



Food and Drug Administration
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MEDOS International Srl
c/o Mr. Jeffrey Shiffman
Senior Regulatory Affairs Specialist
DePuy Spine, Incorporated
325 Paramount Drive
Raynham, Massachusetts 02767

October 8, 2015

Re: K151352
Trade/Device Name: CONCORDE Bullet Spinal System
Regulation Number: 21 CFR 800.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: September 9, 2015
Received: September 10, 2015

Dear Mr. Shiffman:

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" (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 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 yours,

Mark N. Melkerson -S

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)

K151352

Device Name

CONCORDE Bullet Spinal System

Indications for Use (Describe)

The CONCORDE Bullet Spinal 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 either a PLIF or TLIF 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 Bullet Spinal 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 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 the 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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510(K) SUMMARY

A. Submitter Information

Manufacturer: Medos International Sàrl
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2400 Le Locle, Switzerland

Submitter: DePuy Spine, Inc.
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Raynham, MA 02767

Contact Person: Jeffrey Shiffman
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Raynham, MA 02767

Telephone number: 508-977-3857

Fax number: 908-828-3797

Email: jshiffma@its.jnj.com

B. Date Prepared May 8, 2015

C. Device Name

Trade/Proprietary Name: CONCORDE Bullet Spinal System

Common/Usual Name: Intervertebral Body Fusion Device
Vertebral Body Replacement Device

Classification Name (Code): Intervertebral body fusion device
per 21 CFR § 888.3080 (MAX)
Spinal intervertebral body fixation orthosis
per 21 CFR § 888.3060 (MQP)

D. Predicate Device Name

Trade name: Bengal System, Bengal Stackable System, Devex System, Ocelot Stackable Cage System, Concorde (Bullet and Inline) Lumbar Interbody System, Cougar System, Cougar LS Lateral Cage System, Leopard System (K140759) – **Primary predicate**

DePuy Spine BENGAL, CONCORDE, COUGAR, DEVEX, and
LEOPARD Systems (K081917) – **Additional predicate**
DEVEX Mesh System (K023835) – **Additional predicate**

E. Device Description

The CONCORDE Bullet Spinal System is a system of intervertebral body fusion devices consisting of cages and implantation instrumentation. The cages feature a bulleted nose to aid in implant insertion. The proposed cages will offer a titanium alternative at certain geometries to the primary predicate system, which is currently only available in polymer/carbon fiber composite. The cages are available in varying shape and size configurations to match patient anatomy. The cages have ridges or teeth that resist rotation and migration and have cavities to accept packing of bone graft. The proposed cages will be implanted with the same instrumentation currently used in the system. The proposed cages will be offered sterile or non-sterile.

F. Intended Use

The CONCORDE Bullet Spinal 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 either a PLIF or TLIF 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 Bullet Spinal 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 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 the use with DePuy Spine supplemental internal fixation products.

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

The proposed additions to the CONCORDE Bullet Spinal System are equivalent to the predicate and reference devices within the system (reference K140759 and K081917), except for a change in the material. Currently, the CONCORDE Bullet Spinal System cages are available in polymer/carbon fiber composite. The proposed cages will be available in titanium alloy, the same material as used in the DEVEX System (K023835).

H. Materials

The proposed additions to the CONCORDE Bullet Spinal System cages will be manufactured from Ti-6Al-4V-Eli titanium alloy and conforms to the standard specifications for surgical implant applications defined in ASTM F136.

I. Performance Data

A summary of performance data per ASTM F-2077 is included to characterize the subject CONCORDE Bullet Spinal System cages addressed in this notification. Dynamic axial compression testing verified the mechanical strength of the proposed titanium implants. A finite element analysis also confirmed the axial compressive strength of the material compared to the predicate. No other testing was required because the only modification that would affect performance compared to predicate and reference devices within the CONCORDE Bullet Spinal System (K140759, K081917) is the material, which is used for the same indications in the predicate DEVEX System (K023835).

J. Conclusion

Both the Performance Testing and Substantial Equivalence Justification demonstrate that the proposed device is substantially equivalent to the predicate devices. Based on the 510(k) flowchart and the review of performance data, the proposed titanium cages in the CONCORDE Bullet Spinal System are substantially equivalent to the predicate devices. The technological characteristics between the proposed device and its predicates are substantially equivalent and the performance data raises no new questions of safety or effectiveness. Additionally, the proposed device does not constitute a new intended use.