March 8, 2023

Medos International SÀRL
Mr. Delano Martins
Senior Regulatory Affairs Specialist
Chemin-Blanc 38
Le Locle 2400 Switzerland

Re: K223688
Trade/Device Name: CONDUIT™ Lateral Lumbar Intervertebral Fusion Cage; CONDUIT™ Instruments
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: December 8, 2023
Received: December 9, 2023

Dear Mr. Martins:

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 -S

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)*
K223688

Device Name
CONDUIT™ Lateral Lumbar Intervertebral Fusion Cage;
CONDUIT™ Instruments

Indications for Use *(Describe)*
The CONDUIT™ LLIF Cages 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, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. CONDUIT™ LLIF Cage is to be used with supplemental fixation. The CONDUIT™ LLIF Cages (>20 degrees) must be used with CONDUIT™ Lateral Switch Plate and supplemental fixation. When used with or without the CONDUIT™ Lateral Switch Plate, the system is indicated for use with supplemental spinal fixation systems cleared by the FDA for use in the lumbar spine. 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)*

☒ 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 - K223688

A. Submitter Information

Manufacturer:	Medos International SÀRL Chemin-Blanc 38 Le Locle 2400 Switzerland
Submitter:	DePuy Synthes Spine 325 Paramount Drive Raynham, MA 02767
Contact Person:	Mr. Delano Martins
Telephone	+1 (904) 699-5797
E-Mail	dmart152@its.jnj.com

B. Date Prepared February 17, 2023

C. Device Name

Trade/Proprietary Name:	CONDUIT™ Lateral Lumbar Intervertebral Fusion Cage; CONDUIT™ Instruments
Device Classification and Regulation:	Class II per 21 CFR §888.3080
Product Codes:	MAX

D. Predicate Device Names

Primary Predicate:	CONDUIT™ Cages and FIBERGRAFT™ BG Putty (K222276)
Additional Predicate:	EIT Cellular Titanium® LLIF Cage (K201605); EIT Cellular Titanium® Lumbar Cage LLIF (K181644); NuVasive Brigade System, Brigade Lateral System (K203714); SYNFIX Evolution System (K162358); CONDUIT Lateral Switch Plate (K221325); CONDUIT Instruments (K210728)

E. Device Description Summary

The purpose of this Traditional 510(k) is to seek marketing clearance for 22-degree and 30-degree lordosis angled CONDUIT™ Lateral Lumbar Intervertebral Fusion (LLIF) Cages in the CONDUIT™ line of lumbar interbody cages with additional cage height of 14 to 18 mm. The CONDUIT™ line of lumbar interbody cages includes lordosis angles of 0, 8, and 16 degrees.

The CONDUIT™ LLIF Cage is used to restore intervertebral height and to facilitate intervertebral body fusion in the spine using an LLIF (Lateral Lumbar Intervertebral Fusion) approach with cancellous bone graft and/or corticocancellous bone graft materials, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. The CONDUIT™ LLIF Cage is intended to be used from L2-S1 in patients with DDD and up to Grade I spondylolisthesis or retrolisthesis at one or two contiguous levels. The device is intended to be used alongside supplemental spinal fixation, either applied anteriorly or posteriorly (e.g., using posterior pedicle screws). The CONDUIT™ Lateral Switch Plate is an optional device that connects to the CONDUIT™ LLIF Cage and adjacent vertebral body(s) to provide additional migration resistance and stability via DePuy Synthes AEGIS Screws. When used with or without the CONDUIT™ Lateral Switch Plate, the system is indicated for use with supplemental spinal fixation systems cleared by the FDA for use in the lumbar spine.

The CONDUIT™ LLIF Cage is made from Ti-6Al-4V alloy (ISO 5832-3) by an additive manufacturing process. The design contains solid structures and porous structures. The hollow geometry of the implants allows the cage to be packed with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion.

F. Indented Use/Indications for Use

The CONDUIT™ 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, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion. CONDUIT™ LLIF Cage is to be used with supplemental fixation. The CONDUIT™ LLIF Cages (>20 degrees) must be used with CONDUIT™ Lateral Switch Plate and supplemental fixation. When used with or without the CONDUIT™ Lateral Switch Plate, the system is indicated for use with supplemental spinal fixation systems cleared by the FDA for use in the lumbar spine. 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 comprise an implant system which has indications for use similar to those of the predicate devices.

F. Non-Clinical Test Summary and Conclusions

The following tests and analyses were performed on the subject device system to demonstrate that the additional angles of the CONDUIT™ LLIF Cage are 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 (ASTM F2077-18)

Expulsion analysis (ASTMF1839-08) and Subsidence analysis (ASTM F2267-04) were evaluated to demonstrate substantial equivalence.

The additional angled CONDUIT™ LLIF Cages with CONDUIT™ Lateral Switch Plate Construct testing was evaluated and due to the high level of confidence in previous dynamic testing as well as the addition of a Switch Plate resulting in a non-worst-case condition in all Static type tests (ASTM F2077, ASTM F2267 and F1839) was evaluated to demonstrate substantial equivalence.

MRI Safety Testing per ASTM F2052-15, ASTM F2182-17, ASTM F2119-07 and ASTM F2182-19e2 was evaluated to demonstrate substantial equivalence.

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.