510(K) PREMARKET NOTIFICATION SUMMARY

(K070905)

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

Establishment Registration Number: 3003845138

MAY 24 2007

Contact Person: Greta M. Hols
Phone: (703) 278-3953
Fax: (703) 278-3954

Date Summary Prepared: March 16, 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
K061169 NSI Hexed and Non-Hexed Implant System
K964220 Steri-Oss Replace Titanium Implant System
K023113 Nobel BioCare Replace TiUnite Endosseous Implant
K061319 Implant Direct Spectra System (RePlant)

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Greta M. Hols
Southern Implants, Incorporated
10355 B Democracy Lane
Fairfax, Virginia 22030

MAY 24 2007

Re: 070905
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: March 26, 2007
Received: April 02, 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.

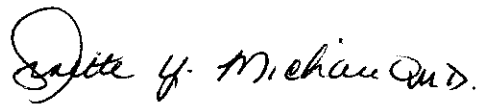
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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: K070905

Device Name: Endosseous Dental Implant System

Indication for 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.

CONCURRENCE OF CDRH OFFICE OF DEVICE EVALUATION

Prescription Use ✓ OR Over-the-counter Use _____.

(Per 21 CFR801.109)

Kei Mulay for MSR

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

510(k) Number: K070905