January 19, 2023

Medos International, SARL
% Karin Mcdonough
Senior Regulatory Affairs Specialist
DePuy Synthes
325 Paramount Dr.
Raynham, Massachusetts 02767

Re: K223108
Trade/Device Name: TELIGEN System, TELIGEN Access Probe, TELIGEN Clear
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, HRX
Dated: December 22, 2022
Received: December 22, 2022

Dear Karin Mcdonough:

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,

Jesse Muir -S

For: 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223108

Device Name
TELIGEN System, TELIGEN Access Probe, TELIGEN Clear

Indications for Use *(Describe)*
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, when used with UNAS, can be pre-calibrated with the Brainlab Navigation System. TELIGEN Access Probe, when used with UNAS, can be pre-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.

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

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510(k) Summary

A. Submitter Information

510(k) Sponsor: Medos International, SARL

Contact Person: Karin McDonough
Senior Regulatory Affairs Specialist
325 Paramount Drive
Raynham, MA 02767
USA

Telephone: +1-508-977-3851

Email: kmcdono3@its.jnj.com

B. Date Prepared

19 January 2023

C. Device Name

Trade/Proprietary Name:	TELIGEN System, TELIGEN Access Probe, TELIGEN Clear
Common/Usual Name:	Orthopedic Stereotaxic Instrument
Device Classification and Regulation:	Class II OLO – 21 CFR §882.4560 HRX – 21 CFR §888.1100
Classification Product and Panel Code	OLO – Orthopedic HRX – Orthopedic

D. Predicate Device Names

Primary Predicate Device:

Synthes Navigable Pedicle Preparation Instruments (K122211) – HAW, OLO

Additional Predicate Devices:

Discectomy Navigation Ready Instruments and Universal Navigation Adaptor Set (UNAS) (K212756) – OLO

Reference Device:

TELIGEN System (K213978) – HRX

Brainlab Spine & Trauma Navigation System (K212245) – OLO

Medtronic StealthStation® System (K133444) – HAW, OLO

E. Device Description

The TELIGEN Procedure Kit and the TELIGEN Procedure Kit Pro are sterile, single use kits intended for use in surgical spinal procedures allowing for access, visualization, discectomy, graft delivery and navigation.

The TELIGEN Procedure Kit and the TELIGEN Procedure Kit Pro 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 as well as the instruments included in the TELIGEN Procedure Kit.

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.

F. Indications for Use

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, when used with UNAS, can be pre-calibrated with the Brainlab Navigation System. TELIGEN Access Probe, when used with UNAS, can be pre-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 Navigation Ready TELIGEN Access Probe and TELIGEN Clear are consistent with those of the predicate devices. Compared to the non-sterile, reusable predicate devices, the subject devices are offered as sterile, single use instruments. This does not raise new questions of safety and effectiveness based on application of recognized consensus standards and design controls.

H. Materials

- TELIGEN Access Probe: Stainless Steel, Parylene C Coating
- TELIGEN Clear: Stainless Steel

I. Performance Data

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

- Accuracy Verification:
  - Fulfillment of navigation systems instrument accuracy requirements
  - Instrument Length Comparison to Predicate Device
  - Array Characteristics Comparison to Predicate Device
- Rigidity of Connections and Instrument during Use
- CAD Model Evaluation
- Simulated Use Evaluation

J. Conclusion

The indications for use of the Navigation Ready TELIGEN Access Probe and TELIGEN Clear are consistent with those of the predicate devices. The technological characteristics of the Navigation Ready TELIGEN Access Probe and TELIGEN Clear in terms of design, materials and performance are consistent with those of the predicate devices. The Navigation Ready TELIGEN Access Probe and TELIGEN Clear are substantially equivalent to the predicate devices.