September 29, 2023

Medos International SÀRL
℅ Nicole Aeschbacher
Senior Regulatory Affairs Specialist
Synthes GmbH
Eimattstrasse 3
Oberdorf, BL 4436
Switzerland

Re: K231527
Trade/Device Name: TriALTIS Navigation Enabled Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: May 26, 2023
Received: May 26, 2023

Dear Nicole Aeschbacher:

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,

Tejen D. Soni -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231527

Device Name
TriALTIS Navigation Enabled Instruments

Indications for Use *(Describe)*
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 Medtronic StealthStation® System. The Navigation Enabled Instruments are indicated for use in surgical spinal procedures, in which:

• the use of EXPEDIUM 4.5, EXPEDIUM 5.5, EXPEDIUM 6.35, VIPER 2, VIPER SAI, EXPEDIUM VERSE, VIPER PRIME (without stylet control), 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 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.

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:	Nicole Aeschbacher Senior Regulatory Affairs Specialist Eimattstrasse 3 4436 Oberdorf BL Switzerland
Telephone:	+41-61-5641798
Email:	naeschba@its.jnj.com

B. Date Prepared

29 September 2023

C. Device Name

Trade/Proprietary Name:	TriALTIS Navigation Enabled Instruments
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:

Navigation Enabled Instruments (K200791) – OLO

Reference devices:

Medtronic StealthStation S8 Spine Hardware and Software (K162309, HAW and K170011, OLO)

TriALTIS™ Spine System (K231479, NKB)

E. Device Description

Navigation Enabled Instruments are reusable instruments used for the preparation and placement of DePuy Synthes EXPEDIUM™ 4.5, EXPEDIUM™ 5.5, EXPEDIUM™ 6.35, VIPER™ 2, VIPER™ SAI, VIPER PRIME™, EXPEDIUM VERSE™, 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 of these instruments is achieved using the Medtronic StealthStation navigation system and 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 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 Medtronic StealthStation® System. The Navigation Enabled Instruments are indicated for use in surgical spinal procedures, in which:

- the use of EXPEDIUM™ 4.5, EXPEDIUM™ 5.5, EXPEDIUM™ 6.35, VIPER™ 2, VIPER™ SAI, EXPEDIUM VERSE™, VIPER PRIME™ (without stylet control), 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 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.

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 the TriALTIS Navigation Enabled Instruments 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 DePuy Synthes Pedicle Screw System, the TriALTIS Spine System. Similarly to predicate devices, TriALTIS Navigation Enabled Instruments include drills, taps and screwdrivers and are indicated for use when implanting DePuy Synthes screws. This does not raise new questions of safety and effectiveness based on application of recognized consensus standards and design controls.

H. Materials

The TriALTIS Navigation Enabled Instruments are manufactured from stainless steel or titanium alloy, from which one of the devices is coated with AlTiN (Aluminum Titanium Nitride Coating).

I. Performance Data

A dimensional comparison and engineering analysis demonstrates that the TriALTIS Navigation Enabled Instrument meet performance requirements as it pertains to:

- Rigidity of Connections and Instrument During Use,
- Instrument Verification, and
- Accuracy Verification

Compatibility testing was performed with Medtronic StealthStation System S8 using StealthStation Spine Software Version 1.2.0 (1.2.0-20) using automatic intraoperative 3D Scan on an OARM Imaging System according to set up and installation instructions outlined in Medtronic's StealthStation S8 Spine with O-arm and 3D Fluoro Imaging Pocket Guide.

J. Conclusion

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