July 31, 2020

Medos International, SARL
℅ Nicole Aeschbacher
Regulatory Affairs Specialist
DePuy Synthes Spine
Eimattstrasse 3
Oberdorf, CH-BL 4436
Switzerland

Re: K200791
Trade/Device Name: Navigation Enabled Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 25, 2020
Received: March 26, 2020

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 (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,

Shumaya Ali, MPH
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)*
K200791

Device Name

Navigation Enabled Instruments

Indications for Use *(Describe)*

Navigation Enabled Instruments are reusable instruments intended 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 intended; 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) or SYMPHONYTM OCT system is indicated,

• 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.

These procedures include but are not limited to spinal fusion. The Navigation Enabled Instruments are also compatible with Synthes Small Battery Drive II System 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.

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510(k) Summary

A. Submitter Information

510(k) Sponsor: Medos International, SARL

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B. Date Prepared

March 25, 2020

C. Device Name

Trade/Proprietary Name: Navigation Enabled Instruments

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:

Navigated CD HORIZON® SOLERA® Screwdrivers and Taps (K140454)

Secondary Predicate Device:

Navigated INFINITY™ Instruments (K173338)

Reference Devices:

Medtronic StealthStation S8 Spine Hardware and Software (K162309 and K170011)

Expedium Spine System, Viper System, Viper 2 System (K111136)

Expedium Verse Spine System (K142185)

Expedium Spine System, Viper and Viper 2 Systems (K160904)

SYMPHONYTM OCT System (K181949)

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®, and SYMPHONY™ OCT 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 intended 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 intended; 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) or SYMPHONY™ OCT system is indicated,
- 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.

These procedures include but are not limited to spinal fusion. The Navigation Enabled Instruments are also compatible with Synthes Small Battery Drive II System 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 material, design and performance as well as intended use of the Navigation Enabled Instruments are consistent with those of the predicate devices.

H. Materials

The subject devices are manufactured from stainless steels, titanium alloy and titanium nitride coating.

I. Performance Data

Simulated Use testing was performed with a Medtronic StealthStation navigation system. The testing consisted of assembly of the Navigation Enabled Instruments with the Medtronic NavLock trackers, verification and navigated insertion (manual and under power) of Navigation Enabled Instruments and DePuy Synthes screws into a clinically relevant anatomical specimen / model.

The Simulated Use Evaluation allows to show that:

- Navigation Enabled Instruments can be rigidly connected to the NavLock tracker (rigidity),
- Navigation Enabled Instruments can be adequately verified on the Medtronic StealthStation navigation system (instrument verification),
- Navigation Enabled Instruments can be accurately navigated, and screws accurately placed (accuracy verification).

J. Conclusion

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