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

November 9, 2023

Re: K233366
Trade/Device Name: SYMPHONY OCT System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: September 29, 2023
Received: October 2, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2023.11.09 14:14:17 -05'00'

for

Colin O'Neill, M.B.E.
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)*
K233366

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Prepared on: 2023-09-30

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Medos International SARL
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Applicant Contact Telephone	508-828-3291
Applicant Contact	Ms. Sheree Geller
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Correspondent Contact Telephone	508-828-3291
Correspondent Contact	Ms. Sheree Geller
Correspondent Contact Email	sgeller1@its.jnj.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	SYMPHONY OCT System
Common Name	Posterior cervical screw system
Classification Name	Posterior Cervical Screw System
Regulation Number	888.3075
Product Code	NKG

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K192646	SYMPHONY OCT System	NKG
K203319	SYMPHONY OCT System	NKG

Device Description Summary

21 CFR 807.92(a)(4)

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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are identical for the subject and predicate devices.

Technological Comparison

21 CFR 807.92(a)(6)

The sole change presented is a labeling change to allow for reprocessing of the sterile implants once they are removed from sterile packaging and rendered non-sterile prior to use on a patient. The SYMPHONY OCT System implants remain single use implants identical to the predicate. There is no change to the design of the subject devices including the dimensions, materials, principle of operation, packaging, biocompatibility, or MR Compatibility from the predicate devices. When in sterile packaging, the subject devices are identical to the sterile versions of the predicate. Once removed from sterile packaging but prior to use, the subject devices are identical to the non-sterile versions of the predicate and follow the same cleaning and reprocessing instructions contained in the Instructions for Use as the predicate non-sterile devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

No additional testing was conducted to support this submission. Evaluation of the subject device intended use, technological characteristics, and performance data demonstrates substantial equivalence with the predicate devices.