



January 24, 2020

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

Re: K192014

Trade/Device Name: SYPMHONY™ OCT System  
Regulation Number: 21 CFR 888.3075  
Regulation Name: Posterior Cervical Screw System  
Regulatory Class: Class II  
Product Code: NKG, KWP  
Dated: December 13, 2019  
Received: December 16, 2019

Dear Sheree 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/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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Ronald P. Jean, Ph.D.  
Director (Acting)  
DHT6B: Division of Spinal Devices  
OHT6: Office of Orthopedic Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K192014

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** July 25, 2019

### C. Device Name

*Trade/Proprietary Name:* SYMPHONY™ OCT System

*Common/Usual Name:* Posterior Cervical Screw System

*Regulatory Class:* II

*Review Panel:* Orthopedic

*Product Codes:* NKG – Class II – 21 CFR §888.3075  
Posterior Cervical Screw System

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

### D. Predicate Device Names

*Primary Predicate:* SYMPHONY OCT System (K181949, K190895)

## **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
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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<sup>®</sup> Spine System and VIPER<sup>®</sup> 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 fundamental scientific technology of the subject devices remains unchanged from the predicate devices. This submission presents a sterile tube packaging configuration for polyaxial screw components of the SYMPHONY OCT System. The intended use, technological characteristics, and performance of the SYMPHONY OCT System are equivalent with those of the predicate devices.

**H. Materials**

The SYMPHONY OCT System subject device polyaxial screw components are comprised of Titanium alloy conforming to ASTM F136. The Rod-to-Rod Cross Connectors are comprised of both Titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136 and Nitinol conforming to ASTM F2063.

**I. Performance Data**

Performance data remains unchanged for the subject devices as compared to the predicate devices. Risk analysis was completed for the addition of a sterile tube packaging configuration.

**J. Conclusion**

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