May 26, 2026

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

Re: K254157
Trade/Device Name: CROSSNAV Navigation Enabled Instruments for Disc Preparation and Interbody
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: April 27, 2026
Received: April 27, 2026

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 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254157

Please provide the device trade name(s).

CROSSNAV Navigation Enabled Instruments for Disc Preparation and Interbody

Please provide your Indications for Use below.

Navigation Enabled Instruments are reusable instruments indicated to be used during the preparation and placement of DePuy Synthes implants as well as discectomy and / or bony resection, 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 Navigation 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, TriALTIS™, and the CONDUIT™ Spine System is indicated, if used for implant placement,
- 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 3D 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. The Navigation Enabled Instruments indicated for discectomy and / or bony resection, as well as the CONDUIT implants placement are for use with Medtronic StealthStation System only.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY

A. Submitter Information

510(k) Sponsor: Medos International, SARL

Contact Person: Marina Minnock
Regulatory Affairs Specialist
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Switzerland

Telephone: +41 76 706 07 99

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B. Date Prepared 26 May 2026

C. Device Name

Trade/Proprietary Name: CROSSNAV Navigation Enabled Instruments for Disc Preparation and Interbody

Common/Usual Name: Orthopedic Stereotaxic Instrument

Device Classification and Regulation: Class II
21 CFR §882.4560

Product Code: OLO

D. Predicate Device Names

Primary Predicate Device:

StealthStation S8 Spine Software (K251282) – OLO

Additional Predicate Device:

CROSSNAV Navigation Enabled Instruments and UNAS Navigation Arrays (K241893) – OLO

E. Device Description

Navigation Enabled Instruments (CROSSNAV™ Instruments) are reusable instruments used for the preparation and placement of DePuy Synthes EXPEDIUM™, VIPER™, SYMPHONY™ OCT, TriALTIS™, and CONDUIT™ implants, in either open or percutaneous procedures. The Navigation Enabled Instruments include drills, taps and screwdrivers and can be operated manually or under power. They also include manual tissue and bone removal / manipulation devices as well as interbody sizers and interbody implant inserters. 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 Navigation as well as with the Brainlab Navigation System. Navigation of these instruments is achieved using the VELYS™ SPINE Navigation as well as the Brainlab Navigation System and the Medtronic StealthStation™ Navigation System and their associated tracking arrays.

F. Indications for Use

Navigation Enabled Instruments are reusable instruments indicated to be used during the preparation and placement of DePuy Synthes implants as well as discectomy and / or bony resection, 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 Navigation 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, TriALTIS™, and the CONDUIT™ Spine System is indicated, if used for implant placement,
- 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 3D 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. The Navigation Enabled Instruments indicated for discectomy and / or bony resection, as well as the CONDUIT implants placement are for use with Medtronic StealthStation System only.

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 for Disc Preparation and Interbody are consistent with those of the predicate devices.

The subject devices represent an additional subset of Navigation Enabled Instruments designed for surgical site access, surgical site preparation, and interbody implant trialing and insertion. Similarly to predicate devices, CROSSNAV Navigation Enabled Instruments for Disc Preparation and Interbody are designed for Medtronic StealthStation Navigation System compatibility and utilize the same general characteristics and navigation workflow as previously cleared Navigation Enabled Instruments, including navigation tracker attachment, toolcard selection and intraoperative visualization of instrument position. Compatibility with the Medtronic StealthStation Navigation System is established via the existing DePuy Synthes coupling to NavLock trackers. This does not raise new questions of safety and effectiveness based on application of recognized consensus standards and design controls.

H. Materials

The CROSSNAV Navigation Enabled Instruments for Disc Preparation and Interbody are manufactured from stainless steel alloys. The biocompatibility evaluation of the instruments leveraged equivalence in materials and manufacturing to previously cleared instruments (K241893).

I. Performance Data

The performance data for the CROSSNAV Navigation Enabled Instruments for Disc Preparation and Interbody consists of the following evaluations:

- Dimensional comparisons between subject and predicate devices,
- Quantitative accuracy evaluation in a simulated clinical setting with cadaver specimens,
- Summative usability evaluation in a simulated clinical setting with cadaver specimens.

J. Conclusion

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