March 27, 2026

Medos International SARL
℅ Sophia Chang
Regulatory Affairs Specialist
DePuy Synthes
325 Paramount Dr.
Raynham, MA 02767

Re: K260240
Trade/Device Name: SYMPHONY Navigation Ready Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: January 26, 2026
Received: January 26, 2026

Dear Sophia Chang:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Shumaya Ali -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260240

Device Name
SYMPHONY Navigation Ready Instruments

Indications for Use *(Describe)*
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 and associated tracking arrays.
These procedures include but are not limited to spinal fusion. The SYMPHONY Navigation Ready Instruments can be:
• pre-calibrated with the VELYS™ SPINE Navigation using the VELYS™ SPINE Instrument Arrays,
• pre-calibrated and/or manually calibrated with the Brainlab Navigation System using the UNAS Navigation Arrays,
• manually calibrated with other navigation systems, using tracking arrays supplied by the navigation system manufacturer.
The SYMPHONY Navigation Ready Instruments are intended to support indicated cervical and thoracic polyaxial screw placement.

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.

510(k) SUMMARY

A. Submitter Information

510(k) Sponsor: Medos International SARL

Contact Person: Sophia Chang
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USA

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B. Date Prepared 27 March 2026

C. Device

Trade/Proprietary Name: SYMPHONY ™ Navigation Ready Instruments

Common/Usual Name: Orthopedic Stereotaxic Instrument

Classification Name: Stereotaxic Instrument (21 CFR §882.4560)

Regulatory Class: Class II

Product Code OLO

Review Panel Orthopedic

D. Predicate Device Names

Primary Predicate Device:

Symphony Navigation Ready Instruments and Universal Navigation Adaptor Set (K201661) – OLO

Reference Devices:

TELIGEN System Navigation Ready Instruments (K233254) – OLO
Spine Navigation and Robotic-Assistance Device (K233228) – OLO

E. Device Description

The 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.

F. Indications for Use

The proposed indications for use are as follows:

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 and associated tracking arrays.

These procedures include but are not limited to spinal fusion. The SYMPHONY Navigation Ready Instruments can be:

- pre-calibrated with the VELYS™ SPINE Navigation using the VELYS™ SPINE Instrument Arrays,
- pre-calibrated and/or manually calibrated with the Brainlab Navigation System using the UNAS Navigation Arrays,
- manually calibrated with other navigation systems, using tracking arrays supplied by the navigation system manufacturer.

The SYMPHONY Navigation Ready Instruments are intended to support indicated cervical and thoracic polyaxial screw placement.

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

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

Compared to the predicate devices, the subject devices expand the scope of the SYMPHONY Navigation Ready Instruments for compatibility with an additional Navigation System, the VELYS™ SPINE Navigation. Like predicate devices, the SYMPHONY Navigation Ready Instruments are indicated for use when implanting SYMPHONY OCT screws. Compatibility with the VELYS™ SPINE Navigation is established via the existing VELYS™ Spine Instrument Arrays. This does not raise new questions of safety and effectiveness based on application of recognized consensus standards and design controls.

H. Materials

The subject device is manufactured from stainless steel and silicone rubber.

I. Performance Data

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

- Fulfillment of navigation system instrument accuracy requirements,
- CAD Model Evaluation,
- Simulated Use Evaluation,
- Biocompatibility verification according to ISO 10993-1:2018,
- Sterilization validation of the reusable devices was conducted according to ISO 17664-1:2021.

J. Conclusion

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