Medos International, SARL
% Daria Bochenek
Senior Regulatory Affairs Specialist
DePuy Synthes Spine
Eimattstrasse 3
Oberdorf, 4436 CH

October 18, 2019

Re: K191943
Trade/Device Name: SYMPHONY Navigation Ready Instruments, Universal Navigation Adaptor Set
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: July 19, 2019
Received: July 22, 2019

Dear Daria Bochenek:

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, Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191943

Device Name
SYMPHONY™ Navigation Ready Instruments and Universal Navigation Adaptor Set

Indications for Use *(Describe)*

SYMPHONY Navigation Ready Instruments:
The SYMPHONY Navigation Ready Instruments when used with the compatible Universal Navigation Adaptor Set are intended to assist the surgeon in locating anatomical structures in either open or percutaneous procedures. These are indicated for use in surgical spinal procedures, in which:
• the use of SYMPHONY OCT System is indicated,
• the use of stereotactic surgery may be appropriate, and
• reference to a rigid anatomical structure, such as a vertebrae can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy using a navigation system which includes tracking arrays supplied by the navigation system manufacturer.
These procedures include but are not limited to spinal fusion. The SYMPHONY Navigation Ready Instruments require manual calibration with the Medtronic StealthStation navigation system.
The SYMPHONY Navigation Ready Instruments are intended to support cervical and thoracic polyaxial screw placement.

Universal Navigation Adaptor Set:
The Universal Navigation Adaptor Set (UNAS) is intended for use with the compatible DePuy Synthes Navigation Ready Instruments to assist the surgeon in locating anatomical structures in either open or percutaneous procedures. These are indicated for use in surgical spinal procedures, in which:
• the use of stereotactic surgery may be appropriate, and
• reference to a rigid anatomical structure, such as the pelvis or a vertebrae can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy using a navigation system which includes tracking arrays supplied by the navigation system manufacturer.
These procedures include but are not limited to spinal fusion. The DePuy Synthes Navigation Ready Instrument, when used with UNAS, requires manual calibration with the Medtronic StealthStation navigation system.

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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K191943 510(k)Summary

A. Submitter Information

510(k) Sponsor: Medos International, SARL

Contact Person: Daria Bochenek, Senior Regulatory Affairs Specialist
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4436 Oberdorf
Switzerland

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B. Date Prepared

July 19, 2019

C. Device Name

Trade/Proprietary Name: SYMPHONY™ Navigation Ready Instruments and Universal Navigation Adaptor Set

Common/Usual Name: Orthopedic stereotaxic instrument

Device Classification and Regulation: Class II per 21 CFR § 882.4560

Classification Product and Panel Code: OLO; Orthopedic

D. Predicate Device Names

Primary Predicate Device:

Synthes Navigable Pedicle Preparation (NPP) Instruments (K122211)

Reference Device:

Medtronic StealthStation® System (K133444)

E. Device Description

SYMPHONY Navigation Ready Instruments:

The SYMPHONY Navigation Ready Instruments are reusable instruments used for the preparation for and insertion of SYMPHONY OCT screws, in either open or percutaneous procedures. These instruments are designed for navigated and non-navigated use. Navigation of these instruments is achieved using the DePuy Synthes Universal Navigation Adaptor Set (UNAS). For further details on UNAS, refer to the UNAS labeling.

Universal Navigation Adaptor Set:

The Universal Navigation Adaptor Set contains the Navigation Ring ST used to aid in determining the correct location and trajectory of spinal instruments and implants. The Navigation Ring ST has an interface between the Medtronic StealthStation® navigation system and the DePuy Synthes Navigation Ready Instruments.

The Navigation Ready Instruments include drill guides, drills, trocar, probe, taps and screwdriver. When the Navigation Ring ST is attached to the Navigation Ready Instrument, a Medtronic SureTrak® II Universal Tracker Passive Fighter array (SureTrak II array) can be attached, and the instrument can be manually calibrated with the Medtronic StealthStation navigation system.

F. Indications for Use

SYMPHONY Navigation Ready Instruments:

The SYMPHONY Navigation Ready Instruments when used with the compatible Universal Navigation Adaptor Set are intended to assist the surgeon in locating anatomical structures in either open or percutaneous procedures. These are indicated for use in surgical spinal procedures, in which:

- the use of SYMPHONY OCT System is indicated,
- the use of stereotactic surgery may be appropriate, and
- reference to a rigid anatomical structure, such as a vertebrae can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy using a navigation system which includes tracking arrays supplied by the navigation system manufacturer.

These procedures include but are not limited to spinal fusion. The SYMPHONY Navigation Ready Instruments require manual calibration with the Medtronic StealthStation navigation system.

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Universal Navigation Adaptor Set:

The Universal Navigation Adaptor Set (UNAS) is intended for use with the compatible DePuy Synthes Navigation Ready Instruments to assist the surgeon in locating anatomical structures in either open or percutaneous procedures. These are indicated for use in surgical spinal procedures, in which:

- the use of stereotactic surgery may be appropriate, and
- reference to a rigid anatomical structure, such as the pelvis or a vertebrae can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy using a navigation system which includes tracking arrays supplied by the navigation system manufacturer.

These procedures include but are not limited to spinal fusion. The DePuy Synthes Navigation Ready Instrument, when used with UNAS, requires manual calibration with the Medtronic StealthStation navigation system.

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

The technological characteristics, including material, design and performance as well as intended use of the SYMPHONY Navigation Ready Instruments and Universal Navigation Adaptor Set are consistent with those of the predicate device.

H. Materials

The subject devices are manufactured from stainless steel, anodized aluminum and silicone rubber.

I. Performance Data

The performance data for the subject devices consists of the following evaluations:

- Accuracy Verification:
    - Toggle Analysis (positional and angular deviation)
    - Length Comparison to Reference Device

- Implant/instrument mating conditions
- Simulated Use Evaluation. SYMPHONY Navigation Ready Instruments were assembled with UNAS and with the Medtronic tracking arrays, manually calibrated and navigated. As a result, holes in pedicles and lateral masses of cervical and thoracic spine were prepared and SYMPHONY screws were inserted in a sawbones model. Final screw position in the software was compared with post-operative scan and sawbones model.

J. Conclusion

The indications for use of the SYMPHONY Navigation Ready Instruments and Universal Navigation Adaptor Set are consistent with those of the predicate devices. The technological characteristics of the SYMPHONY Navigation Ready Instruments and Universal Navigation Adaptor Set in terms of design, materials and performance are consistent with those of the predicate device. The SYMPHONY Navigation Ready Instruments and Universal Navigation Adaptor Set are substantially equivalent to the predicate device.