K071416

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MEDTRONIC Sofamor Danek
PYRAMID® +4 Anterior Lumbar Plate System 510(k) Summary
May 2007

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

Contact: Christine Seifert, Regulatory Affairs Group Director

II. **Product Name:** PYRAMID® +4 Anterior Lumbar Plate System
Classification Name: Spinal Interlaminal Fixation Orthosis
Class II Product Code: KWQ
21 CFR: 888.3060

III. **Description:** The subject device represents an expansion of the PYRAMID® ANTERIOR PLATE System. The predicate system will be renamed the PYRAMID® +4 ANTERIOR LUMBAR PLATE System. Like its predicate counterpart, the subject device is intended for use as an anterior fixation device to supplement an anterior lumbar interbody fusion. The variety of the PYRAMID® +4 ANTERIOR LUMBAR PLATE System provides surgeons with options in the placement of the device to avoid interference with the vasculature, while still allowing for fixation. The PYRAMID® +4 ANTERIOR LUMBAR PLATE components are made of titanium alloy.

IV. **Indications for Use:** The Medtronic Sofamor Danek PYRAMID® +4 ANTERIOR LUMBAR PLATE System is indicated for use as an anteriorly placed supplemental fixation device for the lumbosacral level below the bifurcation of the vascular structures or as an or anteriorly lateral placed supplemental fixation device for the L1 – L5 region.

When properly used, this system will help provide temporary stabilization until a solid spinal fusion develops. Specific indications include: 1) Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); 2) Pseudoarthrosis; 3) Spondylolysis; 4) Spondylolisthesis; 5)Fracture; 6) Neoplastic disease; 7) Unsuccessful previous fusion surgery; 8) Lordotic deformities of the spine; 9) Idiopathic thoracolumbar or lumbar scoliosis; 10) Deformity (i.e., scoliosis, lordosis, and/or kyphosis) associated with deficient posterior elements such as that resulting from laminectomy, spina bifida, or myelomenigocele; and/or 11) Neuromuscular deformity (i.e., scoliosis, lordosis, and / or kyphosis) associated with pelvic obliquity.

V. **Substantial Equivalence**: Documentation, including mechanical test results, provided has demonstrated that the PYRAMID® +4 Anterior Lumbar Plate System is substantially equivalent to similar previously cleared devices such as the PYRAMID® Anterior Plate Fixation System (K013665, 12/29/2002) and the XANTUS® Anterior Lateral Supplemental Fixation System (K022070, SE 07/22/02).

PYRAMID® +4 ANTERIOR LUMBAR PLATE System
510(k) APPLICATION

NOTICE

The enclosed materials and descriptions contain information, which is trade secure or confidential under 21 CFR 20.61 and not disclosable to the public under the Freedom of Information Act (FOIA). If you are not able to assure us that the enclosed information will not be disclosed to the public, we request that this submission be handled by FDA in accordance with 21 CFR 20.44 relating to presubmission reviews. Consequently, until you hear otherwise from us, we ask that you keep our application for this device confidential. We consider this premarket notification confidential commercial information. If we disclose this application to anyone except consultants or employees, we will notify the FDA.

I. Submitter Information

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: 901-396-3133
Telefax: 901-346-9738
Contact: Christine Seifert
Director, Regulatory Affairs

Manufacturing Facilities

Warsaw Orthopedic, Inc. (also known as)
Medtronic Sofamor Danek Manufacturing, Inc.
2500 Silveus Crossing
Warsaw, Indiana 46582
Telephone: 219-267-6826

Medtronic Puerto Rico Operations Co., med Rel
Road 909, KM.0.4
Barrio Mariana
Humacao, PR 00792

Device Name

Common or Usual Name:	Metallic Bone Fixation Appliance
Proposed Proprietary or Trade Name:	PYRAMID™ +4 ANTERIOR LUMBAR PLATE System
Classification Name:	Spinal Interlaminal Fixation Orthosis

Establishment Registration Number

1030489	Medtronic Sofamor Danek USA, Inc.
1824199	Warsaw Orthopedic (also known as) Medtronic Sofamor Danek Manufacturing (For reference only)
2647346	Medtronic Puerto Rico Operations Co.

Classification

Class II - 21 CFR 888.3060 (Orthopedic OR 87)
Product Code - KWQ

Performance Standards (FD&C Act Section 514)

We are unaware of any performance standards for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 1 2007

Medtronic Sofamor Danek, Inc.
% Ms. Christine Scifert
Regulatory Affairs Group Director
1800 Pyramid Place
Memphis, TN 38132

Re: K071416
Trade/Device Name: Pyramid® +4 Anterior Lumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: September 25, 2007
Received: September 26, 2007

Dear Ms. Scifert:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071416

Device Name: Pyramid +4 Anterior Lumbar Plate System

Indications For Use:

The Medtronic Spinal and Biologics PYRAMID® +4 ANTERIOR LUMBAR PLATE Fixation System is indicated for use as a supplemental fixation device for the lumbosacral level, anterior below the bifurcation of the vascular structures or laterally above the bifurcation of the vascular structures.

When properly used, this system will help provide temporary stabilization until a solid spinal fusion develops. Specific indications include: 1) Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); 2) Pseudoarthrosis; 3) Spondylolysis; 4) Spondylolisthesis; 5)Fracture; 6) Neoplastic disease; 7) Unsuccessful previous fusion surgery; 8) Lordotic deformities of the spine; 9) Idiopathic thoracolumbar or lumbar scoliosis; 10) Deformity (i.e., scoliosis, lordosis, and/or kyphosis) associated with deficient posterior elements such as that resulting from laminectomy, spina bifida, or myelomenigocele; and/or 11) Neuromuscular deformity (i.e., scoliosis, lordosis, and/or kyphosis) associated with pelvic obliquity.

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)

Mark N Milhous

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

510(k) Number K071416