May 6, 2021

Medos International, SARL
% Ms. Christine Cahillane
Regulatory Affairs Specialist
DePuy Spine
325 Paramount Dr.
Raynham, Massachusetts 02767

Re: K210728
Trade/Device Name: CONDUIT™ Instruments
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: March 9, 2021
Received: March 11, 2021

Dear Ms. Cahillane:

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,

for
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)*
K210728

Device Name
CONDUIT™ Instruments

Indications for Use *(Describe)*
The CONDUIT™ Instruments are intended to be used with the EIT Cellular Titanium® Cages:

EIT Cellular Titanium® Cervical Cage
The EIT Cellular Titanium® Cervical Cages with a microscopic roughened surface and micro and nano-scale features are intervertebral body fusion devices intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The EIT Cellular Titanium Cervical Cages are also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. EIT Cellular Titanium Cervical Cages are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft to facilitate fusion.

EIT Cellular Titanium® ALIF Cage
The EIT Cellular Titanium® ALIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

EIT Cellular Titanium® TLIF Cage
The EIT Cellular Titanium® TLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

EIT Cellular Titanium® LLIF Cage
The EIT Cellular Titanium® LLIF Cages with a microscopic roughened surface and micro and nano-scale features are 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.

EIT Cellular Titanium® T/PLIF Cage
The EIT Cellular Titanium® T/PLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody

fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

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

Manufacturer: Medos International, SARL
Chemin-Blanc 38
2400 Le Locle, Switzerland

Contact: Christine Cahillane
DePuy Synthes
325 Paramount Drive
Raynham, MA 02767

Telephone Number: 508-828-3064
Email Address: ccahilla@its.jnj.com

A. Date Prepared April 5, 2021

B. Device Name

Trade/Proprietary Name: CONDUIT™ Instruments

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

Classification Product and Panel Codes: ODP - Intervertebral Fusion Device with Bone Graft, Cervical

MAX - Intervertebral Fusion Device with Bone Graft, Lumbar

C. Predicate Device Names

Primary Predicate: EIT Cellular Titanium® Interbody Cages (K201605)

D. Device Description

The CONDUIT™ Instruments are non-sterile, reusable instruments that may be used during placement of various EIT Cellular Titanium® Interbody Cages during spinal surgery. The CONDUIT™ Instruments are made from materials commonly used in orthopedic and neurological procedures which meet available national or international standards specifications. The purpose of this submission is to introduce a new set of instruments to be used with the EIT Cellular Titanium® Cervical and Lumbar Cages and there are no changes to the implant devices.

E. Indications for Use

The CONDUIT™ Instruments are intended to be used with the EIT Cellular Titanium® Cages:

EIT Cellular Titanium® Cervical Cage
The EIT Cellular Titanium® Cervical Cages with a microscopic roughened surface and micro and nano-scale features are intervertebral body fusion devices intended for use for anterior

cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The EIT Cellular Titanium Cervical Cages are also to be used with supplemental fixation systems that have been cleared for use in the cervical spine. EIT Cellular Titanium Cervical Cages are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft to facilitate fusion.

EIT Cellular Titanium® ALIF Cage

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EIT Cellular Titanium® TLIF Cage

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EIT Cellular Titanium® LLIF Cage

The EIT Cellular Titanium® 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. 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.

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The EIT Cellular Titanium® T/PLIF Cages with a microscopic roughened surface and micro and nano-scale features in combination with supplemental fixation are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative

disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of nonoperative treatment prior to treatment with the devices.

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

The intended use, technological characteristics, and performance including material, design and performance of the CONDUIT Instruments are consistent with those of the predicate devices.

G. Materials

The CONDUIT Instruments are constructed from Stainless Steel and Radel in conformance with ASTM standards: F899, A276, A693, A564/A564M, and D6934.

H. Performance Testing Summary

Non-clinical testing was conducted in accordance with Design Controls and Risk Management to confirm device performance for its intended use. The results demonstrate that the device performs as well as the predicate devices for the compared design inputs.

I. Conclusion

The indications for use and intended use of the subject device are consistent with those of the predicate devices. Comparison of technological characteristics and results of performance testing demonstrate that the modifications to the design do not introduce any new questions of safety or effectiveness and, are therefore, substantially equivalent to the predicate devices.