February 10, 2023

Medos International, SARL
% Daria Bochenek
Senior Regulatory Affairs Specialist
Synthes Gmbh
Eimattstrasse 3
4436 Oberdorf
Switzerland

Re: K223438
Trade/Device Name: TELIGEN System Peripheral Motor Nerve Stimulation Indications
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: PDQ, OLO, HRX
Dated: November 14, 2022
Received: November 14, 2022

Dear Daria Bochenek:

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,

Patrick Antkowiak -S

for
Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K223438

Device Name
TELIGEN System Nerve Stimulation Indications

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.

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

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:	Daria Bochenek, Senior Regulatory Affairs Specialist Eimattstrasse 3 4436 Oberdorf Switzerland
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B. Date Prepared

01 February 2023

C. Device Name

Trade/Proprietary Name:	TELIGEN System Nerve Stimulation Indications
Common/Usual Name:	PDQ – Neurosurgical Nerve Locator OLO – Orthopedic Stereotaxic Instrument HRX – Arthroscope
Device Classification and Regulation:	Class II PDQ – 21 CFR §874.1820 OLO – 21 CFR §882.4560 HRX – 21 CFR §888.1100
Classification Product and Panel Code	PDQ – Neurology OLO, HRX – Orthopedic

D. Predicate Device Names

Primary Predicate Device:

SENTIO MMG Pedicle Access Needles (K173134) – PDQ

Secondary Predicate Device:

TELIGEN System Navigation Ready Indications (TELIGEN Access Probe, TELIGEN Clear) (K223108) – OLO, HRX

E. Device Description

The TELIGEN Procedure Kit Pro is a sterile, single use kit intended for use in surgical spinal procedures allowing for access, visualization, discectomy, graft delivery, navigation and peripheral motor nerve stimulation.

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

The TELIGEN Access Probe is part of the DePuy Synthes Navigation Ready Instruments Portfolio and is designed for navigated and non-navigated use. Navigation of this instrument is achieved using the DePuy Synthes Universal Navigation Adaptor Set (UNAS). For further details on UNAS, refer to the UNAS labeling.

The TELIGEN Access Probe is intended to stimulate peripheral motor nerves, including spinal nerve roots, for location and identification during surgery. It contains an insulated probe compatible with the SENTIO MMG System. The SENTIO MMG sensors serve to measure a mechanomyographic (MMG) response and the SENTIO MMG System's detection of this response alerts the surgeon of nerve location in the proximity of the TELIGEN Access Probe's distal tip.

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.

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

G. Summary of Similarities and Differences in Technological Characteristics, Performance, and Indications for Use

The technological characteristics, including design, material and performance as well as indications for use of the Nerve Stimulating TELIGEN Access Probe are consistent with those of the predicate devices.

Attribute	Subject Device TELIGEN System Peripheral Motor Nerve Stimulation Indications	Primary Predicate Device SENTIO MMG Pedicle Access Needles (K173134)	Substantially Equivalent
Indications for Use (peripheral motor nerve stimulation specific text in *italic*)	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 when used with the compatible Universal Navigation Adaptor Set (UNAS) and 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.		Yes, substantially equivalent for peripheral motor nerve stimulation indications.

Attribute	Subject Device TELIGEN System Peripheral Motor Nerve Stimulation Indications	Primary Predicate Device SENTIO MMG Pedicle Access Needles (K173134)	Substantially Equivalent
	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. *The TELIGEN Access Probe is indicated for stimulation of peripheral motor nerves, including spinal nerve roots, for location and identification during surgery.*	*The SENTIO MMG Pedicle Access Needles are indicated for use in pedicle pilot hole preparation and stimulation of peripheral motor nerves for location and identification during surgery, including spinal nerve roots.*	
Classification	Class II, Product Code PDQ, added with this submission	Class II, Product Code PDQ	Yes
Instruments	Access Probe Stimulation Wire	Pedicle Access Needle (Trocar and Cannula) Stimulation Wire	Yes
Compatible Nerve Stimulation System	SENTIO MMG System	SENTIO MMG System	Yes
Stimulation device distal tip geometry	Inline blunt tip	Trocar tip Diamond tip Beveled tip	Yes. Since the Pedicle Access Needles provide the function of pilot hole preparation (in addition to

Attribute	Subject Device TELIGEN System Peripheral Motor Nerve Stimulation Indications	Primary Predicate Device SENTIO MMG Pedicle Access Needles (K173134)	Substantially Equivalent
			access), the tip design is defined as trocar, diamond or bevel compared to the blunt tip of TELIGEN Access Probe. This difference does not raise any new safety or performance questions.
Electrical Insulation	The TELIGEN Access Probe has biocompatible electrical insulation applied to select portions. The proximal and distal surface of the instrument is selectively non-insulated stainless steel to connect to the stimulation wire and for tissue stimulation, respectively.	The Pedicle Access Needles have biocompatible electrical insulation applied to select portions. The proximal and distal surface of the instrument is selectively non-insulated stainless steel to connect to the stimulation wire and for tissue stimulation, respectively.	Yes
Proximal Stimulator Connector	Yes	Yes	Yes
Patient contacting materials	Stainless Steel, Parylene C Coating	Stainless Steel, Parylene C Coating	Yes
Delivery	Sterile via Ethylene Oxide Single Use	Sterile via Ethylene Oxide Single Use	Yes

H. Materials

- TELIGEN Access Probe: Stainless Steel, Parylene C Coating

I. Performance Data

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

Electrical Safety Evaluation, Functional Performance Testing and Verification Analysis as well as Sterility. The table below summarizes testing and/or evaluations that were performed on the subject device to show substantial equivalence to the predicate device. Results demonstrated that the subject device is appropriate for peripheral motor nerve stimulation and is substantially equivalent when compared to the legally marketed primary predicate device cleared by FDA.

Test	**Test Method Summary**	**Results**
Electrical Safety Evaluation	Evaluation was performed in accordance with IEC 60601-1: 2005(R)2012.	All evaluations passed acceptance criteria.
Functional Performance Testing and Verification Analysis	• Connector Compatibility • Insulation Effectiveness • SENTIO MMG System Compatibility • Electrical Stimulation Density	All samples and evaluations passed acceptance criteria.
Sterility	Ethylene Oxide sterilization validation performed per ISO 11135.	All samples passed acceptance criteria.

J. Biocompatibility Data

The TELIGEN Access Probe is manufactured from the same materials as the predicate devices.

A risk analysis was performed taking into account the categorization of body contact and duration of use of the medical device. Existing data, endpoint-specific testing, and endpoint assessments were analyzed to cover the identified test methods in Annex A of ISO 10993-1. Additionally, data was leveraged by other means (e.g., authorized use of Master File, predicate and reference devices, well known and characterized materials) to support the biocompatibility of the subject devices.

Biocompatibility endpoints evaluated per ISO 10993-1:

• Physical and/or chemical information

• Cytotoxicity

• Acute Systemic Toxicity

• Irritation or Intracutaneous Reactivity

• Sensitization

• Material mediated pyrogenicity

K. Conclusion

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