510(K) SUMMARY

OCT 18 2012

A. Submitter Information

Manufacturer:	Medos International Sárl Chemin-Blanc 38 2400 Le Locle, Switzerland
Submitter:	DePuy Spine, Inc. 325 Paramount Drive Raynham, MA 02767
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B. Date Prepared September 20, 2012

C. Device Name

Trade/Proprietary Name:	Cougar® LS Lateral Cage System
Common/Usual Name:	Spinal Intervertebral Body Fixation Orthosis, Intervertebral body fusion device
Classification Name:	Spinal Intervertebral Body Fixation Orthosis per 21 CFR §888.3060 Intervertebral body fusion device per 21 CFR §888.3080

D. Predicate Device Name

Trade name: DePuy Spine Cougar® LS Lateral Cage System (K082128, K110454)

E. Device Description

The Cougar® LS Lateral System implants are manufactured from Carbon Fiber Reinforced Polymer (CFRP) material. Cages are available with 15° lordotic configurations, widths of 18mm and 21mm, and heights ranging from 10mm to 20mm in 2mm increments. The cages' lengths are 45mm, 50mm, 55mm, and 60mm.

The cage structure is radiolucent with tantalum X-ray wire so that healing can be assessed by normal radiographic methods. The cages have teeth that resist rotation and migration and have cavities to accept packing of autogenous bone graft.

The implants may be utilized in either an open or minimally invasive surgical approach. The implants are placed using a lateral surgical approach.

F. Intended Use

The Cougar® LS Lateral Cage System is indicated for use in the thoracolumbar spine (i.e., T1 to 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. The 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.

The Cougar® LS Lateral Cage System is also indicated for intervertebral body fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six

months of non-operative treatment. These implants may be implanted via an open or a minimally invasive lateral approach. When used as an interbody fusion 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 modification to the DePuy Cougar LS Lateral System (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 LS 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.

G. Materials

The proposed cages are manufactured from Carbon Fiber Filled PEEK-OPTIMA LT1 Compound (CFRP).

H. Performance Data

Performance data per ASTM F2077-11 and ASTM F2267-04 was submitted to characterize the subject Cougar LS Lateral Cage implants addressed in this notification. This testing was comprised of static and dynamic compression, static and dynamic compressive shear, expulsion, and subsidence testing on the proposed 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

Medos International Sárl
% Depuy Spine, a Johnson and Johnson Company
Ms. Kristen Lehmuller
Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02767

OCT 18 2012

Re: K122896
Trade/Device Name: Cougar® LS Lateral Cage Implants
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: September 20, 2012
Received: September 21, 2012

Dear Ms. Lehmuller:

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,

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): K122896

Device Name: Cougar® LS Lateral Cage Implants

Indications For Use:

The Cougar® LS Lateral Cage System is indicated for use in the thoracolumbar spine (i.e., T1 to 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. The 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.

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Prescription Use ___X ___ AND/OR Over-The-Counter Use ___ ___

(Part 21 CFR 801 Subpart D) (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 K122896