August 25, 2022

Medos International, SARL
% LiJuan He
Associate Director, Regulatory Affairs
DePuy Spine
325 Paramount Dr.
Raynham, Massachusetts 02767

Re: K221325
Trade/Device Name: CONDUIT™ Lateral Switch Plate
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD
Dated: July 27, 2022
Received: July 28, 2022

Dear LiJuan He:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221325

Device Name
CONDUIT™ Lateral Switch Plate

Indications for Use *(Describe)*
When used with or without the CONDUIT™ Lateral Switch Plate, the EIT Cellular Titanium® LLIF Cage is indicated for use with supplemental spinal fixation systems cleared by the FDA for use in the lumbar spine.

The EIT Cellular Titanium® LLIF Cage with a microscopic roughened surface and micro and nano-scale features is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft. EIT Spine LLIF is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Type of Use *(Select one or both, as applicable)*

[X] 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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DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

510(K) SUMMARY

A. Submitter Information

Manufacturer:	Medos International SARL Chemin-Blanc 38 2400 Le Locle, Switzerland
Submitter:	DePuy Synthes Spine 325 Paramount Drive Raynham, MA 02767
Contact Person: *Telephone:* *Email:*	LiJuan He 978-406-7629 lhe10@its.jnj.com

B. Date Prepared August 19, 2022

C. Device Name

Trade/Proprietary Name:	CONDUIT™ Lateral Switch Plate
Device Classification and Regulation:	Class II per 21 CFR §888.3080
Product Codes:	MAX, OVD

D. Predicate Device Names

Primary Predicate:	Nuvasive Modulus XLIF (K192760)
Additional Predicate:	EIT Cellular Titanium® Lumbar Cage LLIF (K181644); EIT Cellular Titanium® Cervical Cage (K201605)

E. Device Description Summary

The CONDUIT™ Lateral Switch Plate ("Plate") is an optional device that connects to the EIT Cellular Titanium® LLIF Cage ("Cage") and adjacent vertebral body(s) to provide additional migration resistance and stability via DePuy Synthes AEGIS Screws ("Screws"). The subject device is not considered to be supplemental fixation. Both the Plate and Screws are manufactured from ASTM F136 titanium alloy (Ti-6Al-4V ELI). The Plate is supplied sterile in one- and two-hole configurations in a variety of sizes to attach to one or both adjacent vertebral bodies.

DePuy Synthes
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F. Indented Use/Indications for Use

When used with or without the CONDUIT™ Lateral Switch Plate, the EIT Cellular Titanium® LLIF Cage is indicated for use with supplemental spinal fixation systems cleared by the FDA for use in the lumbar spine.

The EIT Cellular Titanium® LLIF Cage with a microscopic roughened surface and micro and nano-scale features is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These spinal implants are to be used with autogenous bone graft and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft. EIT Spine LLIF is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

G. Indications for Use Comparison

The subject device (Plate) with the EIT Cellular Titanium® Lumbar LLIF Cage and screws comprise an implant system which has indications for use similar to those of the predicate devices**.**

F. Non-Clinical Test Summary and Conclusions

1. Mechanical Testing

The following tests and analyses were performed on the subject device system to demonstrate that the CONDUIT™ Lateral Switch Plate is substantially equivalent to other predicate devices:

- Dynamic Axial Compression (ASTM F2077-18)
- Dynamic Compression Shear (ASTM F2077-18)
- Static Axial Compression analysis (ASTM F2077-18)
- Static Compression Shear analysis (ASTM F2077-18)
- Subsidence analysis (ASTM F2267-04)
- Expulsion analysis

2. The subject devices were evaluated and tested in accordance with ISO 10993-1:2018, Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process. The results demonstrate the subject devices comply with the applicable requirements of ISO 10993-1:2018
3. MRI Safety Testing per ASTM F2052-15, ASTM F2182-17, ASTM F2119-07 and ASTM F2182-19e2

The subject device is substantially equivalent to legally marketed predicate devices with respect to indications for use, design, function, material composition, and performance testing per testing standards.