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1 of 3

Medtronic Sofamor Danek
PROGENIX® Plus
510(k) Summary
June 2008

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I. **Company:** **Medtronic Sofamor Danek USA**
1800 Pyramid Place
Memphis, TN 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

Contact: **Ryan Massey**
Regulatory Affairs Specialist

II. **Proposed Proprietary Trade Name:** PROGENIX® Plus
Classification Name: Resorbable calcium salt bone void filler device
Product Code: NUN
Regulation No.: 872.3930

III. **Product Description/Purpose of Application**

PROGENIX® contains human demineralized bone matrix (DBM) in a biocompatible carrier. The carrier is a mixture of bovine collagen with a natural polysaccharide (sodium alginate). The components are mixed in phosphate buffered saline to achieve a flowable or moldable consistency. PROGENIX® is available in two forms: Putty and Plus. The PROGENIX® Plus version contains two different sized demineralized bone particles.

PROGENIX® DBM Putty and PROGENIX® Plus are single use products intended for use in the oralmaxillofacial region. Additionally, these products are not designed to impart any mechanical strength to the surgical site. Both versions are provided in ready-to-use malleable forms that may be molded or manipulated by the surgeon into various shapes. These products have been shown to be osteoinductive in an athymic rat assay, as well as osteoconductive, allowing for bony ingrowth across the graft site while resorbing at a rate consistent with bony healing.

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The purpose of this Special 510(k): Device Modification application is to include a new formulation (PROGENIX® Plus) to the previously cleared PROGENIX® product line. The subject device, like the predicate device, contains human demineralized bone matrix (DBM) in a biocompatible carrier, however PROGENIX® Plus will also contain two different sized demineralized bone particles. The indications for PROGENIX® Plus will be identical to the previously cleared PROGENIX® product (K080462, SE 05/13/08).

IV. Indications

PROGENIX® DBM Putty and PROGENIX® Plus are intended for the augmentation of deficient maxillary and mandibular alveolar ridges and the treatment of oralmaxillofacial and dental intraosseous defects including but not limited to:

Ridge augmentation
Filling of cystic defect
Filling of extraction sites
Filling of lesions of periodontal origin
Craniofacial augmentation
Filling of defects of endodontic origin
Mandibular reconstruction
Repair of traumatic defects of the alveolar ridge, excluding maxillary and mandibular fracture
Filling of resection defects in benign bone tumors, benign cysts or other osseous defects in the alveolar ridge wall.

V. Substantial Equivalence

Documentation is provided that demonstrates PROGENIX® Plus is substantially equivalent to previously cleared bone void fillers such as PROGENIX® DBM

Putty (Medtronic Sofamor Danek, K080462, SE 05/13/08) and GRAFTON® DBM Crunch (Osteotech Inc., K051188, SE 01/03/06).

VI. Osteoinductivity Potential

All DBM used in the preparation of PROGENIX® Plus must induce bone formation when evaluated in a validated athymic nude rat assay. Additionally, PROGENIX® must also induce bone formation in this assay system prior to being released for use. The raw material and final product screening must show histologic evidence of osteoinduction through the presence of osteoblasts, chrondoblasts and/or woven bone. Osteoinduction assay results using the athymic rat assay should not be interpreted to predict clinical performance in human subjects.

VIII. Viral Inactivation

PROGENIX® Plus is produced from tissue and collagen that undergoes processing steps validated to inactivate a panel of viruses representative of those that are clinically relevant. The cortical bone used to produce the DBM undergoes a proprietary process demonstrated to inactivate viruses. Furthermore, the DBM undergoes additional steps that are also effective at inactivating viruses. The viral inactivation testing demonstrates suitable viral inactivation potential of the processing methods for a wide range of potential human viruses. These processing steps further reduce the risk of viral contamination beyond donor screening and testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ryan Massey
Regulatory Affairs Specialist
Medtronic Sofamor Danek USA
1800 Pyramid Place
Memphis, Tennessee 38132

JUL 18 2008

Re: K081950
Trade/Device Name: PROGENIX® Plus
~~Regulation Number:~~ ~~21CFR 872.3930~~
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NUN
Dated: July 3, 2008
Received: July 9, 2008

Dear Mr. Massey:

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~~,

for 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

510(k) Number (if known): K 081950

Device Name: PROGENIX® Plus

Indications for Use:
PROGENIX® DBM Putty and PROGENIX® Plus are intended for the augmentation of deficient maxillary and mandibular alveolar ridges and the treatment of oralmaxillofacial and dental intraosseous defects including but not limited to:

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Filling of cystic defect

Filling of extraction sites

Filling of lesions of periodontal origin

Craniofacial augmentation

Filling of defects of endodontic origin

Mandibular reconstruction

Repair of traumatic defects of the alveolar ridge, excluding maxillary and mandibular fracture

~~Filling of resection defects in benign bone tumors, benign cysts or other osseous~~ defects in the alveolar ridge wall.

Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number: K081950