JAN 24 2008

510(k) Summary
Crystal®
510(k) Number K073351

Manufacturer Identification

Submitted by:

Spinal Elements, Inc.
2744 Loker Ave. W., Suite 100
Carlsbad, CA 92010
760-607-0121

Contact Information:

Kerri DiMartino
Regulatory Affairs Specialist
Spinal Elements, Inc.
2744 Loker Ave. W., Suite 100
Carlsbad, CA 92010
760-607-1816
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Date Prepared: November 28, 2007

Device Indentification

Proprietary Name: Crystal®
Common Name: Intervertebral Body Fusion Device

Device Classification: 21 CFR 888.3080 (orthosis, spinal intervertebral fusion)

Device Description

Spinal Elements' Crystal device is a generally box-shaped devices with various holes located throughout its geometry and teeth on the superior and inferior surfaces. The device may be made from titanium alloy (Ti-6Al-4V) or polyetheretherketone (PEEK).

Intended Use of the Device

When used as a vertebral body replacement, the Crystal device is 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).

This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacer can be packed with allograft or autograft

When used as an intervertebral body fusion device, the Crystal device is intended for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with

degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone.

Substantial Equivalence
Crystal was shown to be substantially equivalent through comparison to predicate intervertebral body fusion devices.

Performance Data
Mechanical testing indicates that the Crystal device is capable of performing in accordance with its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 24 2008

Spinal Elements, Incorporated
c/o Ms. Kerri DiMartino
Regulatory Affairs Specialist
2744 Loker Avenue West, Suite 100
Carlsbad, CA 92010

Re: K073351
Trade/Device Name: Crystal Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: November 28, 2007
Received: November 29, 2007

Dear Ms. DiMartino:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the 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

Indications for Use

510(k) Number (if known): K073351

Device Name: Crystal®

Indications for Use:
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This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacer can be packed with allograft or autograft.

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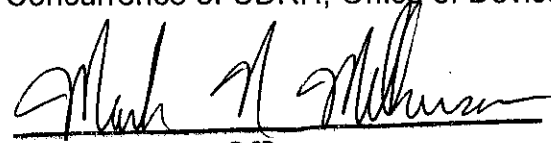
Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

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