September 16, 2024

Medos International SARL
% Marina Minnock
Regulatory Affairs Specialist
Synthes GmbH
Eimattstrasse 3
Oberdorf, BL 4436
Switzerland

Re: K241893
Trade/Device Name: CROSSNAV Navigation Enabled Instruments and Universal Navigation Adaptor Set (UNAS)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 28, 2024
Received: June 28, 2024

Dear Marina Minnock:

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.

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)*
K241893

Device Name
CROSSNAV Navigation Enabled Instruments and Universal Navigation Adaptor Set (UNAS)

Indications for Use *(Describe)*
Navigation Enabled Instruments:

Navigation Enabled Instruments are reusable instruments indicated to be used during the preparation and placement of DePuy Synthes screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or percutaneous procedures. The Navigation Enabled Instruments are designed for use with only the specific DePuy Synthes implant system(s) for which they are indicated and with the VELYS Spine System as well as with the Brainlab Navigation System and the Medtronic StealthStation® Navigation System. The Navigation Enabled Instruments are indicated for use in surgical spinal procedures, in which:
• the use of EXPEDIUM™, VIPER™, SYMPHONY™ OCT and the TriALTIS™ Spine System is indicated,
• the use of stereotactic surgery may be appropriate, and
• reference to a rigid anatomical structure, such as the pelvis or a vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or fluoroscopic image reconstruction) and/or an image data based model of the anatomy.
These procedures include but are not limited to spinal fusion. The Navigation Enabled Instruments are also compatible with DePuy Synthes Power Systems and the Medtronic IPC® POWEREASE System.
The Navigation Enabled Instruments used in conjunction with the SYMPHONY OCT System are intended to support indicated cervical and thoracic polyaxial screw placement only.

Universal Navigation Adaptor Set (UNAS):

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 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 DePuy Synthes Navigation Ready Instruments, when used with UNAS, can be:
• pre-calibrated with the VELYS Spine System using VELYS Spine Instrument Arrays,
• pre-calibrated and/or manually calibrated with the Brainlab Navigation System,
where other navigation systems require manual calibration and tracking arrays supplied by the navigation system manufacturer.
Via the CROSSNAV Adaptor, the UNAS Navigation Arrays are also compatible with DePuy Synthes Navigation Enabled Instruments indicated for use with the Brainlab 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

A. Submitter Information

510(k) Sponsor: Medos International, SARL

Contact Person: Marina Minnock
Regulatory Affairs Specialist
Eimattstrasse 3
4436 Oberdorf BL
Switzerland

Telephone: +41-76-706 07 99

Email: mminnock@its.jnj.com

B. Date Prepared

13 September 2024

C. Device Name

Trade/Proprietary Name: CROSSNAV Navigation Enabled Instruments and Universal Navigation Adaptor Set (UNAS)

Common/Usual Name: Orthopedic Stereotaxic Instrument

Device Classification and Regulation: Class II
OLO – 21 CFR §882.4560

Classification Product and Panel Code: OLO – Orthopedic

D. Predicate Device Names

Primary Predicate Device:

CROSSNAV Navigation Enabled Instruments (K233255) – OLO

Additional Predicate Devices:

UNAS Navigation Arrays (K201661) – OLO
Brainlab Navigation System (K221618) – OLO
UNAS Navigation Rings (K233254) – OLO

E. Device Description

Navigation Enabled Instruments

Navigation Enabled Instruments (CROSSNAV™ Instruments) are reusable instruments used for the preparation and placement of DePuy Synthes EXPEDIUM™, VIPER™, SYMPHONY™ OCT and TriALTIS™ screws, in either open or percutaneous procedures. The Navigation Enabled Instruments include drills, taps and screwdrivers and can be operated manually or under power. These instruments are designed for navigated and non-navigated use. Navigation Enabled Instruments also include the CROSSNAV™ Adaptor to facilitate navigation of the Navigation Enabled Instruments with the VELYS Spine System as well as with the Brainlab Navigation System. Navigation of these instruments is achieved using the VELYS Spine System as well as Brainlab Navigation System and the Medtronic StealthStation Navigation System and their associated tracking arrays.

Universal Navigation Adaptor Set (UNAS)

The Universal Navigation Adaptor Set (UNAS) contains reusable spine surgical instruments used to aid in determining the correct location and trajectory of spinal instruments and implants. The UNAS has an interface between third-party navigation systems and the DePuy Synthes Navigation Ready Instruments as well as the Navigation Enabled Instruments. The UNAS can only be used with the VELYS Spine System as well as Brainlab and Medtronic StealthStation® navigation systems. The UNAS includes:

- Brainlab compatible UNAS Navigation Arrays,
- VELYS Spine/Brainlab compatible Navigation Rings and
- Medtronic compatible Navigation Ring ST.

The Navigation Rings and Navigation Ring ST mate with compatible DePuy Synthes Navigation Ready Instruments. These instruments include implant site preparation and implant insertion instruments as well as access and discectomy instruments.

When the VELYS Spine/Brainlab compatible Navigation Ring is attached to the Navigation Ready Instrument:

- a VELYS Spine Instrument Array can be attached and the instrument can be used with the VELYS Spine System as a pre-calibrated instrument, or
- a UNAS Navigation Array can be attached and the instrument can be used with the Brainlab Navigation System as either a manually calibrated and/or pre-calibrated instrument.

Via the CROSSNAV Adaptor, the UNAS Navigation Arrays are also compatible with DePuy Synthes Navigation Enabled Instruments indicated for use with the Brainlab Navigation System.

When the Navigation Ring ST is attached to the Navigation Ready Instrument, a Medtronic SureTrak® II Universal Tracker Fighter array (SureTrak II array) can be attached, and the instrument can be manually calibrated only with the Medtronic StealthStation Navigation System.

F. Indications for Use

Navigation Enabled Instruments

Navigation Enabled Instruments are reusable instruments indicated to be used during the preparation and placement of DePuy Synthes screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or percutaneous procedures. The Navigation Enabled Instruments are designed for use with only the specific DePuy Synthes implant system(s) for which they are indicated and with the VELYS Spine System as well as with the Brainlab Navigation System and the Medtronic StealthStation® Navigation System. The Navigation Enabled Instruments are indicated for use in surgical spinal procedures, in which:

- the use of EXPEDIUM™, VIPER™, SYMPHONY™ OCT and the TriALTIS™ Spine System is indicated,
- the use of stereotactic surgery may be appropriate, and
- reference to a rigid anatomical structure, such as the pelvis or a vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or fluoroscopic image reconstruction) and/or an image data based model of the anatomy.

These procedures include but are not limited to spinal fusion. The Navigation Enabled Instruments are also compatible with DePuy Synthes Power Systems and the Medtronic IPC® POWEREASE System.

The Navigation Enabled Instruments used in conjunction with the SYMPHONY OCT System are intended to support indicated cervical and thoracic polyaxial screw placement only.

Universal Navigation Adaptor Set (UNAS)

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 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 DePuy Synthes Navigation Ready Instruments, when used with UNAS, can be:

- pre-calibrated with the VELYS Spine System using VELYS Spine Instrument Arrays,
- pre-calibrated and/or manually calibrated with the Brainlab Navigation System,

where other navigation systems require manual calibration and tracking arrays supplied by the navigation system manufacturer.

Via the CROSSNAV Adaptor, the UNAS Navigation Arrays are also compatible with DePuy Synthes Navigation Enabled Instruments indicated for use with the Brainlab Navigation System.

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 CROSSNAV Navigation Enabled Instruments and UNAS Navigation Arrays are consistent with those of the predicate devices.

Compared to the predicate devices, the subject devices expand the scope of the Navigation Enabled Instruments for compatibility with an additional Navigation System, the Brainlab Navigation System. Similarly to predicate devices, CROSSNAV Navigation Enabled Instruments and UNAS Navigation Arrays include drills, taps, screwdrivers, and the CROSSNAV Adaptor and are indicated for use when implanting DePuy Synthes screws. Compatibility with the Brainlab Navigation System is established via the existing DePuy Synthes UNAS Navigation 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 devices are manufactured from stainless steel, titanium alloy, and RADEL, several of these devices are coated with TiN (Titanium Nitride), AlTiN (Aluminum Titanium Nitride), or Tungsten Carbide.

I. Performance Data

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

- Fulfillment of navigation systems instrument accuracy requirements as stated by the navigation manufacturer,
- CAD Model Evaluation,
- Simulated Use Evaluation.

J. Conclusion

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