Dear Ms. Geller:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

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

Enclosure
Indications for Use

510(k) Number (if known)
K173787

Device Name

Indications for Use (Describe)
The Vertebral Body Replacement (VBR) Spinal Systems are 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.

The VBR Spinal Systems are also indicated for treating fractures of the thoracic and lumbar spine.

The VBR Spinal 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.

The VBR Spinal Systems are intended for use with DePuy Spine supplemental internal fixation.

Type of Use (Select one or both, as applicable)
- [ ] Prescription Use (Part 21 CFR 801 Subpart D)
- [x] Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known)
K173787

Device Name
BENGAL System

Indications for Use (Describe)
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 products 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 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)

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Indications for Use

510(k) Number (if known)
K173787

Device Name
CONCORDE Bullet Lumbar Interbody System,
COUGAR System

Indications for Use (Describe)
The CONCORDE Bullet and COUGAR 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). Additionally the CONCORDE Bullet and COUGAR Systems 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 either a PLIF or TLIF approach (CONCORDE Bullet) or an anterior approach (COUGAR) 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 CONCORDE Bullet and COUGAR 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 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)

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Indications for Use

510(k) Number (if known)
K173787

Device Name
CONCORDE System, CONCORDE Inline Lumbar Interbody System, CONCORDE Curve Lumbar Interbody System, DEVEX System, LEOPARD System

Indications for Use (Describe)
The CONCORDE, CONCORDE Inline, CONCORDE Curve, 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, CONCORDE Inline) or TLIF (CONCORDE, CONCORDE Inline, CONCORDE Curve, DEVEX, LEOPARD) approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with DePuy Spine supplemental internal fixation products.

The CONCORDE, CONCORDE Inline, CONCORDE Curve, 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 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)

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Indications for Use

510(k) Number (if known)
K173787

Device Name
COUGAR LS Lateral Cage System

Indications for Use (Describe)
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 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.

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)

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Indications for Use

510(k) Number (if known)
K173787

Device Name
DePuy PULSE Cervical Cage System

Indications for Use (Describe)
The DePuy PULSE Cervical Cage System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic neck 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. The DePuy PULSE Cervical Cage System implants are used to facilitate fusion in the cervical spine (C2-T1) and are placed via an anterior approach using autogenous bone. DePuy PULSE Cervical Cage System implants are intended to be used with supplemental internal fixation systems.

Type of Use (Select one or both, as applicable)
- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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DePuy PULSE Lumbar Cage System

Indications for Use

The DePuy PULSE Lumbar Cage 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 a PLIF or TLIF approach using autogenous bone. When used as intervertebral body fusion devices these implants are intended for use with DePuy Spine supplemental internal fixation products.
Indications for Use

510(k) Number (if known)
K173787

Device Name
Lumbar I/F Cage System

Indications for Use (Describe)
The Lumbar I/F Cage System is indicated for an open posterior approach using autogenous bone graft in patients with degenerative disc disease (DDD) at one or two spinal levels from L2-S1 whose condition requires the use of interbody fusion combined with posterolateral fusion (360° fusion) and posterior pedicle screw fixation. These patients may have had previous non-fusion spinal surgery at the involved spinal level(s).

Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies.

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)

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510(K) SUMMARY

A. Submitter Information

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

Submitter: DePuy Synthes Spine
325 Paramount Drive
Raynham, MA 02767

Contact Person: Sheree Geller
325 Paramount Drive
Raynham, MA 02767

Telephone: (508) 828-3291
Fax: (508) 828-3797
Email: sgeller1@its.jnj.com

B. Date Prepared

December 11, 2017

C. Device Name

Trade/Proprietary Names: X-MESH® Expandable Cage System
OCELOT® Stackable Cage System
Stackable Cage System
Surgical Titanium Mesh System
BENGAL Stackable Cage System
BENGAL System
CONCORDE® System
CONCORDE® Inline Lumbar Interbody System
CONCORDE® Curve Lumbar Interbody System
CONCORDE® Bullet Lumbar Interbody System
COUGAR® System
COUGAR® LS Lateral Cage System
DEVEX® System
LEOPARD® System
DePuy PULSE Cervical Cage System
DePuy PULSE Lumbar Cage System
LUMBAR I/F CAGE® System
**Common/Usual Names:**
Vertebral Body Replacement (VBR) devices
Intervertebral Body Fusion (IBF) devices

**Classification Names:**
21 CFR §888.3060 – Class II – MQP
Spinal intervertebral body fixation orthosis
21 CFR §888.3080 – Class II – MAX, ODP
Intervertebral body fusion device
21 CFR §878.3300 – Class II – EZX
Surgical mesh

**D. Predicate Device Names**

**Primary Predicate:**
X-MESH® Expandable Cage System (K080568)

**Additional Predicates:**
OCELOT® Stackable Cage System (K001340, K140759)
Stackable Cage System (K990148)
Surgical Titanium Mesh System
(K900138, K003043, K020522, K030249)
BENGAL Stackable Cage System (K073649, K140759)
BENGAL System (K081917, K103488)
CONCORDE® System (K081917)
CONCORDE® Inline Lumbar Interbody System
(K110694, K140759)
CONCORDE® Curve Lumbar Interbody System
(K101923)
CONCORDE® Bullet Lumbar Interbody System
(K103488, K140759, K151352, K151773)
COUGAR® System (K081917, K140759, K162327)
COUGAR® LS Lateral Cage System (K140759, K162327)
DEVEX® System (K081917, K140759)
LEOPARD® System (K031635, K081917, K140759)
DePuy PULSE Cervical Cage System (K120517)
DePuy PULSE Lumbar Cage System (K120966)
LUMBAR I/F CAGE® System (P960025)

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1 The devices subject to P960025 were reclassified from Class III (PMA) to Class II (510(k)) in September 2007
E. Submission Purpose

Obtain clearance for magnetic resonance compatibility labeling of the systems listed.

F. Device Descriptions

**X-MESH® Expandable Cage System**

The X-MESH Expandable Cage System is designed to restore biomechanical integrity throughout the thoracic and lumbar spine following vertebrectomy or corpectomy for patients with spine tumors or fractures. The system is available in many heights, and different endplate shapes, sizes and angles. The surgeons have the option to place the standard or angled endplates. The spikes on the endplates help anchor the device.

**OCELOT® Stackable Cage System**

The OCELOT Stackable Cage System consists of one or more stackable vertebral body replacement components and a supplemental internal fixation system. One or more OCELOT Stackable Cage System implants may be stacked to the desired height, as determined by the surgeon. A titanium alloy screw can be passed through a center hole in the cages and with a nut provide a rigid and compressed assembly.

**Stackable Cage System**

The Stackable Cage System is designed to restore biomechanical integrity throughout the thoracic and lumbar spine following vertebrectomy or corpectomy. A Stackable Cage construct consists of one or more cages that are stacked to the desired height, as determined by the surgeon. Ridges or teeth allow the cages to be assembled, and a locking screw and nut secure the components as a construct.

**Surgical Titanium Mesh System**

The Surgical Titanium Mesh System is designed to restore biomechanical integrity throughout the thoracic and lumbar spine following vertebrectomy or corpectomy for patients with spine tumors or fractures. The system consists of various shapes and sizes of mesh, standard or angled rings and screws, endplates, and endcaps. The surgeons have the option to place the standard or angled rings and screws, endplates and endcaps within the mesh. These interface devices may be used to provide increased surface area at the mesh/bone interface, which provides additional support and increased resistance to subsidence.

**BENGAL Stackable Cage System**

The BENGAL Stackable Cage System consists of both one piece (monolithic) and two- to three-piece (stackable) vertebral body replacement components and a supplemental internal fixation system that offer a variety of size options to allow surgeons to achieve a desired height. The two- or three-piece (stackable) construct can be assembled from a variety of different sized components. A titanium alloy screw is then passed through a hole in the cages and with a nut provides a rigid and compressed assembly.

**BENGAL System, CONCORDE® System, CONCORDE® Inline Lumbar Interbody System, CONCORDE® Curve Lumbar Interbody System, CONCORDE® Bullet**
Lumbar Interbody System, COUGAR® System, COUGAR® LS Lateral Cage System, DEVEX® System, LEOPARD® System

The BENGAL, CONCORDE, CONCORDE Bullet, CONCORDE Inline, CONCORDE Curve, COUGAR, DEVEX and LEOPARD Systems consist of polymer/carbon fiber composite or titanium cages and implantation instrumentation. 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.

DePuy PULSE Cervical Cage System

The DePuy PULSE Cervical Cage System is designed for use as a cervical intervertebral body fusion device and consists of polymer cages and implantation instrumentation. The cages are available in various geometries and sizes to accommodate patient anatomy. The polymer 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.

DePuy PULSE Lumbar Cage System

The DePuy PULSE Lumbar Cage System is designed for use as a lumbar intervertebral body fusion device and consists of polymer cages and implantation instrumentation. The cages are available in various geometries and sizes to accommodate patient anatomy. The polymer 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.

LUMBAR I/F CAGE® System

The LUMBAR I/F CAGE is made of a polymer/carbon fiber composite material, is radiolucent, and available is two designs: the Jaguar I/F Cage and the Saber I/F Cage. The Jaguar I/F Cage is a rectangular cage with ridged teeth to resist implant pullout. The Saber I/F Cage, also a rectangular cage, has a curved lateral wall and rounded edges with pyramidal teeth to resist implant pullout. Each of these designs has both parallel and wedged configurations.

G. Intended Use


The Vertebral Body Replacement (VBR) Spinal Systems are 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.

The VBR Spinal Systems are also indicated for treating fractures of the thoracic and lumbar spine.
The VBR Spinal 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.

The VBR Spinal Systems are intended for use with DePuy Spine supplemental internal fixation.

**BENGAL System**

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 products 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 products.

**CONCORDE® System, CONCORDE® Inline Lumbar Interbody System, CONCORDE® Curve Lumbar Interbody System, DEVEX® System, LEOPARD® System**

The CONCORDE, CONCORDE Inline, CONCORDE Curve, 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, CONCORDE Inline) or TLIF (CONCORDE, CONCORDE Inline, CONCORDE Curve, DEVEX, LEOPARD) approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with DePuy Spine supplemental internal fixation products.

The CONCORDE, CONCORDE Inline, CONCORDE Curve, 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 products.

**CONCORDE® Bullet Lumbar Interbody System, COUGAR® System**

The CONCORDE Bullet and COUGAR 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).

Additionally the CONCORDE Bullet and COUGAR Systems 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 either a PLIF or TLIF approach (CONCORDE Bullet) or an anterior approach (COUGAR) 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 CONCORDE Bullet and COUGAR 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 products.

**COUGAR® LS Lateral Cage System**

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 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.

**DePuy PULSE Cervical Cage System**

The DePuy PULSE Cervical Cage System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic neck 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. The DePuy PULSE Cervical Cage System implants are used to facilitate fusion in the cervical spine (C2-T1) and are placed via an anterior approach using autogenous bone. DePuy PULSE Cervical Cage System implants are intended to be used with supplemental internal fixation systems.

**DePuy PULSE Lumbar Cage System**

The DePuy PULSE Lumbar Cage 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 a PLIF or TLIF approach using autogenous bone. When used as intervertebral body fusion devices these implants are intended for use with DePuy Spine supplemental internal fixation products.

**LUMBAR I/F CAGE® System**

The Lumbar I/F Cage System is indicated for an open posterior approach using autogenous bone graft in patients with degenerative disc disease (DDD) at one or two spinal levels from L2-S1 whose condition requires the use of interbody fusion combined with posterolateral fusion (360° fusion) and posterior pedicle screw fixation. These patients may have had previous non-fusion spinal surgery at the involved spinal level(s). Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies.

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

The subject devices maintain the design characteristics of the predicate devices. Intended use remains consistent with the predicate devices. The subject devices are provided with additional labeling language regarding magnetic resonance (MR) compatibility.

**I. Materials**

The subject device materials remain identical to the predicate device materials, which consist of Poly-Ether-Ether-Ketone (PEEK), Carbon Fiber Reinforced PEEK, Tantalum X-ray Markers, implant grade Titanium alloy, and unalloyed Titanium.
J. Performance Data

Non-clinical testing was conducted in alignment with the following standards:

- ASTM F2213 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
- ASTM F2052 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

Results demonstrated compatibility conditions of the subject devices in the MR environment.

K. Conclusion

Evaluation of subject device intended use and technological characteristics demonstrates substantial equivalence with the predicate devices. Performance data supports the addition of magnetic resonance compatibility information to subject device labeling.