June 14, 2024

DePuy Synthes
Marina Minnock
Regulatory Affairs Specialist
Eimattstrasse 3
Oberdorf, 4436
Switzerland

Re: K233254
Trade/Device Name: TELIGEN System Navigation Ready Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: October 11, 2023
Received: June 7, 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.

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,

Jesse Muir -S

Digitally signed by Jesse Muir -S
Date: 2024.06.14 17:26:02 -04'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233254

Device Name

TELIGEN System Navigation Ready Instruments

Indications for Use *(Describe)*

TELIGEN Navigation Ready Instruments:

The TELIGEN System is indicated to provide minimally invasive access, visualization, illumination, magnification and discectomy of the surgical area of the spine.

The TELIGEN Access Probe and TELIGEN Clear are Navigation Ready Instruments and when used with the compatible Universal Navigation Adaptor Set (UNAS) are intended to assist the surgeon in locating anatomical structures in either open or percutaneous procedures. The navigation feature is used 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 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.

TELIGEN Clear and TELIGEN Access Probe, when used with UNAS Navigation Rings, can be pre-calibrated with:

• the VELYS Spine System using the VELYS Spine Instrument Arrays,
• the Brainlab Navigation System using the UNAS Arrays.

TELIGEN Access Probe in conjunction with UNAS can also be manually calibrated with other navigation systems, using tracking arrays supplied by the navigation system manufacturer.

The TELIGEN Access Probe is indicated for stimulation of peripheral motor nerves, including spinal nerve roots, for location and identification during surgery.

Discectomy Navigation Ready Instruments:

The Discectomy Navigation Ready Instruments when used with the compatible Universal Navigation Adaptor Set are intended to assist the surgeon in locating anatomical structures to facilitate disc space preparation, including discectomy or bony resection. 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 3D fluoroscopic image reconstruction) and/or an image data-based model of the anatomy using a navigation system and associated

navigation arrays.

These procedures include but are not limited to spinal fusion. The Discectomy Navigation Ready Instruments can be pre-calibrated with the VELYS Spine System (only for TELIGEN Graft Delivery Cannula and the curettes) as well as the Brainlab Navigation System.

Universal Navigation Adaptor Set:

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

• pre-calibrated with the VELYS Spine System using VELYS Spine System 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.

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

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

Telephone: +41 76 706 0799

Email: mminnock@its.jnj.com

B. Date Prepared 05 June 2024

C. Device Name

Trade/Proprietary Name: TELIGEN System Navigation Ready Instruments

Common/Usual Name: Orthopedic Stereotaxic Instrument

Device Classification and Regulation:
Class II
OLO – 21 CFR §882.4560
HRX – 21 CFR §888.1100
PDQ – 21 CFR §874.1820

Classification Product and Panel Code
OLO – Neurology
HRX – Orthopedic
PDQ – Neurology

D. Predicate Device Names

Primary Predicate Device:

TELIGEN System Navigation Ready Indications – K223108 – OLO

Additional Predicate Device:

Discectomy Navigation Ready Instruments and Universal Navigation Adaptor Set – K212756 – OLO

E. Device Description

TELIGEN Navigation Ready Instruments

TELIGEN Navigation Ready Instruments are part of TELIGEN Kits.

The TELIGEN Kits are sterile, single use kits intended for use in surgical spinal procedures allowing for access, visualization, discectomy, graft delivery, navigation and peripheral motor nerve stimulation.

The TELIGEN Kits include a camera, ports and port holder, TELIGEN Clear, a soft tissue retractor, a port cutter cartridge and bone graft delivery instruments. Additionally, the TELIGEN Procedure Kit Pro includes an Access Probe.

TELIGEN Access Probe and TELIGEN Clear are part of the DePuy Synthes Navigation Ready Instruments Portfolio and 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.

Discectomy Navigation Ready Instruments

The Discectomy Navigation Ready Instruments are reusable instruments used for disc space preparation, including discectomy or bony resection. 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) and associated navigation arrays. For further details on UNAS, refer to the UNAS labeling.

Universal Navigation Adaptor Set

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. 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:

- VELYS Spine System Instrument Array can be attached and the instrument can be used with the VELYS Spine System as pre-calibrated instrument, or
- 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.

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

TELIGEN Navigation Ready Instruments:

The TELIGEN System is indicated to provide minimally invasive access, visualization, illumination, magnification and discectomy of the surgical area of the spine.

The TELIGEN Access Probe and TELIGEN Clear are Navigation Ready Instruments and when used with the compatible Universal Navigation Adaptor Set (UNAS) are intended to assist the surgeon in locating anatomical structures in either open or percutaneous procedures. The navigation feature is used 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 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.

TELIGEN Clear and TELIGEN Access Probe, when used with UNAS Navigation Rings, can be pre-calibrated with:

- the VELYS Spine System using the VELYS Spine Instrument Arrays,
- the Brainlab Navigation System using the UNAS Arrays.

TELIGEN Access Probe in conjunction with UNAS can also be manually calibrated with other navigation systems, using tracking arrays supplied by the navigation system manufacturer.

The TELIGEN Access Probe is indicated for stimulation of peripheral motor nerves, including spinal nerve roots, for location and identification during surgery.

Discectomy Navigation Ready Instruments:

The Discectomy Navigation Ready Instruments when used with the compatible Universal Navigation Adaptor Set are intended to assist the surgeon in locating anatomical structures to

facilitate disc space preparation, including discectomy or bony resection. 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 3D fluoroscopic image reconstruction) and/or an image data-based model of the anatomy using a navigation system and associated navigation arrays.

These procedures include but are not limited to spinal fusion. The Discectomy Navigation Ready Instruments can be pre-calibrated with the VELYS Spine System (only for TELIGEN Graft Delivery Cannula and the curettes) as well as the Brainlab Navigation System.

Universal Navigation Adaptor Set:

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

- pre-calibrated with the VELYS Spine System using VELYS Spine System 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.

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 TELIGEN System Navigation Ready Instruments are consistent with those of the predicate devices.

Compared to the predicate devices, the subject devices expand the scope of the TELIGEN System Navigation Ready Instruments to establish compatibility with an additional navigation system, namely the VELYS Spine System. TELIGEN System Navigation Ready Instruments include TELIGEN Access Probe, TELIGEN Clear, TELIGEN Graft Delivery Cannula, and the associated curettes, in conjunction with UNAS Navigation Rings, previously cleared for compatibility with different

navigation systems. This does not raise new questions of safety and effectiveness based on application of recognized consensus standards and design controls.

H. Materials

The TELIGEN System Navigation Ready Instruments are manufactured as follows:

TELIGEN Access Probe

Stainless steel with-Parylene C coating
Stainless steel
Plastic (Polycarbonate)

TELIGEN Clear

Stainless steel
Plastic (polycarbonate, polyethylene, thermoplastic urethane (TPU))
Nitrile rubber

TELIGEN Graft Delivery Cannula and the curettes

Stainless steel,
TiAlN (Titanium Aluminum Nitride Coating)
Radel® (Polyphenylsulfone)
Silicone rubber

UNAS Navigation Rings:

Stainless steel
Titanium alloy

I. Performance Data

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

- Accuracy Verification through engineering analysis,
- 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 the TELIGEN System Navigation Ready Instruments are consistent with those of the predicate devices. The technological characteristics of the TELIGEN System Navigation Ready Instruments in terms of design, materials and performance are consistent with those of the predicate devices. The TELIGEN System Navigation Ready Instruments are substantially equivalent to the predicate devices.