DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 12, 2016

Medos International, Sarl
℅ Mr. Eric Zhu
Regulatory Affairs Specialist
DePuy Spine, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K162327
Trade/Device Name: COUGAR® LS Lateral Cage System, COUGAR® System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: November 9, 2016
Received: November 10, 2016

Dear Mr. Eric Zhu:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162327

Device Name
COUGAR® LS Lateral Cage System and COUGAR® System

Indications for Use *(Describe)*
COUGAR® LS Lateral Cage System:

The COUGAR LS Lateral Cage System is indicated for use in the thoracolumbar spine (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 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 from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels.

Additionally, the COUGAR LS Lateral Cage System can be used in patients diagnosed with spinal deformities as an adjunct to fusion. These patients should be skeletally mature and have undergone six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and may be implanted via an open or a minimally invasive lateral approach using autogenous bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. When use as an interbody fusion device, this system is intended for use with DePuy Spine supplemental internal fixation.

COUGAR® System:

The COUGAR System is indicated for use as 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). Additionally the COUGAR System can be used in patients diagnosed with spinal deformities as an adjunct to fusion. These patients should be skeletally mature and have undergone six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and are placed via an anterior approach using autogenous bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. When used as an interbody fusion device these implants are intended for use with DePuy Spine supplemental internal fixation products.

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. 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

A. Submitter Information

Manufacturer:
Medos International Sárl
Chemin-Blanc 38
2400 Le Locle, Switzerland

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

Contact Person: Eric Zhu
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Raynham, MA 02767
Telephone number: (508) 828-3730
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Email: Ezhu@its.jnj.com

B. Date Prepared

August 17, 2016

C. Device Name

Trade/Proprietary Name: COUGAR® LS Lateral Cage System
COUGAR® System

Common/Usual Name: Intervertebral Body Fusion Device;
Spinal Intervertebral Body Fixation Orthosis

Classification and Regulation: Class II per 21 CFR 888.3080
Classification Product and Panel Code: MAX, MQP; Orthopedic

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D. Predicate Device Name

The subject devices are substantially equivalent to the primary predicate devices cleared under K140759, and the following additional predicate devices: COUGAR® (K081917, K113348), COUGAR® LS Lateral Cage System (K082128, K110454, K122896), Concorde Bullet Lumbar Interbody System (K151773), Medtronic CAPSTONE® Spinal System (K123027) and NuVasive CoRoent® Lumbar System (K151472).

E. Device Description

The COUGAR and COUGAR LS Lateral Cage Systems consists of PEEK/carbon fiber composite cages (CFRP). Cages are available in parallel or lordotic configurations and are available in various sizes to match patient anatomy. The cage structure is radiolucent with tantalum x-ray markers 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 bone graft material. The COUGAR LS Lateral Cage System may be implanted via an open or a minimally invasive lateral approach. The COUGAR implants are placed via an anterior approach.

F. Indications for Use

COUGAR LS Lateral Cage System:

The COUGAR LS Lateral Cage System is indicated for use in the thoracolumbar spine(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 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 from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels.

Additionally, the Cougar LS Lateral Cage System can be used in patients diagnosed with spinal deformities as an adjunct to fusion. These patients should be skeletally mature and have undergone six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and may be implanted via an open or a minimally invasive lateral approach using autogenous bone and/or allogenic bone graft

comprised of cancellous and/or corticocancellous bone graft. When used as an interbody fusion device, this system is intended for use with DePuy Spine supplemental internal fixation.

COUGAR System:

The COUGAR System is indicated for use as 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). Additionally the COUGAR System can be used in patients diagnosed with spinal deformities as an adjunct to fusion. These patients should be skeletally mature and have undergone six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and are placed via an anterior approach using autogenous bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. When used as an interbody fusion device these implants are intended for use with DePuy Spine supplemental internal fixation products.

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. 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.

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

The technological characteristics of the subject devices remain unchanged from their currently marketed predicate versions in their design, material, performance, and intended use.

H. Materials

The materials of the subject devices remain unchanged from the currently marketed predicate devices. Both the COUGAR and COUGAR-LS Lateral Cage implants are manufactured from Carbon Fiber Reinforced PEEK-OPTIMA LT1 Compound (CFRP) with tantalum x-ray markers that conform to ASTM F-560.

I. Performance Data

A literature analysis of published clinical data is provided to support the modified Indications for Use. The clinical and radiographic outcomes demonstrate that lumbar interbody fusion devices similar to the COUGAR and COUGAR LS Lateral Cage System are as safe and effective as the predicate devices for the modified Indications for Use. No additional testing was required as there were no changes to the technological characteristics of the Subject Cage Systems.

J. Conclusion

Based on the technological characteristics, comparison to predicate devices and clinical performance data from the clinical literature, the subject COUGAR and COUGAR LS Lateral Cage Systems are as safe and as effective as the predicate devices due to similar intended use and technological characteristics.