DEC 1 3 2011

510(K) SUMMARY

A. Submitter Information

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

Contact Person: Kevin G. Stevens
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B. Date Prepared November 11, 2011

C. Device Name

Trade/Proprietary Name: Cougar® Implant System

Classification Name: Spinal Vertebral Body Replacement Device
21 CFR 888.3060,
Orthosis, Spinal Intervertebral Fusion
21 CFR 888.3080

D. Predicate Device Name

Trade name: DePuy Spine Cougar® System (K081917)
DePuy Spine X-Mesh System (K080568)
DePuy Spine Leopard® System (K031635)
DePuy Spine Cougar LS Lateral Cage® System (K110454)
DePuy Spine Concorde Curve® System (K101923)

E. Device Description

The Cougar® System consists of implants available in various heights and lordotic configurations with an open architecture to accept packing of autogenous bone graft materials.

F. Intended Use

The COUGAR 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 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 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 COUGAR 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. The COUGAR System is also indicated for treating fractures of the thoracic and lumbar spine. The COUGAR 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, the COUGAR System is intended for use with DePuy Spine supplemental internal fixation.

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

The proposed modification to the DePuy Cougar® Implant (i.e. increase in lordotic angle) results in a device that is substantially equivalent to the predicates. The footprint of the subject devices remains unchanged from the predicate Cougar devices. The increase in lordotic angle provides the same

strength and performance as the predicate devices. The materials, and technology remain identical to the predicate system.

H. Materials

The proposed cages are manufactured from carbon-fiber reinforced PEEK Optima material. This material is identical to the predicate devices.

I. Performance Data

Performance data per ASTM F2077-11, ASTM-F2267-04, and DePuy Spine internal protocols were submitted to characterize the subject Cougar® Implants that are the subject of this PreMarket notification. This testing was comprised of static and dynamic compression testing on the proposed device as well as subsidence and expulsion testing.

J. Conclusion

DePuy Spine provided Performance Testing to demonstrate that the increase in lordotic angle (1) does not change the intended use of the device and (2) the change in scientific technology (i.e. change in lordotic angle) does not raise new questions of safety and effectiveness. The data presented in this PreMarket Notification demonstrates that the subject devices are as safe and effective as the chosen predicate devices.

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

DEC 13 2011

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

Re: K113348
Trade/Device Name: Cougar® Implant System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: November 11, 2011
Received: November 14, 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,

Erin Keith

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):

Device Name: COUGAR™ System

Indications For Use:

The COUGAR 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 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 anterior (COUGAR) approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with DePuy Spine supplemental internal fixation.

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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 K113348