K092336

BIOMET SPINE

510(k) Summary

Preparation Date:	July 31, 2009
Applicant/Sponsor:	Biomet Spine 100 Interpace Parkway Parsippany, NJ 07054
Contact Person:	Vivian Kelly Phone: 973-299-9300 Fax: 973-257-0232
Trade name:	C-Thru™ Anterior Spinal System
Common Name:	Cervical and non-cervical spinal spacer
Classification Name:	Intervertebral fusion device, 21 CFR §888.3080 Spinal Intervertebral Body Fixation Orthosis, 21 CFR § 888.3060
Device Panel /Product Code:	Orthopedic ODP & MQP

OCT 15 2009

Device Description:

The C-Thru™ Anterior Spinal System consists of a spacer constructed of medical grade Polyetheretherketone (PEEK) with tantalum radiographic markers for spinal applications.

Indications for Use:

The C-Thru™ Anterior Spinal System is indicated for vertebral body replacement and intervertebral fusion. When used as a vertebral body replacement device, the C-Thru™ Spacers are indicated for use in the thoracolumbar spine (i.e., T1 to L5) for partial replacement of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The C-Thru™ Spacers are also indicated for partial vertebral body replacement for the treatment of fractures of the thoracic and lumbar spine. The C-Thru™ Spacers 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.

When used as a cervical intervertebral fusion device, the C-Thru™ Anterior Spinal System is intended for spinal fusion procedures at one level (C2 to T1) in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. The C-Thru™ Spacers are intended for use with supplemental fixation and autogenous bone graft to facilitate the fusion.

Summary of Technologies:

The technological characteristics (material, design and sizing) of the C-Thru™ Spacer is the same as, or similar to, the predicate devices.

Substantial Equivalence:

The C-Thru™ Anterior Spinal System is substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics, and principles of operation and do not present any new issues of safety or effectiveness. An example of a predicate intervertebral body fusion device distributed for the similar indications includes the Expandable PEEK Implant (K040928 and K082406), and Novel® Spinal Spacer System (K081730), while the Small Stature Spacer System (K063393) has similar design features. Based upon the mechanical testing, C-Thru™ Anterior Spinal System is substantially equivalent for its intended use to other spacers currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Biomet Spine
% Ms. Vivian Kelly
100 Interpace Parkway
Parsippany, New Jersey 07054

OCT 1 5 2009

Re: K092336
Trade/Device Name: C-Thru™ Anterior Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: ODP, MQP
Dated: July 31, 2009
Received: August 4, 2009

Dear Ms. Kelly:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K092336

Device Name: C-Thru™ Anterior Spinal System

Indications for Use:

The C-Thru™ Anterior Spinal System is indicated for vertebral body replacement and intervertebral fusion. When used as a vertebral body replacement device, the C-Thru™ Spacers are indicated for use in the thoracolumbar spine (i.e., T1 to L5) for partial replacement of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The C-Thru™ Spacers are also indicated for partial vertebral body replacement for the treatment of fractures of the thoracic and lumbar spine. The C-Thru™ Spacers 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.

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Prescription Use **X** (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092336

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