K033171

APR 2 7 2004

510(k) Summary

Name/Address of Submitter: Northern Implants, LLC.
10565 Lee Highway, Suite 100
Fairfax, VA 22030

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

Date Summary Prepared: September 23, 2003

Device Name: Endosseous Implant and Accessories

Trade Name: NSI Hexed and Non-Hexed Implant System

Purpose: The purpose of this 510(k) is to include additional implants and accessories in the NSI Hexed and Non-Hexed Endosseous Implant System (K003620) and K020617 that did not fall within the size range and design shapes identified in our original 510(k) submissions for our system. Additionally, it is to expand upon the intended usage to include the option for immediate loading.

Predicate Devices:

K003620 NSI Hexed and Non-Hexed Implant System
K020617 NSI Hexed and Non-Hexed Implant System
K874590 Innovative Implants and Cover Screws
K970499 Branemark System Zygomaticus Fixture System
K894593 Straumann USA Hollow Cylinder implant, 15° angled
K022562 Nobel Biocare Various Branemark System Dental Implant Products
K024111 and K012965 Astra Dental Implants
K030007 ITI Straumann Dental Implant System
K024004 Friadent XiVE Transgingival Dental Implant System

Device Description and Intended Use: The NSI Implant System is intended for implantation 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 in the mandible on splinted multiple-unit implant restorations anterior to the mental foramen when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 7 2004

Ms. Greta M. Hols
Director of Operations
Northern Implant, LLC
10565 Lee Highway Suite 100
Fairfax, Virginia, 22030

Re: K033171
Trade/Device Name: Endosseous Dental Implant System and Immediate Loading
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: February 5, 2004
Received: February 10, 2004

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.

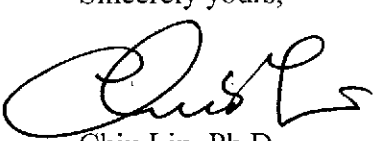
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4613. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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: K033171

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 placement and function in the mandible on splinted multiple-unit implant restorations supported by a minimum of four implants anterior to the mental foramen 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)

Robert S Betz DDS for Dr. Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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