Medtronic Sofamor Danek
MASTERGRAFT® Putty
510(k) Summary
June 2008

SEP 17 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:** MASTERGRAFT® Putty
Classification Name: Bone Grafting Materials, Synthetic
Product Code: LYC
Regulation No.: 872.3930

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

MASTERGRAFT® Putty is made from a combination of medical grade purified collagen and biphasic calcium phosphate ceramic. The collagen component is Type I bovine collagen. The biphasic ceramic portion of MASTERGRAFT® Putty is provided in a 15 percent hydroxyapatite and 85 percent b-tricalcium phosphate formulation. MASTERGRAFT® Putty is supplied as a sterile, dry, solid, construct that is hydrated for single patient use and is a moldable form of bone void filler. The device is an osteoconductive, porous implant that allows for bony ingrowth across the graft site while resorbing at a rate consistent with bone healing. The product is biocompatible. MASTERGRAFT® Putty has been shown to heal bone defects.

The purpose of this 510(k) application is to expand the indication for the MASTERGRAFT® Putty device to include use in the oral and oral/maxillofacial regions.

IV. **Indications**

K081784

MASTERGRAFT® Putty is combined with either sterile water and/or autograft to provide a bone void filler that is resorbed/remodeled and is replaced by host bone during the healing process. MASTERGRAFT® Putty is packed into bony voids or gaps to fill and/or augment dental oral/maxillofacial bony tissue. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Procedures include:

- Filling of periodontal defects
- Filling of dental extraction sockets
- Filling of cystic defects
- Sinus lifts
- Alveolar ridge augmentation
- Oral/maxillofacial augmentation or reconstruction.

MASTERGRAFT® Putty may be used with or without internal fixation, and may be mixed with autograft as a bone graft extender.

V. Substantial Equivalence

Documentation was provided which demonstrated MASTERGRAFT® Putty to be substantially equivalent to the previously cleared MASTERGRAFT® Putty (K071813), MSD Biphasic Calcium Bone Void Filler (K010701), Calcium Hydroxylapatite Implant (K030682), Osteon (K062834) and MBCP™ (K051885).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

SEP 17 2008

Re: K081784
Trade/Device Name: MASTERGRAFT® Putty
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: September 15, 2008
Received: September 15, 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.

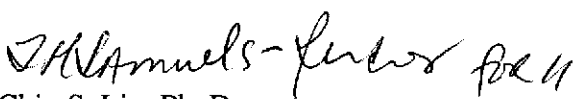
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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,



Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081784

1 of 1

510(k) Number (if known):

Device Name: MASTERGRAFT® Putty

Indications for Use:

MASTERGRAFT® Putty is combined with either sterile water and/or autograft to provide a bone void filler that is resorbed/remodeled and is replaced by host bone during the healing process. MASTERGRAFT® Putty is packed into bony voids or gaps to fill and/or augment dental oral/maxillofacial bony tissue. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Procedures include:

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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: K081784