



February 8, 2018

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

Re: K173537
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: November 13, 2017
Received: November 16, 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.

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.

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,

Vincent J. Devlin -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)

K173537

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.

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510(k) Summary

A. Submitter Information

510(k) Sponsor: Medos International, SARL

Contact Person: Desiree Saracino
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Telephone number: (508) 977-3842
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B. Date Prepared November 13, 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: K171425: CONCORDE LIFT™ Expandable Interbody Fusion Device

E. Device Description

The CONCORDE LIFT Inserter is temporarily attached to the CONCORDE LIFT Expandable Interbody Fusion Device for implantation. A component of the CONCORDE

LIFT Inserter, the driver, is then used to increase or decrease the height of the CONCORDE LIFT Expandable Interbody Fusion Device. The CONCORDE LIFT Inserter is intended to be used in conjunction with all sizes of the CONCORDE LIFT Expandable Interbody Device. The Inserter is fabricated from 17-4 PH Stainless Steel and 465 Stainless Steel that meets the requirements of ASTM F899. The inserter is provided non-sterile and is reusable.

The purpose of this submission is to capture the modifications made to the CONCORDE LIFT Expandable Interbody System Inserter.

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.

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.

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 Inserter are consistent with those of the predicate devices.

H. Materials

The CONCORDE LIFT Inserter is manufactured from 17-4 PH Stainless Steel, and 465 Stainless Steel that meets the requirements of ASTM F899.

I. Performance Data

The minor modification to the design of the device and material change do not change the technological characteristics of the device. The design modification is supported by the results of feasibility testing.

J. Conclusion

Based on the indications for use, technological characteristics, and comparison to the predicate device, the CONCORDE LIFT Inserter is substantially equivalent to the legally marketed predicate device.

