

510(K) SUMMARY

MAR 17 2011

Submitter: DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02767

Contact Person: Eugene Bang
Regulatory Affairs Associate
Voice: (508) 977-3966
Fax: (508) 828-3797
Email: ebang@its.jnj.com

Date Prepared: December 21, 2010

Trade Name: CONCORDE® Curve System

Device Class: Class II

Product Code(s): MAX, MQP

Classification Name: Intervertebral Body Fusion Device
per 21 CFR §888.3080
Spinal Intervertebral Body Fixation Orthosis
per 21 CFR §888.3060

Predicate Device: CONCORDE® Curve System (K101923)

Device Description: The Concorde Curve System consists of polymer/carbon fiber composite cages and implantation instruments. Cages are available in varying shape and size configurations to match patient anatomy. The polymer/carbon fiber cage structure is radiolucent with tantalum x-ray markers so that healing can be assessed by normal radiographic methods. The cages have ridges or teeth that resist rotation and migration and have cavities to accept packing of bone graft.

Intended Use:

The CONCORDE, CONCORDE Bullet, CONCORDE Curve, COUGAR, DEVEX, and LEOPARD Systems are indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Patients should have six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and are placed via either a PLIF (CONCORDE, CONCORDE Bullet), TLIF (CONCORDE, CONCORDE Bullet, CONCORDE Curve, DEVEX, LEOPARD) or anterior (COUGAR) approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with DePuy Spine supplemental internal fixation products.

The CONCORDE, CONCORDE Bullet, CONCORDE Curve, COUGAR, DEVEX, and LEOPARD Systems are indicated for use in the thoracolumbar spine (i.e., T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. These systems are also indicated for treating fractures of the thoracic and lumbar spine. These systems 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 vertebral body replacement device these systems are intended for use with DePuy Spine supplemental internal fixation products.

Materials:

The CONCORDE® Curve System is made from carbon-fiber reinforced polymer with tantalum wires.

Technological Characteristics:

The purpose of this submission is to obtain market clearance for the proposed sterile components to the CONCORDE® Curve System. The proposed device is identical to the predicate device except that the proposed device will be terminally sterilized by DePuy Spine. The design characteristics, performance, intended use, materials, and technology remain identical to the predicate system.

Performance Data:

Testing was performed to determine the effects of gamma radiation on the cages. The testing was performed in compliance with ASTM F2077, static axial and dynamic axial testing was performed to demonstrate substantial equivalence post-sterilization and again with the predicate device.

Conclusion:

Based on the predicate comparison and testing, the subject device CONCORDE® Curve System is substantially equivalent to the predicate device.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DePuy Spine, Inc.
% Mr. Eugene Bang
Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02767

MAR 17 2011

Re: K103743
Trade/Device Name: CONCORDE[®] Curve System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: February 15, 2011
Received: February 16, 2011

Dear Mr. Bang:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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.

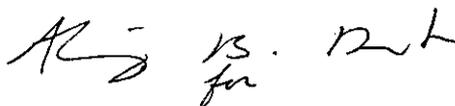
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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 (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson" with a stylized flourish at the end.

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 STATEMENT

510(k) Number (if known): K103743

Device Name: CONCORDE® Curve System

Indications For Use:

The CONCORDE, CONCORDE Bullet, CONCORDE Curve, COUGAR, DEVEX, and LEOPARD Systems are indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Patients should have six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and are placed via either a PLIF (CONCORDE, CONCORDE Bullet), TLIF (CONCORDE, CONCORDE Bullet, CONCORDE Curve, DEVEX, LEOPARD) or anterior (COUGAR) approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with DePuy Spine supplemental internal fixation products.

The CONCORDE, CONCORDE Bullet, CONCORDE Curve, COUGAR, DEVEX, and LEOPARD Systems are indicated for use in the thoracolumbar spine (i.e., T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. These systems are also indicated for treating fractures of the thoracic and lumbar spine. These systems 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 vertebral body replacement device these systems are intended for use with DePuy Spine supplemental internal fixation products.

Prescription Use X

AND/OR

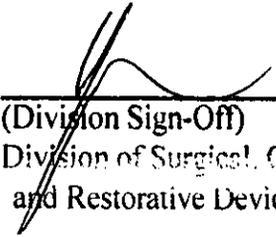
Over-The-Counter Use _____

(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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103743