

JUN 6 - 2005

**Medtronic Sofamor Danek  
CENTERPIECE™ Plate Fixation System  
510(k) Summary - K050082  
May 2005**

**Submitter:** Medtronic Sofamor Danek USA, Inc.  
1800 Pyramid Place  
Memphis, TN 38132

**Contact Person:** Richard Treharne  
(901) 396-3133

**Common Name:** Appliance, Fixation, Interlaminar

**Trade Name:** CENTERPIECE™ Plate Fixation System

**Classification:** 21 CFR 888.3050: Spinal interlaminar fixation orthosis.  
Product Code: NQW

**Device Description:** The CENTERPIECE™ Plate Fixation System consists of a variety of sizes of plates and screws. The CENTERPIECE™ Plate Fixation System components are made of from medical grade titanium or titanium alloy.

**Intended Use:** The CENTERPIECE™ Plate Fixation System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The CENTERPIECE™ Plate Fixation System is used to hold the graft material in place in order to prevent the graft material from expulsion, or impinging the spinal cord.

**Functionality & Safety Testing:** Mechanical testing was performed on the CENTERPIECE™ Plate Fixation System and was included in this submission.

**Substantial Equivalence** The CENTERPIECE™ Plate Fixation System is substantially equivalent to a previously cleared device used to perform laminoplasty procedures, namely the Kirschner Orthopedic Wire, K850631 Kirschner Medical Corp. (SE 05/01/85).



JUN 6 - 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K050082  
Trade/Device Name: CENTERPIECE™ Plate Fixation System  
Regulation Number: 21 CFR 888.3050  
Regulation Name: Spinal interlaminar fixation orthosis  
Regulatory Class: II  
Product Code: NQW  
Dated: April 8, 2005  
Received: April 11, 2005

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.

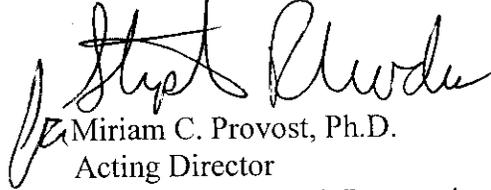
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 – Richard W. Treharne, Ph.D.

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,

A handwritten signature in black ink, appearing to read "Miriam C. Provost". The signature is written in a cursive style with a large initial "M".

Miriam C. Provost, Ph.D.

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): K050082

Device Name: CENTERPIECE™ Plate Fixation System

**Indications for Use:**

The CENTERPIECE™ Plate Fixation System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The CENTERPIECE™ Plate Fixation System is used to hold the graft material in place in order to prevent the graft material from expulsion, or impinging the spinal cord.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Signatory)  
Division of General Restorative  
and Neurological Devices

510(k) Number K050082