



OCT 26 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K033926

Trade/Device Name: HOURGLASS™ Vertebral Body Spacer
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: June 8, 2004
Received: June 9, 2004

Dear Dr. Treharne:

This letter corrects our substantially equivalent letter of July 7th, 2004 regarding the attachment of incorrect Indications for Use statement page. The correct Indications for Use page is attached.

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.

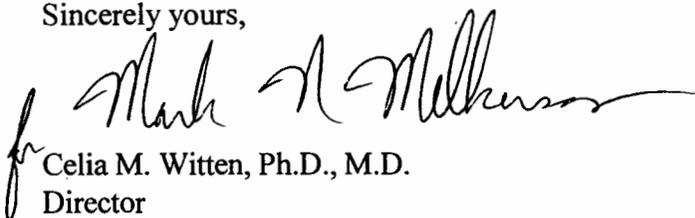
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style and is positioned to the right of the typed name.

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

K033926

(Pg 1/1)

JUL - 7 2004

**HOURGLASS™ Vertebral Body Spacer
510(k) Summary
December 2003**

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

II. Proprietary Trade Name: HOURGLASS™ Vertebral Body Spacer

III. Product Description

The HOURGLASS™ device is a PEEK spacer, which inserts between vertebral bodies in the anterior thoracic and lumbar spine. The device is intended for vertebral body replacement to aid in the surgical correction and stabilization of the spine. The construct is not intended to be employed as a stand-alone device. The HOURGLASS™ device is fabricated and manufactured from Polyetheretherketone (PEEK OPTIMA LT) as described by ASTM F-2026. The Tantalum markers used for this product are made to the voluntary standard of ASTM F-560.

The HOURGLASS™ device must be used with additional anterior and/or posterior spinal instrumentation to augment stability

IV. Indications

The HOURGLASS™ Vertebral Body Spacer is intended for vertebral body replacement to aid in surgical correction and stabilization of the spine. The device is indicated for use in the thoracolumbar spine (T1-L5) to replace and restore height of a resected vertebral body or portion thereof, excised for the treatment of tumor or trauma (i.e., fracture). The HOURGLASS™ device is to be used with supplemental fixation. Specifically, the HOURGLASS™ device is to be used with the Medtronic Sofamor Danek ZPLATE-II® Anterior Fixation System, DYNALOK™ CLASSIC Spinal System, VANTAGE™ Anterior Fixation System, TSRH® Spinal System, CD HORIZON® Spinal System, the GDLH® Spinal System or their successors. Additionally, the HOURGLASS™ device is intended to be used with bone graft.

V. Substantial Equivalence

Documentation was provided which demonstrates the HOURGLASS™ Vertebral Body Spacer to be substantially equivalent to the previously cleared VERTE-STACK™ Spinal System (K030736 and K031780) and the ZPLATE-II® Anterior Fixation System in terms of its size, indications for use and use with supplemental fixation.

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