K042714

DEC 2 9 2004

510(K) Summary

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

December 8, 2004

Trade Name: Spinal Concepts Inc. FIDJI® Types 1,2,3, and 4
Classification Name: Vertebral Body Replacement
Product Code: MQP

Predicate Device: FIDJI types 1,2,3, and 4 are substantially equivalent to the Synthes Vertebral Spacer (K011037), EBI CAS Spine Spacer (K042268), and Medtronic Sofamor Danek Vertestack (K031780).

Device Description: The FIDJI Vertebral Body Replacement Types 1, 2, 3, and 4 devices are hollow blocks that are machined from PEEK OPTIMA® (polyetheretherketone, ASTM F2026); the blocks are tapered to aid in maintaining lordosis of the spine following implantation. The devices have angled teeth on the cephalad and caudal surfaces. The devices include tantalum inserts that serve as a location and orientation markers for radiographs.

Intended Use: FIDJI types 1,2,3, and 4 are vertebral body replacement devices that are intended for use in the thoracic and/or thoracolumbar spine (T1 - 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). These devices are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. These devices are intended to be used with bone graft and supplemental fixation, such as the Spinal Concepts, Inc. InCompass System.

Mechanical Testing: Mechanical testing demonstrated that FIDJI types 1,2,3, and 4 exhibit the functional requirements to support their use as vertebral body replacements under normal physiologic loads in the spine.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 9 2004

Ms. Lisa Peterson
Regulatory Affairs Manager
Spinal Concepts, Inc.
5301 Riata Park Court, Building. F
Austin, Texas 78727

Re: K042714
Trade/Device Name: FIDJI Vertebral Body Replacement Types 1, 2, 3, and 4
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: December 3, 2004
Received: December 6, 2004

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 (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 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

K042714

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K042714

Device Name:

Spinal Concepts, Inc. **FIDJI Vertebral Body Replacement Types 1, 2, 3, and 4**

Indications for Use:

FIDJI types 1, 2, 3, and 4 are vertebral body replacement devices that are intended for use in the thoracic and/or thoracolumbar spine (T1-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 device 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. These devices are intended to be used with bone graft and supplemental fixation, such as the Spinal Concepts, Inc. InCompass System.

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)

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

510(k) Number K042714