APR 2 2 2003

Medtronic Sofamor Danek
MasterGraft™ Matrix
510(K) Summary (K023553)
April 2003

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

II. **Proposed Proprietary Trade Name:** MasterGraft™ Matrix

III. **Product Description**

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.

IV. **Indications**

MasterGraft™ Matrix combined with autogenous bone marrow is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. MasterGraft™ Matrix is to be gently packed into bony voids or gaps of the skeletal system (e.g., the spine, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. MasterGraft™ Matrix provides a bone void filler that resorbs and is replaced with bone during the healing process.

V. **Substantial Equivalence**

Documentation was provided which demonstrated MasterGraft™ Matrix to be substantially equivalent to the previously cleared MasterGraft™ Resorbable Ceramic (K020986 and K012506).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 2003

Richard W. Treharne, Ph.D.
Senior Vice President, Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 31832

Re: K023553
Trade/Device Name: MasterGraft™ Matrix
Regulatory Class: Unclassified
Product Code: MQV
Dated: February 11, 2003
Received: February 12, 2003

Dear Dr. 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.

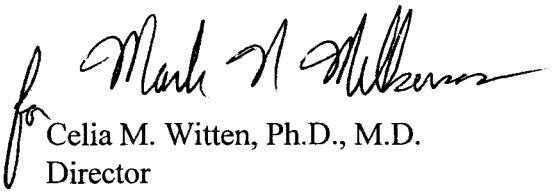
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-__. 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/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023553

Device Name: MasterGraft™ Matrix

Indications for Use:

MasterGraft™ Matrix combined with autogenous bone marrow is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. MasterGraft™ Matrix is to be gently packed into bony voids or gaps of the skeletal system (e.g., the spine, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. MasterGraft™ Matrix provides a bone void filler that 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 Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-counter Use** _____
(Per 21 CFR 801.109)
(Optional 1-2-96)

for Mark N Milhern

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

510(k) Number K023553