K051386 DEC 16 2005

Medtronic Sofamor Danek
MasterGraft® Putty and MasterGraft® Matrix
510(K) Summary
May 2005

I. **Company:** **Medtronic Sofamor Danek USA**
1800 Pyramid Place
Memphis, TN 38132

Contact: **Richard W. Treharne**
Sr. Vice President Regulatory Affairs
(901) 396-3133

II.

Proposed Proprietary Trade Name:	MasterGraft® Putty
Classification Name:	Bone Void Filler
Product Code:	MQV
Regulation No.:	888.3045

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

MasterGraft® Putty is made of medical grade combination of purified Type 1 bovine collagen and hydroxyapatite and β-tricalcium phosphate ceramic. The ceramic portion of MasterGraft® Putty is provided in a 15 percent hydroxyapatite and 85 percent β-tricalcium phosphate formulation. When mixed with either autogenous bone marrow, and/or sterile water, and/or autograft the product forms into a putty, which is moldable. The product is supplied sterile for single patient use. MasterGraft® Putty 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™ Matrix is made of medical grade combination of purified collagen and hydroxyapatite and β-tricalcium phosphate ceramic. The collagen is a highly purified bioresorbable lyophilized bovine tendon that is primarily Type I collagen. The ceramic portion of MasterGraft™ Matrix is provided in a 15 percent hydroxyapatite and 85 percent β-tricalcium phosphate formulation. The product is supplied sterile in a premixed strip form for single patient use. MasterGraft™ Matrix is a 3-dimensional, 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.

The purpose of this 510(k) application is to add the MasterGraft® Putty device to the previously cleared MasterGraft® product family.

IV. Indications

MasterGraft® Putty combined with either autogenous bone marrow, and/or sterile water, and/or autograft is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. MasterGraft® Matrix is to be combined with autogenous bone marrow and like MasterGraft® Putty is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Both devices are to be gently packed into bony voids or gaps of the skeletal system (e.g., the posterolateral spine, pelvis, ileum, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Both devices provide a bone void filler that resorbs and is replaced with bone during the healing process.

V. Substantial Equivalence

Documentation was provided which demonstrated MasterGraft®Putty to be substantially equivalent to the previously cleared MasterGraft® Matrix Resorbable Ceramic (K020986 and K012506), and to Orthovita's Vitoss Scaffold Foam Flow Bone Graft Material (K032288) and DePuy's HEALOS® Bone Graft Material (K043308 and K012751).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2005

Mr. Richard W. Treharne
Sr. Vice President, Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K051386/S2
Trade/Device Name: MasterGraft® Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: December 7, 2005
Received: December 9, 2005

Dear Mr. Treharne:

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 Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

510(k) Number (if known):

Device Name: MasterGraft® Putty/MasterGraft® Matrix

Indications for Use:

MasterGraft® Putty combined with either autogenous bone marrow, and/or sterile water, and/or autograft is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. MasterGraft® Matrix is to be combined with autogenous bone marrow and like MasterGraft® Putty is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Both devices are to be gently packed into bony voids or gaps of the skeletal system (e.g., the posterolateral spine, pelvis, ileum, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Both devices provide a bone void filler that resorbs and is replaced with bone during the healing process.

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 K051386