K042859

NOV 2 4 2004

Medtronic Vertelink KOBRA™ GPS Fixation System
Summary of Safety and Effectiveness
October 2004

I. **Company:** **Medtronic Vertelink, Inc**
30 Hughes, Suite 206
Irvine, CA, 92618
(949) 455-1128

Contact: **Samuel M. Shaolian**
Vice President, Product Development

II. **Proposed Proprietary Trade Name: Vertelink KOBRA™ Fixation System**

III. **Classification Name: Spinal Intervertebral Fixation Orthosis and/or Pedicle Screw Spinal System (per 21 CFR Section 888.3060 and/or 888.3070)**
Class: Class II
Product Code: MNH, MNI, KWQ

IV. Product Description

The Medtronic Vertelink KOBRA™ GPS Fixation System consists of a variety of cannulated rods and cannulated multi-axial screws used to build a spinal construct. Instrumentation is also available to facilitate implantation of the device components.

The KOBRA™ GPS Fixation System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine. The KOBRA™ GPS implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

V. Indications

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the KOBRA™GPS 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 KOBRA™GPS 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; (3) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of a solid fusion mass.

VI. Substantial Equivalence

Documentation, including test reports, was provided which demonstrated the Vertelink KOBRA™ GPS Fixation System to be substantially equivalent to the Vertelink KOBRA™ Fixation System components previously cleared in K032102 and to the CD HORIZON® Spinal System (K000453).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 2004

Mr. Samuel M. Shaolian
Vice President, Product Development
Medtronic Vertelink, Inc.
30 Hughes, Suite 206
Irvine, California 92618

Re: K042859
Trade/Device Name: Vertelink KOBRA™ GPS Fixation System
Regulation Number: 21 CFR 888.3060, 888.3070
Regulation Name: Spinal intervertebral body fixation orthosis, Pedicle screw spinal system
Regulatory Class: II
Product Code: KWQ, MNI, MNH
Dated: October 14, 2004
Received: October 15, 2004

Dear Mr. Shaolian:

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 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/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

Indications for Use

510(k) Number (if known): K042859

Device Name: Vertelink KOBRA™ GPS Fixation System

Indications For Use:

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the KOBRA™GPS 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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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)

for Mark N. Milhous

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

510(k) Number K042859