April 3, 2019

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

Re: K182349
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: February 26, 2019
Received: February 27, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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,

Melissa Hall -S

for
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182349

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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medos international

510(k) Summary

A. Submitter Information

510(k) Sponsor: Medos International, SARL

Contact Person: Desiree Saracino
DePuy Synthes
325 Paramount Drive
Raynham, MA 02767

Telephone number: (508) 977-3842
Fax number: (508) 828-3797
Email: Dsaracin@its.jnj.com

B. Date Prepared

October 17, 2018

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 Predicate: K171425: CONCORDE LIFT™ Expandable Interbody Fusion Device
Additional Predicate: K173537: CONCORDE LIFT Inserter

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. They are fabricated from titanium alloy (Ti-6Al-4V) 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 device is available in both a convex configuration and a lordotic configuration.

The purpose of this submission is to seek clearance for the CONCORDE LIFT devices with lower starting heights.

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 CONCORDE LIFT are consistent with those of the predicate device.

H. Materials

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

I. Performance Data

ASTM F2077-17 Test Methods for Intervertebral Body Fusion Devices

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 F2213-17 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 device, the subject CONCORDE LIFT is substantially equivalent to the legally marketed predicate device.