K082002

NOV 24 2008

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

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

Contact: **Michelle Obenauer**
Regulatory Affairs Manager

II. **Proposed Proprietary Trade Name:** PROGENIX® Plus
Classification Name: Resorbable calcium salt bone void filler device
Product Code: MQV and MBP
Regulation No.: 888.3045

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 versions: Putty and Plus. PROGENIX® Plus is a putty containing two different sized demineralized bone particles.

PROGENIX® is a single use product intended for use as a bone graft substitute, bone graft extender and bone void filler in bony voids or gaps of the skeletal system (i.e. spine, pelvis and extremities) not intrinsic to the stability of the bony structure. Additionally, this product is not designed to impart any mechanical strength to the surgical site. PROGENIX® is provided in ready-to-use malleable forms that may be molded or manipulated by the surgeon into various shapes. This product has been shown to be osteoconductive as well as osteoinductive in an athymic rat assay, allowing for bony ingrowth across the graft site while resorbing at a rate consistent with bony healing.

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 contains two different sized demineralized bone particles as well as a change in the amount of sodium alginate. The indications for PROGENIX® Plus will be identical to the previously cleared PROGENIX® product (K072265, SE 01/09/08).

IV. Indications

PROGENIX® Plus is intended for use as a bone graft substitute in bony voids or gaps of the skeletal system not intrinsic to the stability of the bony structure (i.e. spine, pelvis and extremities). The voids or gaps may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. PROGENIX® Plus provides a bone void filler that is resorbed/remodeled and is replaced by host bone during the healing process. The device may either be use alone or mixed with autograft bone and used as a bone graft extender.

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, K072265, SE 01/09/08)and GRAFTON® DBM Crunch (Osteotech, Inc., K051195, SE 12/16/05).

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

NOV 24 2008

Medtronic Sofamor Danek USA, Inc.
% Ms. Michelle Obenauer
Regulatory Affairs Manager
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K082002
Trade/Device Name: PROGENIX® Plus
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV, MBP
Dated: November 8, 2008
Received: November 10, 2008

Dear Ms. Obenauer:

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) 276-0120. 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 toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K082002

Device Name: PROGENIX® Plus

Indications

PROGENIX® Plus is intended for use as a bone graft substitute in bony voids or gaps of the skeletal system not intrinsic to the stability of the bony structure (i.e. spine, pelvis and extremities). The voids or gaps may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. PROGENIX® Plus provides a bone void filler that is resorbed/remodeled and is replaced by host bone during the healing process. The device may either be use alone or mixed with autograft bone and used as a bone graft extender.

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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082002