October 4, 2018

Medos International SARL
% Ms. Sheree Geller
Regulatory Affairs Specialist
DePuy Synthes Spine
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K181949
Trade/Device Name: SYMPHONY™ OCT System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: September 14, 2018
Received: September 17, 2018

Dear Ms. Geller:

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,

Ronald P. Jean -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)*
K181949

Device Name
SYMPHONY™ OCT System

Indications for Use *(Describe)*
The SYMPHONY OCT System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the upper thoracic spine (T1-T3):
• Traumatic spinal fractures and/or traumatic dislocations;
• Instability or deformity;
• Failed previous fusions (e.g. pseudarthrosis);
• Tumors involving the cervical/thoracic spine;
• Degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and
• Degenerative disease of the facets with instability.

The SYMPHONY OCT System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

The SYMPHONY OCT System is compatible with occipital fusion components (plates, rods and clamps) from the SYNAPSE Occipital-Cervical-Thoracic (OCT) System and the MOUNTAINEER OCT Spinal System. Additionally, the SYMPHONY OCT System is compatible with SYNAPSE OCT System hooks and rods.

The SONGER Wire/Cable System may be used with the SYMPHONY OCT System to allow for wire/cable attachment to the posterior cervical spine.

The SYMPHONY OCT System may be connected to the EXPEDIUM® Spine System and VIPER® System using connectors and tapered rods. The SYMPHONY OCT System can also be linked to the USS Spinal System and MATRIX Spine System using connectors and tapered rods.

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

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

Submitter: DePuy Synthes Spine
325 Paramount Drive
Raynham, MA 02767

Contact Person: Sheree Geller
325 Paramount Drive
Raynham, MA 02767
Telephone: (508) 828-3291
Fax: (508) 828-3797
Email: sgeller1@its.jnj.com

B. Date Prepared September 13, 2018

C. Device Name

Trade/Proprietary Name: SYMPHONY™ OCT System

Common/Usual Name: Orthosis, Cervical Pedicle Screw Spinal Fixation

Regulatory Class: Unclassified, Pre-Amendment

Review Panel: Orthopedic

Product Codes: NKG – Unclassified – Pre-Amendment Orthosis, Cervical Pedicle Screw Spinal Fixation

KWP – Class II – 21 CFR §888.3050
Appliance, Fixation, Spinal Interlaminal

D. Predicate Device Names

Primary Predicate: SYNAPSE OCT System (K142838)

Additional Predicate: MOUNTAINEER® OCT Spinal System (K151885)

E. Device Description

The SYMPHONY OCT System is a posterior spinal fixation system intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion of the craniocervical junction, the cervical spine (C1 to C7) and the upper thoracic spine (T1-T3). The system is composed of multiple components to allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. The system consists of bone anchors (such as screws) for connection by longitudinal components (such as rods) via an interconnection mechanism (e.g., set screws) with optional transverse connectors (e.g., cross connectors) to link the longitudinal components for additional stability.

F. Intended Use

The SYMPHONY OCT System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the upper thoracic spine (T1-T3):

- Traumatic spinal fractures and/or traumatic dislocations;
- Instability or deformity;
- Failed previous fusions (e.g. pseudarthrosis);
- Tumors involving the cervical/thoracic spine;
- Degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and
- Degenerative disease of the facets with instability.

The SYMPHONY OCT System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

The SYMPHONY OCT System is compatible with occipital fusion components (plates, rods and clamps) from the SYNAPSE Occipital-Cervical-Thoracic (OCT) System and the MOUNTAINEER OCT Spinal System. Additionally, the SYMPHONY OCT System is compatible with SYNAPSE OCT System hooks and rods.

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The SYMPHONY OCT System may be connected to the EXPEDIUM® Spine System and VIPER® System using connectors and tapered rods. The SYMPHONY OCT System can also be linked to the USS Spinal System and MATRIX Spine System using connectors and tapered rods.

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

The intended use, technological characteristics, and performance of the SYMPHONY OCT System are consistent with those of the predicate devices.

H. Materials

The SYMPHONY OCT System implant components are comprised of Titanium alloy conforming to ASTM F136, Cobalt-Chromium-Molybdenum alloy conforming to ASTM F1537, and Nitinol conforming to ASTM F2063.

I. Performance Data

Non-clinical testing was conducted in alignment with the following standards:

- ASTM F1717 *Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*
- ASTM F2706 *Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model*

The following performance tests were completed in a comparative manner, supporting substantial equivalence:

- Static Torsion
- Dynamic Torsion
- Static Compression
- Dynamic Compression

The *Limulus* amoebocyte lysate (LAL) test was conducted to assess pyrogenicity in alignment with FDA Guidance Document *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile* issued January 21, 2016 (amended March 16, 2016).

J. Conclusion

Evaluation of the subject device intended use, technological characteristics, and performance data demonstrates substantial equivalence with the predicate devices.