October 18, 2022

Medos International, SARL
Daria Bochenek
Senior Regulatory Affairs Specialist
Chemin-Blanc 38
Le Locle, CH-NE 2400
Switzerland

Re: K213978
Trade/Device Name: TELIGEN Procedure Kit
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: September 16, 2022
Received: September 16, 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,

For

Laura C. Rose, Ph.D.
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)*
K213978

Device Name
TELIGEN System

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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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
Telephone:	+41 61 965 61 54
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Email:	dbochene@its.jnj.com

B. Date Prepared

15 September 2022

C. Device Name

Trade/Proprietary Name:	TELIGEN System
Common/Usual Name:	HRX –Arthroscope;
Device Classification and Regulation:	Class II HRX – 21 CFR §888.1100
Classification Product and Panel Code	HRX – Orthopedic

D. Predicate Device Names

Primary Predicate Device:

Voyant System (K191579) – HRX

Additional Predicate Devices:

XTool™ MIS Discectomy Device (K122861) – HRX

Reference device:

OVS1 Video System (K123359) – FCW, GCJ

E. Device Description

The TELIGEN Procedure Kit is part of the TELIGEN System. It is a sterile, single use kit intended for use in surgical spinal procedures to allow for access, visualization, discectomy and graft delivery.

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

The TELIGEN HD Camera Control System (CCS) is part of the TELIGEN System. It operates the TELIGEN Camera which is used for illumination and visualization of the surgical site. The image collected at the camera head, is transferred to the CCS and subsequently displayed on the monitor.

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.

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 are consistent with those of the predicate devices.

H. Materials

- TELIGEN Camera: glass lens, plastic (polycarbonate, acrylonitrile butadiene styrene, polyvinyl chloride, PEEK), stainless steel.
- TELIGEN Ports: plastic (polypropylene).
- TELIGEN Port Holder: plastic (polycarbonate, glass fiber reinforced polyarylamide).
- TELIGEN Clear: stainless steel.

I. Performance Data

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

Design Verification and Validation Testing, Human Factor/Usability, Electrical Safety, Thermal Safety & EMC Testing, Software and Systems Testing.

J. Conclusion

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