K031672

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510(K) Summary

Submitted By: Lisa Peterson
Regulatory Affairs Specialist
Spinal Concepts, Inc.
5301 Riata Park Court, Bldg. F
Austin, TX 78727
512-918-2700

Date: May 29, 2003

Trade Name: Spinal Concepts Inc. InFix® System
Classification Name: Vertebral Body Replacement
Product Code: MQP

Predicate Devices: InFix® is substantially equivalent to the Interpore Cross GEO™ Structure, which was cleared as an oval shaped configuration on August 3, 2001 (K010530) and as a rectangular shaped configuration on February 6, 2002 (K020048) and Interpore Cross International Anterior Fixation Device (AFD) cleared on January 23, 2003 (K022143).

Device Description: InFix® is manufactured from implantable grade titanium 6AL-4V alloy that conforms to ASTM F-136, and is available in various sizes and dimensions. The device is comprised of two opposing endplates supported by vertical members or "struts" that can be varied in height such that the surgeon can fix the vertebrae in a proper anatomical alignment and lordosis.

Each of the struts includes a load-sharing mechanism that allows a limited amount of strain across the fusion mass while supporting the load bearing surfaces. An Ultra High Molecular Weight Polyethylene (UHMWPE) end cap may be placed inside the device prior to packing of bone graft to effectively block the posterior opening in the device and contain the material inside.

Holes in the titanium endplates provide space for bone in-growth while angled spikes (teeth) penetrate the vertebral endplates and provide resistance to rotation and migration.

Intended Use: The InFix System is 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). InFix 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 InFix is intended to be used with bone graft.

Substantial Equivalence: Mechanical testing demonstrates that InFix® is substantially equivalent to the Interpore Cross GEO™ Structure and Interpore Cross International Anterior Fixation Device (AFD)predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 2003

Ms. Lisa Peterson
Regulatory Affairs Specialist
Spinal Concepts Incorporated
5301 Riata Park Court, Bldg. F
Austin, Texas 78727

Re: K031672
Trade Name: InFix® System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: May 29, 2003
Received: June 5, 2003

Dear Ms. Peterson:

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): **K031672**

Device Name: Spinal Concepts, Inc. **InFix® System**

Indications for Use:

The InFix System is 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).

InFix 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 InFix is intended to be used with bone graft.

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

510(k) Number K031672

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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