Medtronic Sofamor Danek
MASTERGRAFT® Strip
510(K) Summary
July 2008

JUN - 2 2009

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® Strip
Classification Name: Resorbable calcium salt bone void filler device
Product Code: MQV
Regulation No.: 888.3045

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

MASTERGRAFT® Strip is made from a combination of medical grade purified collagen and biphasic calcium phosphate ceramic. In the MASTERGRAFT® Strip device, the collagen is a highly purified (>95%) Type I bioresorbable lyophilized collagen. The biphasic ceramic portion of all devices is provided in a 15% hydroxyapatite and 85% b-tricalcium phosphate formulation.

MASTERGRAFT® Strip is supplied sterile in a premixed strip form for single patient use.

MASTERGRAFT® Strip is a biocompatible, osteoconductive, porous implant that allows for bony ingrowth across the graft site while resorbing at a rate consistent with bone healing. The device readily absorbs bone marrow aspirate and has been shown to heal bone defects.

The purpose of this 510(k) application is to add MASTERGRAFT® Strip to the MASTERGRAFT® family of products. Like the previously cleared

predicates, MASTERGRAFT® Matrix (K023553, SE 04/22/2003, bone void filler) and MASTERGRAFT® Putty (K071813, SE 11/09/07, autograft extender), the subject system is intended to be combined with autogenous bone marrow as a bone void filler for bony voids or gaps that are not intrinsic to the stability of the bony structure. In addition, MASTERGRAFT® Strip can be mixed with autogenous bone and used as a bone graft extender.

IV. Indications

MASTERGRAFT® Strip is to be combined with autogenous bone marrow and is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure; MASTERGRAFT® Strip can also be used with autograft as a bone graft extender.

The device is to be gently packed into bony voids or gaps of the skeletal system (i.e., the posterolateral spine, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device resorbs and is replaced with bone during the healing process.

V. Substantial Equivalence

Documentation is provided that demonstrates MASTERGRAFT® Strip to be substantially equivalent to the previously cleared MASTERGRAFT® Matrix (K023553), MASTERGRAFT® Putty (K071813), OssiMend Bone Graft Material (K052812), Collagraft Strip Bone Graft Material (K000122) and Integra MOZAIK™ Osteoconductive Scaffold – Strip (K063124).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUN - 2 2009

Re: K082166
Trade/Device Name: MASTERGRAFT® Strip
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: II
Product Code: MQV
Dated: May 21, 2009
Received: May 22, 2009

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 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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K082166

Device Name: MASTERGRAFT® Strip

Indications for Use:
MASTERGRAFT® Strip is to be combined with autogenous bone marrow and is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure and can be used as a bone graft extender.

The device is to be gently packed into bony voids or gaps of the skeletal system (i.e., the posterolateral spine, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device resorbs and is replaced with bone during the healing process.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __x__ OR Over-The-Counter Use _____
Per 21 CFR 801.109

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K082166

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