510(K) SUMMARY

MAR - 2 2011

A. Submitter Information

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

Contact Person: Kevin G. Stevens
Regulatory Affairs Project Manager
Voice: (508) 977-6445
Fax: (508) 828-3797
E-Mail: ksteven1@its.jnj.com

B. Date Prepared 24 November 2010

C. Device Name

Trade/Proprietary Name: Concorde Bullet and Bengal Spine Systems

Common/Usual Name: Spine System

Classification Name: Spinal Vertebral Body Replacement Device (888.3060)
Intervertebral Body Fusion Device (888.3080)

D. Predicate Device Name

Trade name: DePuy Spine Concorde Bullet Spine System (K081917)
DePuy Spine Bengal Spine System (K081917)

E. Device Description

The Concorde Bullet and Bengal Systems consist 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.

F. Intended Use

The CONCORDE System is 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 or TLIF approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with DePuy Spine supplemental internal fixation.

The BENGAL System is indicated for use as an intervertebral body fusion device 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 level of the cervical spine with accompanying radicular symptoms. Patients should have six weeks of non-operative treatment prior to surgery. BENGAL implants are used to facilitate fusion in the cervical spine (C2-T1) and are placed via an anterior approach using autogenous bone. When used as an interbody fusion device, DePuy Spine supplemental fixation may be used.

The CONCORDE and BENGAL System 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. This system is also indicated for treating fractures of the thoracic and lumbar spine. This system 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. When used as a vertebral body replacement device this system is intended for use with DePuy Spine supplemental internal fixation.

F. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use

The proposed devices are identical to the predicate devices except that the proposed devices will be terminally sterilized by DePuy Spine. The design, materials, and technology remain identical to the predicate systems.

G. Materials

These systems are manufactured from composite material with a matrix of carbon-fibre reinforced poly-ether-ether-ketone (PEEK) and tantalum beads. The materials remain unchanged from the predicate.

H. Performance Data

Testing is performed in compliance with ASTM F2077. Static axial and Dynamic Axial testing was performed to demonstrate substantial equivalence post-sterilization and aging with the predicate device.

I. Conclusion

Both the Performance Testing and Substantial Equivalence Justification demonstrate that the device is as safe, as effective, and performs as well as the predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DePuy Spine, Inc.
% Mr. Kevin G. Stevens
Regulatory Affairs Project Manager
325 Paramount Drive
Raynham, Massachusetts 02767

MAR - 2 2011

Re: K103488
Trade/Device Name: Concorde Bullet and Bengal Spine System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP, MQP
Dated: February 03, 2011
Received: February 04, 2011

Dear Mr. Stevens:

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,

for

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):

Device Name: Concorde Bullet and Bengal Spine System

Indications For Use:

The CONCORDE System is 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 or TLIF approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with DePuy Spine supplemental internal fixation.

The BENGAL System is indicated for use as an intervertebral body fusion device 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 level of the cervical spine with accompanying radicular symptoms. Patients should have six weeks of non-operative treatment prior to surgery. BENGAL implants are used to facilitate fusion in the cervical spine (C2-T1) and are placed via an anterior approach using autogenous bone. When used as an interbody fusion device, DePuy Spine supplemental fixation may be used.

The CONCORDE and BENGAL System 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. This system is also indicated for treating fractures of the thoracic and lumbar spine. This system 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. When used as a vertebral body replacement device this system is intended for use with DePuy Spine supplemental internal fixation.

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 K103488