



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

Medos International, Sàrl  
% Ms. Jaclyn Porsolt  
Regulatory Affairs Specialist  
DePuy Spine, a Johnson & Johnson Company  
325 Paramount Drive  
Raynham, Massachusetts 02767

November 20, 2015

Re: K151773

Trade/Device Name: CONCORDE® Bullet Lumbar Interbody System  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: MAX, MQP  
Dated: October 21, 2015  
Received: October 22, 2015

Dear Ms. Porsolt:

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 Parts 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)  
K151773

K151773  
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Device Name  
CONCORDE® Bullet Lumbar Interbody System

### Indications for Use (Describe)

The CONCORDE Bullet 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). Additionally, the CONCORDE Bullet 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 either a PLIF or TLIF 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 CONCORDE Bullet 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)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## 510(k) SUMMARY

### A. Submitter Information

**Manufacturer:** Medos International Srl  
Chemin-Blanc 38  
2400 Le Locle, Switzerland

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

**Contact Person:** Jaclyn Porsolt  
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Raynham, MA 02767  
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*Fax number:* (508) 828-3797  
*Email:* jporsol1@its.jnj.com

**B. Date Prepared** November 13, 2015

### C. Device Name

*Trade/Proprietary Name:* CONCORDE<sup>®</sup> Bullet Lumbar Interbody 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; Orthopedic

*Subsequent Regulation:* 21 CFR 888.3060

*Subsequent Classification Product and Panel Code:* MQP; Orthopedic

### D. Predicate Device Name

The subject device is substantially equivalent to the primary predicate device, CONCORDE Bullet Lumbar Interbody System (K140759), and additional predicate devices, Medtronic CAPSTONE<sup>®</sup> Spinal System (K123027) and Stryker Spine AVS<sup>®</sup> PL and AVS<sup>®</sup> UniLIF PEEK Spacers (K143163).

**E. Device Description**

The CONCORDE Bullet Lumbar Interbody System consists of polymer/carbon fiber composite cages. The 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 teeth that resist rotation and migration and have cavities to accept the packing of bone graft. The cages are offered in both sterile and non-sterile forms. The CONCORDE Bullet System is implanted using Class I manual surgical instruments that are considered exempt from premarket notification.

The purpose of this 510(k) submission is to modify the indications for use to include treatment of spinal deformities as an adjunct to fusion and the use of allogenic bone graft comprised of cancellous and/or corticocancellous bone graft as an alternative to autogenous bone graft.

**F. Indications for Use**

The CONCORDE Bullet 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). Additionally, the CONCORDE Bullet 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 either a PLIF or TLIF 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.

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

The technological characteristics of the subject CONCORDE Bullet Lumbar Interbody System 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. The devices are manufactured from Carbon Fiber Reinforced PEEK-OPTIMA LT1 Compound (CFRP). The tantalum x-ray markers 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 CONCORDE Bullet Lumbar Interbody 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 CONCORDE Bullet Lumbar Interbody System.

**J. Conclusion**

Based on the technological characteristics, comparison to predicate devices and clinical performance data, the subject CONCORDE Bullet Lumbar Interbody System is as safe and as effective as the predicate devices due to similar intended use and technological characteristics.