5. 510(k) Summary as required by 21 CFR 807.92(c)

APR 2 0 2007

510(k) Owner: Vertebration, Inc.
3375 Brentwood Court
Powell, OH 43065
Phone: (614) 437-2027
Facsimile: (614) 437-2034

Contact person: Barbara S. Fant, Pharm.D.
Clinical Research Consultants, Inc.
310 Terrace Avenue
Suite 201
Cincinnati, OH 45220
Phone: (513) 961-8200
Facsimile: (513) 961-2858

Date: January 5, 2007

Trade Name: XYcor™ Spinal Implant for Minimally Invasive Spinal Surgery

Common name: Vertebral body replacement device

Classification Name: Spinal Intervertebral body fixation orthosis
21 CFR 888.3060

Product Code: MQP

Identification of a Legally Marketed Predicate Device

The XYcor™ Spinal Implant is substantially equivalent to the InFix® System marketed by Abbott Spine, 510(k) Premarket Notification Number: K031672, FDA Product Code MQP. Secondly, it is substantially equivalent to the SYNEX™ System manufactured by Synthes Spine, 510(k) Premarket Notification Number: K003836, FDA Product Code MQP; and, to the DEVEX™ System manufactured by DePuy Spine; 510(k) Premarket Notification Number: K023835, FDA Product Code MQP.

General Description

The XYcor™ Spinal Implant is a vertebral body replacement device fabricated from titanium. The XYcor™ Spinal Implant deploys with a self-locking mechanism. The footprint of XYcor™ Spinal Implant prior to deployment is of comparable size and shape to the DEVEX™ System and, after deployment, is of comparable size to the InFix® System.

Intended Use

The XYcor™ Spinal Implant is indicated for use as a vertebral body replacement device intended for use in the thoracic and/or thoracolumbar spine (T3-L5) to replace a collapsed, damaged, or unstable vertebral body resected or excised (i.e., partial or total vertebrectomy procedures) due to tumor or trauma (i.e., fracture). The XYcor™ Spinal Implant 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.

The XYcor™ Spinal Implant is intended for use with bone graft and supplemental internal fixation. The supplemental internal fixation systems that may be used with the XYcor™ System include Medtronic Sofamor Danek TSRH 3D, DePuy Spine Expedium or Monarch pedicle screw fixation systems, Biomet, Polaris, Array or Omega-21 pedicle screw fixation systems, and other pedicle screw-rod/plate fixation systems that have biomechanical properties similar to those of the above-listed systems, including trans-facet fixation systems but excluding semi-rigid or flexible rod-screw systems.

Performance Data

Mechanical testing was performed on the XYcor™ Spinal Implant and the results are presented. The XYcor™ Spinal Implant demonstrated sufficient strength for static and dynamic compressive and torsional loading modes and resistance to subsidence and expulsion. The results did not raise any issues on the safety or effectiveness of the device.

Basis of Substantial Equivalence

The XYcor™ Spinal Implant is substantially equivalent to INFIX® System manufactured by Abbott Spine under 510(k) Premarket Notification Number K010530, FDA Product Code MQP, and regulation 21CFR§888.3060 (spinal intervertebral body fixation orthosis) in material, intended use, basic design concept, size of the footprint, and biomechanical properties. Secondly, it is also substantially equivalent to the SYNEX™ Spacer System manufactured by Synthes Spine under 510(k) Premarket Notification Number K003836, FDA Product Code MQP, and regulation 21CFR§888.3060 (spinal intervertebral body fixation orthosis) in its self-locking mechanism after distraction, and to the DEVEX ™ System manufactured by DePuy Spine under 510(k) Premarket Notification Number K023835, FDA Product Code MQP, and regulation 21CFR§888.3060 (spinal intervertebral body fixation orthosis) in its shape prior to deployment and the posterior approach used in surgical placement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 20 2007

Vertebration Incorporated
c/o Dr. Barbara Fant
310 Terrace Avenue – Suite 201
Cinncinnati, Ohio 45220

Re: K070082
Trade Name: XYcor™ Spinal Implant
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: March 19, 2007
Received: March 21, 2007

Dear Dr. Fant:

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/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K070082

Device Name: **XYcor™ Spinal Implant**

Indications for Use:

The XYcor™ Spinal Implant is indicated for use as a vertebral body replacement device intended for use in the thoracic and/or thoracolumbar spine (T3-L5) to replace a collapsed, damaged, or unstable vertebral body resected or excised (i.e., partial or total vertebrectomy procedures) due to tumor or trauma (i.e., fracture). The XYcor™ Spinal implant 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.

The XYcor™ Spinal Implant is intended for use with bone graft and supplemental internal fixation. The supplemental internal fixation systems that may be used with the XYcor™ Spinal Implant include Medtronic Sofamor Danek TSRH 3D, DePuy Spine Expedium or Monarch pedicle screw fixation systems, Biomet, Polaris, Array or Omega-21 pedicle screw fixation systems, and other pedicle screw-rod/plate fixation systems that have biomechanical properties similar to those of the above-listed systems, including trans-facet fixation systems but excluding semi-rigid or flexible rod-screw systems.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K070082

Prescription Use __X_____ OR ~~Over-The-Counter Use~~ _____