K080860

MAY 29 2008

510(K) SUMMARY

Creaspine SupStance Small Vertebral Body Replacement System

Proprietary Name:	Creaspine SupStance Small Vertebral Body Replacement System
Common Name:	Spinal Vertebral Body Replacement System
Proposed Regulatory Class:	Class II Spinal intervertebral body fixation orthosis 21 CFR 888.3060
Device Product Code:	87 MQP, Spinal Vertebral Body Replacement Device
For Information Contact:	Marc Bernard Regulatory Affairs Director PTIB Xavier Arnozan Avenue du Haut-Lévèque 33600 Pessac – France Telephone +33 557 102 854 Fax: +33 557 102 886 Email: marc.bernard@creaspine.com
Date Summary Prepared:	March 26, 2008

Predicate Devices

The Creaspine SupStance Small Vertebral Body Replacement System is substantially equivalent to the following legally marketed spinal vertebral body replacement devices:

- Surgical Titanium Mesh™ System (DePuy-Acromed™, Inc., K003043)
- Surgical Dynamics Mesh Cage System (United States Surgical, K003709)
- Spine Wave StaXx™ XD System (Spine Wave, K052670)

Device Description

The Creaspine SupStance Small Vertebral Body Replacement System is a vertebral body replacement system intended to replace a vertebral body. The SupStance Small VBR System consists of the SupStance Small VBR implants and the instrumentation required for implantation of the device. The SupStance Small VBR implant is a cage composed of fused hollow trapezoidal tubes with open sides and integral end caps. The SupStance

Small VBR cages are available in three sizes (12mm, 14mm, and 16mm) and cover a range of heights from 18mm to 50mm.

Like the sides of the cages, the SupStance Small VBR end caps have large openings for introduction of allograft and/or autograft and evenly spaced round serrations for fixation to the vertebral endplates. The end caps have a various (total) sagittal angle of 0°, 5°, and 8° to accommodate spinal anatomy.

The SupStance Small VBR cages are fabricated from poly-ether-ether-ketone (PEEK) with 6% BaSO4 contrast filler. The implants are provided non-sterile and may be implanted via an anterior approach or a costo-tranverse approach.

Intended Use

The Creaspine SupStance Small Vertebral Body Replacement System is a vertebral body replacement system intended to replace a vertebral body. The SupStance Small VBR System is designed for use in the thoracolumbar spine (T1- L5) to replace a collapsed, damaged, or unstable vertebral body during tumor or trauma (i.e., fracture) management procedures. The SupStance Small VBR System is intended to be used with supplemental internal fixation systems. Anterior thoracolumbar plates and screws or pedicle screw and rod systems are among the options for the surgeon to use.

The use of allograft and/or autograft with the SupStance Small VBR System is optional.

Statement of Technological Comparison

The subject components share the same intended use, basic design concepts, and materials as that of the predicate devices. Performance testing included the types of mechanical testing recommended for vertebral body replacement systems (static and dynamic compression testing, static and dynamic torsion testing, and expulsion testing) in the "FDA Guidance for Industry and FDA Staff, Spinal System 510(k)s" (issued May 3, 2004). The data collected confirms that the mechanical properties of the proposed SupStance Small VBR System are comparable to those of the predicate devices. The information and data collected support a claim of substantial equivalence for the proposed SupStance Small VBR System to the specified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 29 2008

Creaspine
% Medical Device Consultants, Inc.
Ms. Cynthia J. Nolte
Senior Regulatory Consultant
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K080860
Trade/Device Name: Creaspine SupStance Small Vertebral Body Replacement System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: March 26, 2008
Received: March 28, 2008

Dear Ms. Nolte:

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): K080860

Device Name: Creaspine SupStance Small Vertebral Body Replacement System

Indications for Use:

The Creaspine SupStance Small Vertebral Body Replacement System is a vertebral body replacement system intended to replace a vertebral body. The SupStance Small VBR System is designed for use in the thoracolumbar spine (T1- L5) to replace a collapsed, damaged, or unstable vertebral body during tumor or trauma (i.e., fracture) management procedures. The SupStance Small VBR System is intended to be used with supplemental internal fixation systems. Anterior thoracolumbar plates and screws or pedicle screw and rod systems are among the options for the surgeon to use.

The use of allograft and/or autograft with the SupStance Small VBR System is optional.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (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)

Neil R.P. Ogden for mkm

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

510(k) Number K080860