JUN 10 2014

510(K) Summary

K140374

I. SUBMITTER NAME & ADDRESSS: Medtronic Sofamor Danek USA, Inc
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738
Establishment Registration: 1030489

CONTACT PERSON: Kelly Anglin
Senior Regulatory Affairs Specialist

DATE PREPARED: May 13, 2014

II. PROPOSED PROPRIETARY TRADE NAME: MASTERGRAFT® Putty

DEVICE CLASSIFICATION NAME: Bone grafting material, synthetic
Bone grafting material, animal source

REGULATION NUMBER: 21 CFR 872.3930

CLASSIFICATION PRODUCT CODE: LYC, NPM

CLASS: II

III. IDENTIFICATION OF LEGALLY MARKETED DEVICES:

Table 1. Legally Marketed Devices

Device name	510(k) number	Substantial Equivalence date
MASTERGRAFT® Putty	K081784	09/17/2008

IV. DEVICE DESCRIPTION:

MASTERGRAFT® Putty is made from a combination of medical grade purified collagen of bovine origin and biphasic calcium phosphate ceramic. The collagen component in the MASTERGRAFT® Putty device is Type I bovine collagen. The biphasic ceramic portion of MASTERGRAFT® Putty is provided in a 15 percent hydroxyapatite and 85 percent β-

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. MASTERGRAFT® Putty is a 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 Changes Being Effected 510(k) application is to notify FDA of the additional contraindication in the Instructions for Use (IFU).

V. 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:

- 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 maybe mixed with autograft as a bone graft extender.

VI. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS:

Table 2. Summary of the technological Characteristics		
Comparison Feature	**Subject MASTERGRAFT® Putty**	**Predicate MASTERGRAFT® Putty K081784 (S.E.09/17/2008)**
Indication for Use	Identical	K081784 (S.E. 09/17/2008)
Fundamental Scientific Technology • Operating Principle • Mechanism of Action	Identical	K081784 (S.E. 09/17/2008)
Basic Design	Identical	K081784 (S.E. 09/17/2008)
Performance	Identical	K081784 (S.E. 09/17/2008)
Sterilization	Identical	K081784 (S.E. 09/17/2008)
Shelf-Life	Identical	K081784 (S.E. 09/17/2008)
Packaging	Identical	K081784 (S.E. 09/17/2008)
Use of rigid fixation	Identical	K081784 (S.E. 09/17/2008)
Safety and Effectiveness profile	Identical	K081784 (S.E. 09/17/2008)

VII. DISCUSSION OF NON-CLINICAL TESTING:

Non-clinical testing was performed in accordance with FDA Recognized Consensus Standards and FDA Guidelines, where applicable. Two animal studies were performed: a two-month rabbit bilateral posterolateral spine fusion to assess MASTERGRAFT® Putty (K071813 S.E. 11/09/07, K051386 S.E. 12/16/2005) as a suitable bone graft extender and a four-month sheep study evaluating the ability of MASTERGRAFT® Putty to effect bony healing and repair.

VIII. CONCLUSION:

Documentation provided in this submission demonstrates that the subject device is substantially equivalent to the previously cleared MASTERGRAFT® Putty device K081784 (S.E. 09/17/2008). The subject device is substantially equivalent to predicate MASTERGRAFT® Putty in several categories including: indication, material components, sterility, shelf-life, and biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 10, 2014

Medtronic Sofamor Danek USA, Incorporated
Ms. Kelly Anglin
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, TN 38132

Re: K140374
Trade/Device Name: MASTERGRAFT® Putty
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone grafting material, synthetic
Bone grafting material, animal source
Regulatory Class: II
Product Code: LYC, NPM
Dated: May 13, 2014
Received: May 15, 2014

Dear Ms. Anglin:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K140374

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 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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