MAY 2 8 2004

BONE GRAFT WASHER
510(k) Summary
May 2004

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

II. **Proprietary Trade Name: BONE GRAFT WASHER**

III. **Regulation Number: 888.3060 - KWQ**

IV. **Product Description**

The BONE GRAFT WASHER is a temporary implant used to prevent bone graft extrusion. The washer is also intended to provide temporary stabilization and augment development of a solid spinal fusion. The BONE GRAFT WASHER consists of a variety of sizes of washers used with a screw.

The purpose of this submission is to make include modified washers and an additional screw to the system.

V. **Indications**

Each BONE GRAFT WASHER is intended to stabilize the bone graft at one level (T1-S1) as an aid to spinal fusion. It may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials (e.g., commercially pure titanium or titanium alloy).

VI. **Substantial Equivalence**

Documentation was provided which demonstrated the BONE GRAFT WASHER to be substantially equivalent to itself.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 8 2004

Richard W. Treharne, Ph.D.
Vice President Research and Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K041217
Trade Name: Bone Graft Washer
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation System
Regulatory Class: Class II
Product Code: KWQ
Dated: June 17, 2003
Received: June 18, 2003

Dear Dr. Treharne:

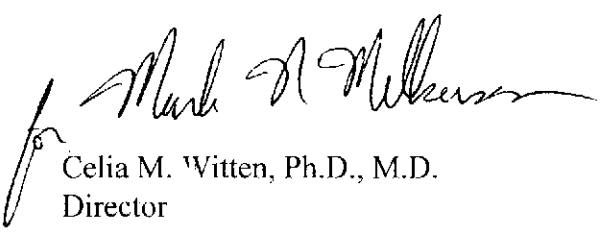
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) 594-4659. 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): K041217

Device Name: BONE GRAFT WASHER

Indications for Use:

Each BONE GRAFT WASHER is intended to stabilize the bone graft at one level (T1-S1) as an aid to spinal fusion. It may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials (e.g., commercially pure titanium or titanium alloy).

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)

for Mark N Milhouse

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

510(k) Number K041217