K022070 p1/2

JUL 2 2 2002

Medtronic Sofamor Danek
XANTUS™ Anterior Lateral Supplemental Fixation System
510(k) Summary
June 2002

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

Contact Person: Richard Treharne

Trade Name: XANTUS™ Anterior Lateral Supplemental Fixation System

Classification Name: Spinal Intervertebral Body Fixation Orthosis, Class II

Predicate Device(s): The XANTUS™ Anterior Lateral Supplemental Fixation System is substantially equivalent to K014267, Medtronic Sofamor Danek XANTUS™ Anterior Lateral Supplemental Fixation System, which was cleared on January 25, 2002.

Device Description: The XANTUS™ Anterior Lateral Supplemental Fixation System consists of a variety of shapes and sizes of plates, screws, bolts, and nuts, as well as ancillary products and instrument sets. XANTUS™ Anterior Lateral Supplemental Fixation System anterior implant components can be locked into a variety of configurations, with each construct being tailor-made for the individual case. Implant components from other previously cleared Medtronic Sofamor Danek Spinal Systems can be used in conjunction with XANTUS™ Anterior Lateral Supplemental Fixation System. These components include the ZPLATE-ATL™ Anterior Fixation System screws and the DYNA-LOK® Spinal System nut. Refer to those package inserts for proper specific instructions for use.

Intended Use:

The XANTUS™ Anterior Lateral Supplemental Fixation System is intended for screw/bolt fixation/attachment to the anterolateral intervertebral bodies from T1 to L5 only. This system is to be used only on one side and placed in such a manner as to be as far away from blood vessels such as the aorta and nerve roots as possible.

When properly used, this system will provide temporary stabilization until a solid spinal fusion develops. Specific indications include:

1. Degenerative Disc Disease (DDD as defined as 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.
11. Neuromuscular deformity (i.e., scoliosis, lordosis, and/or kyphosis) associated with pelvic obliquity.

Functionality & Safety Testing: Mechanical testing was performed on the Subject XANTUS™ Anterior Lateral Supplemental Fixation System which determined it to be substantially equivalent to the predicate XANTUS™ Anterior Lateral Supplemental Fixation System.

Conclusion: The XANTUS™ Anterior Lateral Supplemental Fixation System is substantially equivalent to K014267, the XANTUS™ Anterior Lateral Supplemental Fixation System .

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2 2002

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

Re: K022070
Trade/Device Name: XANTUS™ Anterior Lateral Supplemental Fixation System
Regulatory Number: 21 CFR 888.3050
Regulation Name: Spinal Interlaminal Fixation Orthosis
Regulatory Class: II
Product Code: KWP, MNH
Dated: June 18, 2002
Received: June 26, 2002

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 and additionally 21 CFR Part 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022070

Device Name: XANTUS™ Anterior Lateral Supplemental Fixation System

Indications for Use:

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

for Mark N. Milleman

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

Concurrence of CDRH, Office of Evaluation (ODE)

510(k) Number K022070 MNM K022070 MNM

Prescription Use ____ **OR** **Over-the-counter Use** ____
(Per 21 CFR 801.109)
(Optional 1-2-96)

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