DEC 12 2003

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Irvine, CA 92618
Phone 949-455-1128
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SUMMARY

Submitter's name: Address:	Vertelink corporation 30 Hughes, Suite 206 Irvine, CA 92618
Phone: Fax number:	949-455-1128 949-455-1158
Name of contact person:	Greg Holland Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411 fax: 949-552-2821
Date the summary was prepared:	July 2, 2003
Name of the device: Trade or proprietary name: Common or usual name: Classification name:	Vertelink KOBRA™ Fixation System Vertelink KOBRA™ Fixation System Spinal Fixation System Spinal Intervertebral Body Fixation Orthosis (per 21 CFR section 888.3060) Spondylolisthesis Spinal Fixation Device System (per 21 CFR section 888.3070) Pedicle Screw Spinal System (per 21 CFR section 888.3070)

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

CD HORIZON® Spinal System, manufactured by Medtronic Sofamor Danek, Inc. USA. The clearance number is K030932.

Description of the device:

The Vertelink KOBRA™ Spinal Fixation System is designed to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the acute and chronic instabilities or deformities of the lumbar spine, spinal tumor and failed previous fusions. It can be used in either percutaneous or open surgery procedures.

The system is composed of titanium pedicle screws and rods that are implanted in posterior manner either during an open surgical procedure or percutaneously using minimally invasive techniques.

In both open and percuataneous techniques the pedicle screws are placed under fluoroscopic guidance and in the percutaneous technique the pathway between the screw portals is cannulated using minimally invasive techniques. In the percutaneous fixation technique, six (6) small holes (no greater than 1.2cm) are used to introduce the construct.

Both open and percutaneous techniques use accessories and tools to provide effective placement.

Indications:

1) Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
2) Spinal stenosis
3) Spondylolisthesis
4) Spinal deformities
5) Fractures
6) Pseudarthrosis
7) Tumor resection

8) Failed previous Fusion

When used as Fixation system the multiaxial screw components are also indicated for skeletally mature patients:

a) Having severe spondylolisthesis (grade 3 or 4) of the L5-S1 vertebral joint.
b) Who are receiving fusion using authogeneous bone graft only
c) Who are having the device fixed or attached to the lumbar or sacral spine (L3 and bellow)
d) Who are having the device removed after the development of solid fusion mass.

Summary of the technological characteristics of our device compared to the predicate device:

As can be seen in the Comparison section, the Vertelink KOBRA™ Fixation System and CD HORIZON® Spinal System have similar technological characteristics and are equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2003

Vertelink Corporation
C/o Mr. Greg Holland
Regulatory Specialists, Inc.
3722 Avenue Sausalito
Irvine, California 92606

Re: K032102
Trade/Device Name: Vertelink KOBRA™ Spinal Fixation System
Regulation Number: 21 CFR 888.3060, 21 CFR 888.3070
Regulation Name: Spinal intervertebral body fixation orthosis, Pedicle screw spinal system
Regulatory Class: II
Product Code: KWQ, MNH, MNI
Dated: October 14, 2003
Received: October 15, 2003

Dear Mr. Holland:

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.

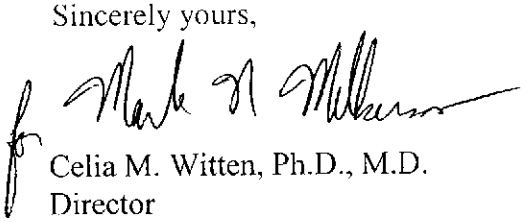
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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,



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): K032102 S1

Device Name: Vertelink KOBRA™ Fixation System

Indications For Use:

1) Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) Spinal stenosis, 3) Spondylolisthesis, 4) Spinal deformities, 5) Fractures, 6) Pseudarthrosis,7) Tumor resection, 8) Failed previous Fusion. When used as Fixation system the multiaxial screw components are also indicated for skeletally mature patients: a. Having severe spondylolisthesis (grade 3 or 4) of the L5-S1 vertebral joint, b. Who are receiving fusion using authogeneous bone graft only, c. Who are having the device fixed or attached to the lumbar or sacral spine (L3 and below), d. Who are having the device removed after the development of solid fusion mass.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milhous

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...ivision ... neral, Restorative
...nd Neuro... gical Devices

...) Nu... K032102

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