

FEB 18 2000

K994122

BONE GRAFT WASHER
510(k) Summary

February 14, 2000

- I. Company:** Medtronic Sofamor Danek USA
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133
- II. Proposed Proprietary Trade Name:** BONE GRAFT WASHER
- III. Description**

The BONE GRAFT WASHER is used with a 6.5mm low profile screw to provide bone graft stabilization during the development of a solid spinal fusion. Instrumentation is also available to facilitate implantation of the device components.

BONE GRAFT WASHER components are fabricated from medical grade titanium alloy described by such standards as ASTM F136 or ISO 5832-3. The BONE GRAFT WASHER may also be fabricated from commercially pure titanium described by such standards as ASTM F67 or ISO 5832-2. The implant components may be sold either sterile or non-sterile.

IV. 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).

V. Substantial Equivalence

The BONE GRAFT WASHER is substantially equivalent to other commercially accepted devices.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K994122
Trade Name: Bone Graft Washer
Regulatory Class: II
Product Code: KWQ
Dated: December 3, 1999
Received: December 7, 1999

Dear Dr. Treharne:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

A handwritten signature in black ink, appearing to read "James E. Dillard III". The signature is fluid and cursive, with a long horizontal stroke at the end.

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K99-4122

Device Name: BONE GRAFT WASHER

Indications for Use:

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

Concurrence of CDRH, Office of Evaluation (ODE)

NAD for ISO

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K994122

Prescription Use X
(Per 21 CFR 801.109)
(Optional 1-2-96)

OR

Over-the-counter Use _____