FEB 18 2005

510(k) SUMMARY

SpineWorks LLC's Stansion Matrix™

Submitter's Name, Address, Telephone Number, And Contact Person

SpineWorks, LLC
2802 Florida Street
Huntington Beach, CA 92648
Phone: (805) 797-3003
Facsimile: (714) 960-5250

Contact Person: Douglas W. Neary

Date Prepared

August 2004

Name of the Device

Stansion Matrix™ Vertebral Body Replacement

Common or Usual Name

Vertebral Body Replacement (MQP)

Classification Name

Spinal Vertebral Body Replacement

Predicate Devices

- Interpore Cross International GEO™ Structure
- Depuy AcroMed, Inc. Stackable Cage™ System
- Osteotech, Inc. VBR
- Orthovita Endoskeleton TA VBR

Intended Use

The Stansion Matrix is indicated for use in the thoracolumbar spine (*i.e.,* T1 to L5) to replace a portion of a diseased vertebral body that is resected or excised for the treatment of tumors, where the defect is contained within a single

vertebral body, in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The device is also indicated for treating fractures of the thoracic and lumbar spine. The Stansion Matrix is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period of time. The device is intended for use with supplemental rigid posterior pedicle screw fixation.

Principles of Operation

The device is a single piece titanium VBR that is open on all sides to maximize bone ingrowth. It is available in three sizes. The device is implanted via the posterior approach, according to similar methods as the predicates. An insertion tool is provided with the device to facilitate its implantation.

Technological Characteristics

The technological characteristics of the Stansion Matrix are very similar to the predicates with respect to shape, sizes, materials, and method of use. Like several of the predicates, the Stansion Matrix is made of titanium alloy. The minor differences in the design and the range of available sizes compared to the predicates do not raise any new questions of safety or effectiveness.

Summary Basis for the Finding of Substantial Equivalence

The Stansion Matrix has the same intended use and very similar indications for use to the predicate devices. The Stansion Matrix also is similar to the predicates with respect to its shape, size range, materials, and method of use. Any minor differences in technological features do not raise new issues of safety or effectiveness, as confirmed by performance testing. Therefore, the Stansion Matrix is substantially equivalent to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2005

Spine Works, L.L.C.
C/o Jonathan S. Kahan, Esq.
Hogan & Harston L.L.P.
555 13th Street N.W.
Washington, DC 20004

Re: K042600
Trade/Device Name: Stansion Matrix™
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: January 21, 2005
Received: January 21, 2005

Dear Mr. Kahan:

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.

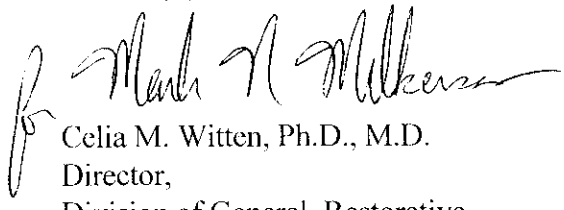
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use Statement

510(k) Number (if known): K042600

Device Name: Stansion Matrix™

Indications for Use: The Stansion Matrix™ ("Stansion Matrix") is indicated for use in the thoracolumbar spine (*i.e.*, T1 to L5) to replace a portion of a diseased vertebral body that is resected or excised for the treatment of tumors, where the defect is contained within a single vertebral body, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The device is also indicated for treating fractures of the thoracic and lumbar spine. The Stansion Matrix is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period of time. The device is intended for use with supplemental rigid posterior pedicle screw fixation.

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 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 Milhern

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

510(k) Number K042600