K013962 p1/2

JUN 2 0 2002

Medtronic Sofamor Danek
EQUATION™ Fixation System
510(k) Summary
May 2002

Submitter:

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

Contact Person:

Richard Treharne
Sr. Vice President Regulatory Affairs

Trade Name:

EQUATION™ Fixation System

Classification Name:

Spinal Intervertebral Body Fixation Orthosis, Class II

Predicate Device(s):

The EQUATION™ Fixation System is substantially equivalent to the CD HORIZON® Spinal System.

Device Description:

The Medtronic Sofamor Danek EQUATION™ Fixation System consists of a variety of shapes and sizes of screws, nuts, and 3.6mm rods and cross connectors. The implant components can be rigidly locked in a variety of configurations, with each construct being tailor-made for the individual case. The implants are made of titanium alloy (Ti-6A1-4V) described by ASTM Standard F136 or ISO 5832-3. Stainless steel and titanium implant components must not be used together in a construct.

Intended Use:

The EQUATION™ Fixation System is a temporary implant system used for correction and stabilization of the posterior spine for the development of a solid spinal fusion. When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the EQUATION™ Fixation System is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and/or (7) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the EQUATION™ Fixation System is indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine

(L3 and below); and (d) who are having the device removed after the development of a solid fusion mass.

Functionality & Safety Testing: Mechanical testing was performed on the EQUATION™ Fixation System and was compared to test data on the previously cleared CD HORIZON® Spinal System. The test results were provided in this submission.

Conclusion: The EQUATION™ Spinal System is substantially equivalent to the CD HORIZON® Spinal System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 0 2002

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

Re: K013962
Trade/Device Name: EQUATION™ Fixation System
Regulatory Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNH, MNI
Dated: April 16, 2002
Received: April 17, 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, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013962

Device Name: EQUATION™ Fixation System

Indications for Use:

The EQUATION™ Fixation System is a temporary implant system used for correction and stabilization of the posterior spine for the development of a solid spinal fusion. When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the EQUATION™ Fixation System is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and/or (7) failed previous fusion (pseudarthrosis).

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

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional 1-2-96)

for Mark N Milhouse

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

510(k) Number K013962