications for Use

II. 510(k) SUMMARY (continued)

7. COMPARISION TO OTHER PREDICATE DEVICES

For reference BASIC is including a summary of other predicate devices with cleared implants produced with titanium alloy, and that have similar dimensions.

Device Name	510(k) Number	Device Description	Equivalence Comparison
B.A.S.I.C. Dental Implant Device Modification	Pending	Implants offered in diameter sizes of 3.5mm, 4.0mm, 4.5mm, and 6.0mm. Implants offered in lengths of 8mm, 9mm, 11mm, 13mm and 15mm. Implant raw material Titanium Alloy or CP Titanium as listed	—
Implant Innovations	K061629	PREVAIL available in 4.0 and 5.0mm Diameters, in lengths of 8.5, 10, 11.5, 13, & 15mm. Material used is Titanium Alloy [Ti6A14V] per ASTM F-136	SE
Zimmer Dental Inc.	K071235	Zimmer® One-Piece Implant, 3.0mm Angled composed of titanium alloy.	SE
MIS Dental Implant System	K070022	Implant Diameters 3.75, 4.10, & 4.80mm Implant lengths 8,10,11.5,13, &16mm produced with medical grade 5 pure titanium	SE
BioHorizons Implant Systems, Inc.	K041938	Implant Collar Heights 2, & 4mm Implant lengths 12,15, & 18	SE

8. STERILIZATION AND BIOCOMPATIBILITY

Sterilization process remains the same, B.A.S.I.C. Dental Implant Systems, Inc. has contracted with Steris Isomedix Service to maintain a valid gamma-ray sterilization process in accordance with ISO 1137 (SAL 10^{-6}) for the B.A.S.I.C. Dental Implant System. Substantiation of a routine sterilization dose will be established using the VDmax25 method, described in ISO 11137. This will meet B.A.S.I.C.'s in-house requirement and requirements for ISO 11137. Gamma sterilization for the implantable components, are provided in sterilized medical Tyvek® pouches.

9. CONCLUSION

The B.A.S.I.C. Dental Implant System is substantially equivalent to B.A.S.I.C. Dental Implant System's predicate device 510(k) number K072595 cleared on 5/09/08. The previously cleared dental implant and the proposed dental implant serve the same intended purpose, use the same techniques, and are restored by the dentist using the same methods. The material modification does not pose any health risks to the patient.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 4 2008

Mr. Dan Blacklock
Vice President
B.A.S.I.C. Dental Implant Systems, Incorporated
3321 Columbia North East
Albuquerque, New Mexico 87107

Re: K082749
Trade/Device Name: Omni-Tight
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: October 15, 2008
Received: November 4, 2008

Dear Mr. Blacklock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K082749

Device Name: Omni-Tight

Indication For Use:

The implant for dental purposes, used to replace missing dental organs (teeth). The implant is self-tapping (threads) and is screwed into a pilot bore formed in the jawbone. Upon healing, the implant receives a post, which has a stem, and is adapted to carry dental supra-structures (false teeth).

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K082749