K082651

510(k) Premarket Notification Summary

Name/Address of Submitter: Southern Implants, Inc.
5 Holland, Bldg. 209
Irvine, CA 92618

Establishment Registration Number: 3003845138

DEC 22 2008

Contact Person: Greta M. Hols
Phone: (866) 700-2100 x 226
Fax: (703) 464-5673

Date Summary Prepared: September 9, 2008

Device Classification Name: Endosseous Implant and Accessories

Device Classification Regulation Number: 21 CFR 872.3640

Device Regulatory Status: Class II Special Controls

Trade Name: Endosseous Dental Implant

Purpose: The purpose of this 510(k) is to include additional implants and accessories in the NSI Hexed and Non-Hexed Endosseous Implant System that did not fall within the size range and design shapes identified in prior 510(k) submissions for our system.

Performance Standards: FDA has not established a performance standard applicable to endosseous implants and their accessories. The materials in the NSI Hexed Implant System meet applicable voluntary standards. Southern Implants screw-type implants and abutments are manufactured from ASTM F67-95 Grade III or Grade IV titanium.

Predicate Devices: K033171 5.0mm and .6.0mm 12° Co-Axis
K052490 4.0mm 12° Co-Axis
K970499 Branemark System Zygomatic Implant

Device Description and Intended Use: The 24° Co-Axis implant is intended to be implanted in the upper or lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or full arch prostheses. It further adds the option for immediate placement and function on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.
This implant is not intended, nor should it be used, in conjunction with an angled abutment.

Technological Characteristics: The physical properties and designs of the additional implants and accessories in the NSI Hexed and Non-Hexed Implant System were compared with legally marketed predicate devices. The technological characteristics were comparable.

Brief Discussion of Clinical Studies: Clinical studies were not conducted, or deemed necessary, for the purpose of this 510(k) submission.

Brief Discussion of Engineering Studies: Engineering studies were conducted as per ISO standard 14801:2003 (E) - (Dentistry - Fatigue test for endosseous dental implants). Testing revealed a stable screw joint at the highest forces tested

Conclusions Drawn: The 24° Co-Axis implant and associated components have the same intended use as, and technological characteristics similar to, the legally marketed predicate devices. Any differences in the technological characteristics did not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Greta M. Hols
Integrations Manager
Southern Implants, Incorporated
5 Holland, Building 209
Irvine, California 92618

DEC 22 2008

Re: K082651
Trade/Device Name: Endosseous Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: December 9, 2008
Received: December 11, 2008

Dear Ms. Hols:

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: K082651

Device Name: Endosseous Dental Implant System

Indication for Use: The 24° Co-Axis implant is intended to be implanted in the upper or lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or full arch prostheses. It further adds the option for immediate placement and function on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

This implant is not intended, nor should it be used, in conjunction with an angled abutment.

Concurrence of CDRH Office of Device Evaluation

Prescription Use X OR Over-the-counter Use _____.
(Per 21 CFR801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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