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510(k) SUMMARY

Inion BioRestore™

K070784

JUL 24 2007

Manufacturer and submitter
Inion Oy, Lääkärinkatu 2, FIN-33520 Tampere, FINLAND

Contact Person
Kati Marttinen, Regulatory Affairs Specialist
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Establishment registration number
9710629

Trade name of the device
Inion BioRestore™

Device classification and product code
Class II (Special controls)
Classification Panel: Dental
Product Code: LYC
Common name: Osteoconductive and osteostimulative bone void filler; Synthetic resorbable bone graft material
Regulation number: 872.3930

Predicate devices
NovaBone ® (K000149)
PerioGlass ® Bioglass ® Bone Graft Particulate (K040278)
Chronos-beta-TCP (K053022)
Theriridge™ Block, Bone Graft Substitute (K023998)
Interpore 200 Porous Hydroxyapatite (K860983)

Conformance with performance standards
No applicable mandatory performance standards exist for this device.
Compliance to voluntary consensus standards is listed in the application.

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Inion BioRestore™

Device description and principles of operation

Inion BioRestore™ is an osteoconductive and osteostimulative bioactive bone graft substitute used either separately or in conjunction with autogenous or allograft bone. When implanted, a kinetic modification of the surface occurs, resulting in the formation of a calcium phosphate layer that is essentially similar in composition and structure to the hydroxyapatite found in bone mineral. This apatite layer provides scaffolding onto which the patient's new bone will grow allowing complete repair of the defect.

Inion BioRestore™ system consists of different size cylinders, blocks and morsels made of degradable bioactive glass. Inion BioRestore™ implants degrade in vivo in six months based on pre-clinical data. The material is radiopaque. Inion BioRestore™ implants are intended for single use and are provided sterile to the user. They are completely synthetic and non-collagenous.

Indications for use

The Inion BioRestore™ implants are bone graft substitutes indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure; packing into bony voids or gaps to fill and/or augment dental intraosseous, oral and craniomaxillofacial defects. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone, including: e.g., alveolar ridge augmentation (sinusotomy, osteotomy, cystectomy); dental extraction sites (ridge maintenance, implant preparation/placement); sinus lifts; cystic defects; and craniofacial augmentation.

Substantial equivalence to marketed products

Based on the performance data and specifications presented, it can be concluded that the intended use, material composition and scientific technology, degradation properties, bioactive, osteoconductive and osteoproductive properties of Inion BioRestore™ implants are substantially equivalent with the predicate Class II devices, when used in the indications for use described above, because the differences between Inion BioRestore™ and the predicate devices do not raise new questions of safety and effectiveness. The calcium-based predicate devices are substantially equivalent predicate devices by being solid synthetic blocks, cylinders and particulates for bone filling in dental and CMF applications, and the use of these devices results in the formation of HA layer and eventually new bone growth to the implant site. All implants are used for non load bearing applications.

Inion Oy
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kati Marttinen
Regulatory Affairs Specialist
Inion Oy
Lääkärinkatu 2
Tampere,
Finland 33520

JUL 2 4 2007

Re: K070784
Trade/Device Name: Inion BioRestore™
Regulation Number: 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: June 5, 2007
Received: June 11, 2007

Dear Ms. Marttinen:

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.

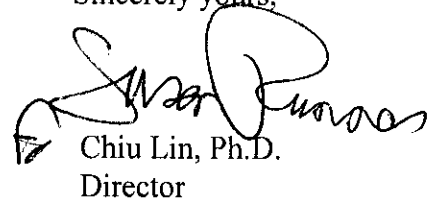
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 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

Statement of Indications for Use

510(k) Number: K070784

Device Name: Inion BioRestore™

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The **INION BIORESTORE™** implants are bone graft substitutes indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure; packing into bony voids or gaps to fill and/or augment dental intraosseous, oral and craniomaxillofacial defects. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone, including: e.g., periodontal/infrabony defects; alveolar ridge augmentation (sinusotomy, osteotomy, cystectomy); dental extraction sites (ridge maintenance, implant preparation/placement); sinus lifts; cystic defects; and craniofacial augmentation.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K070784