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

July 20, 2017

Medos International, SARL
% Ms. Desiree Saracino
Regulatory Affairs Specialist
DePuy Synthes
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K171425
Trade/Device Name: CONCORDE LIFT™
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: June 27, 2017
Received: June 30, 2017

Dear Ms. Saracino:

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)*
K171425

Device Name
CONCORDE LIFT™

Indications for Use *(Describe)*
The CONCORDE LIFT Expandable Interbody Device is a lumbar intervertebral body fusion device, and is indicated for use with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbar spine, L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The CONCORDE LIFT Expandable Interbody Device can be implanted via posterior, transforaminal or lateral approach.

DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Candidates for surgery should be skeletally mature and have had a six-month course of conservative treatment. These patients may have had primary or secondary surgery, but no previous fusion at the involved levels.

The device is not intended to be used as a stand-alone device. It must be used with supplemental internal spinal fixation systems that have been cleared for use in the lumbar spine.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

A. Submitter Information

510(k) Sponsor: Medos International, SARL

Contact Person:
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DePuy Synthes
325 Paramount Drive
Raynham, MA 02767
Telephone number: (508) 977-3842
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B. Date Prepared

July 18, 2017

C. Device Name

Trade/Proprietary Name: CONCORDE LIFT™

Common/Usual Name: Intervertebral Body Fusion Device

Device Classification and Regulation: Class II per 21 CFR § 888.3080

Classification Product and Panel Code: MAX; Orthopedic

D. Predicate Device Name

Primary: K160464: Opticage™ Expandable Interbody Fusion Device

Additional: K152156: Opticage™ Expandable Interbody Fusion Device
K113527: Opticage™ Expandable Interbody Fusion Device
K162879: Elite™ Expandable Interbody Fusion Device (Spineology Inc.)

E. Device Description

The CONCORDE LIFT Expandable Interbody Devices are provided gamma sterilized and are for single use only. The devices are designed for lumbar intervertebral body fusion via posterior, transforaminal or lateral approach. They are fabricated from titanium alloy (Ti-6Al-4V) as per ASTM F136. A cavity internal to each device is intended to hold autogenous bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The CONCORDE LIFT is available in both a convex configuration and a lordotic configuration.

The purpose of this submission is to add MR Conditional labeling, expanded indications and to document minor design modifications.

F. Indications for Use

The CONCORDE LIFT Expandable Interbody Device is a lumbar intervertebral body fusion device, and is indicated for use with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbar spine, L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The CONCORDE LIFT Expandable Interbody Device can be implanted via posterior, transforaminal or lateral approach.

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

The technological characteristics, including material, design and performance of the CONCORDE LIFT Expandable Interbody Fusion Device are consistent with those of the predicate devices.

H. Materials

The CONCORDE LIFT Expandable Interbody Device is manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F136.

I. Performance Data

The CONCORDE LIFT Expandable Interbody Device was tested in accordance with the standards listed below.

ASTM F2052-15 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

ASTM F2119-07 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

ASTM F2182-11a Standard Test Method for Measurement of Radio Frequency Induced Heating on or Near Passive Implants During Magnetic Resonance Imaging

ASTM F2213-06 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

ANSI/AAMI ST72 Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing

J. Conclusion

Based on the indications for use, technological characteristics, and comparison to the predicate devices, the CONCORDE LIFT Expandable Interbody Device is substantially equivalent to the legally marketed predicate devices.