VI. 510(k) Summary

MAY 22 2009

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

CONTACT PERSON: Frank S. Jurczak

DATE PREPARED: July 2, 2008

CLASSIFICATION NAME: Spinal Intervertebral Body Fixation Orthosis, Spinal Intervertebral Fusion

PROPRIETARY NAME: BENGAL® System
CONCORDE™ System
COUGAR™ System
DEVEX® System
LEOPARD® System

PREDICATE DEVICES: Lumbar I/F Cage System (P960025)
DEVEX Mesh System (K023835)
BAK Interbody Fusion System (P950002)
BAK/Cervical (BAK/C) Interbody Fusion System (P980048)
Cimplicity Spinal Fixation System (K073320)
DePuy AcroMed VBR System (K031635), (K030833), (K041722)
CONCORDE VBR Spinal System (K052746)
DEVEX Mesh System (K023835)

DEVICE DESCRIPTION: The BENGAL, CONCORDE, COUGAR, DEVEX, and LEOPARD Systems consist of implants available in various heights and lordotic configurations with an open architecture to accept packing of bone graft materials.

These Systems also contain Class 1 manual surgical instruments and cases that are considered exempt from premarket notification.

INTENDED USE: <u>CONCORDE, COUGAR, DEVEX, and LEOPARD Systems Indications</u>
The CONCORDE, 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), TLIF (CONCORDE, 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.

The CONCORDE, 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.

BENGAL System Indications

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 BENGAL System is 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.

MATERIALS:

The BENGAL, CONCORDE, COUGAR and LEOPARD Systems are made from carbon-fiber reinforced polymer with tantalum beads.
The DEVEX System is manufactured from ASTM F136 implant grade titanium alloy.

PERFORMANCE DATA:

Performance data were submitted to characterize the BENGAL, CONCORDE, COUGAR, DEVEX and LEOPARD Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2009

DePuy Spine, Inc
% Mr. Frank Jurczak
Regulatory Affairs Associate
325 Paramount Drive
Raynham, MA 02767

Re: K081917
Trade/Device Name: DePuy Spine BENGAL, CONCORDE, COUGAR, DEVEX, and LEOPARD Systems
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP, MQP
Dated: May 20, 2009
Received: May 21, 2009

Dear Mr. Jurczak:

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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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/cdrh/industry/support/index.html.

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

IV. Indications for Use

510(k) Number (if known): K081917

Device Name: DePuy Spine Cages (BENGAL, CONCORDE, COUGAR, DEVEX, LEOPARD Systems)

Indications For Use:

CONCORDE, COUGAR, DEVEX, and LEOPARD Systems Indications

The CONCORDE, 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), TLIF (CONCORDE, 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.

The CONCORDE, 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.

BENGAL System Indications

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 BENGAL System is 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_____ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
for Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K081917