K071161

510(K) PREMARKET NOTIFICATION

Name/Address of Submitter: Southern Implants, Inc.
10355 B Democracy Lane
Fairfax, VA 22030

Establishment Registration Number: 3003845138

NOV 1 6 2007

Contact Person: Greta M. Hols
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Date Summary Prepared: April 6, 2007

Device Classification Name: Endosseous Implant and Accessories

Device Classification Regulation Number: 21 CFR 872.3640 and 21 CFR 872.3630

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 Endosseous Implant System that did not fall within the size range and design shapes identified in prior 510(k) submissions.

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

Predicate Devices:
K003620 NSI Hexed and Non-Hexed Implant System
K020617 NSI Hexed and Non-Hexed Implant System
K033171 NSI Hexed and Non-Hexed Implant System
K052490 NSI Hexed and Non-Hexed Implant System
K053478 NSI Hexed and Non-Hexed Implant System
K053353 MegaGen Co. Rescue Implant System

Device Description and Intended Use: The NSI Implant System 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 loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

Sterilization Methods Used: Sterilization of these implants will be achieved using Co60 irradiation, with a minimum dose of 25.0 kGy (2.5 m rads), creating a Sterility Assurance Level of 10^{-6}. Validation of sterilization will be done as specified by the Association for the Advancement of Medical Instrumentation (AAMI). Standards utilized include:

ISO 11137	Sterilization of Health Care Products – Requirements for validation and routine control – Radiation sterilization
ISO 11737-2	Sterilization of Medical Devices – Microbial Methods – Part 2: Tests of sterility performed in the validation of a sterilization process
ISO 13409	Sterilization of Health Care Products – Radiation Sterilization – substantiation of 25kGy as a sterilization dose for small or infrequent production batches.

Packaging Method: Please note that our implants are packaged the same as our existing line of dental implants that are cleared NSI hexed and non-hexed Implant Systems noted above as predicate devices. Implants are placed into plastic tubing (PT6.1) and capped on both ends. The plastic tube is then heat sealed in a blister pack consisting of a transparent film (P.E.T.) and a porous sheet material backing (Tyvek1073B). This blister pack is considered the primary pack (that which provides the microbial barrier) for the implants. The Tyvek is coated with an adhesive. A sterilization indicator sticker is placed on the blister packaging. The blister with its contents are then enclosed in a clear plastic box and sent for sterilization.

Packaging Validation:
All Southern Implants packaging is validated following these standards:

ASTM D 4169-04	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F 88-00	Standard Test Method for Seal strength of Flexible Barrier Materials
ASTM F 1929-98	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F 1980 – 02	Standard Guide for Accelerated Aging of Sterile Medical Device Packages
EN 552	Sterilization of medical devise – Validation and routine control of sterilization by irradiation
EN556	Sterilization of medical devices – Requirements for medical devices to be labeled "Sterile"
EN 868-1:1997	Packaging materials and systems for medical devices with are to be sterilized: Part 1 General requirements and test methods
EN 868-5:1999	Packaging materials and systems for medical devices which are to be sterilized – Part 5: Heat and self-sealable pouches and reels of paper and plastic film construction – Requirements and test methods
EN 868-9: 2000	Packaging materials and systems for medical devices which are to be sterilized – Part 9: Uncoated non-woven materials of polyolefines suitable for use as packaging of medical devices which are to be terminally sterilized – Requirements and test methods.
EN 868-10:2000	Packaging materials and systems for medical devices which are to be sterilized – Part 10: Adhesive coated nonwoven material of polyolefines for use in the manufacture of heat sealable pouches, reels and lids – Requirement s and test methods
ISO 11607	Packaging for terminally sterilized medical devices

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

Surface Modifications: Please note that this is the same surface modification method currently used with our existing line of dental implants that are cleared NSI hexed and non-hexed Implant Systems noted above as predicate devices. The surface of our implant is blasted using 100 micron alumina (Al_2O_3) particles. Alumina is a highly biocompatible material and hence if any particles remain embedded in the surface, they will not pose a complication. The other measure taken to reduce the potential of embeddiment is to blast with relatively low pressure. If the indentations caused are significantly smaller than the size of the blast media, then particles tend to not adhere to the surface. (Our S_a = 1.43 microns is a fraction of the particle size of 110 microns).Each and every implant is visually inspected under a microscope after surface enhancement as a matter of manufacturing protocol. In addition to visual inspection, a sample implant is sent for SEM testing four times a year for evaluation of the surface as well.

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

Conclusions Drawn: The NSI Endosseous Dental Implant System has 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

NOV 1 6 2007

Ms. Greta M. Hols
Director of Operations
Southern Implants, Incorporated
11250 Waples Mill Road, Suite 320
Fairfax, Virginia 22030

Re: K071161
Trade/Device Name: Endosseous Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: September 14, 2007
Received: September 18, 2007

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 Lin, Ph.D.
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: K071161

Device Name: Endosseous Dental Implant System

Indication for Use: The NSI MAX Implant System is intended for implantation in the maxillary or mandibular molar region where bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability, or increased surgical procedures leading to complications. This MAX implant provides 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 loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

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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