April 17, 2026

Sensomedical Labs, Ltd.
Maroun Farah
CEO
Nazareth Industrial Park
Mount Precipice
Nazareth, 1612102
Israel

Re: K253970
Trade/Device Name: Wovyn Depth Electrode
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth electrode
Regulatory Class: Class II
Product Code: GZL
Dated: November 25, 2025
Received: December 11, 2025

Dear Maroun Farah:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253970

Please provide the device trade name(s).

Wovyn Depth Electrode

Please provide your Indications for Use below.

Sensomedical Wovyn Depth Electrodes are intended for temporary (< 30 days) use with recording, monitoring and stimulation equipment for the recording, monitoring and stimulation of electrical signals at the subsurface level of the brain.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY

Wovyn Depth Electrode

Premarket Notification — 510(k) Number: K253970

Submitted pursuant to 21 CFR 807.92

1. Submitter and Device Identification

Submitter's Name	Sensomedical Labs, Ltd.
Address:	Nazareth Industrial Park, Mount Precipice Nazareth 1612102, Israel +972 (0) 4 6800668
Contact Person Name:	Maroun Farah
510(k) Number:	K253970
Device Trade Name:	Wovyn Depth Electrode
Common or Usual Name:	Electrode, Depth
Device Classification:	Class II — 21 CFR 882.1330; Product Code: GZL
Review Panel:	Neurological and Physical Medicine
Primary Predicate:	SENSO SEEG Depth Electrode — 510(k) K213170 (Sensomedical Labs, Ltd.)
Secondary Predicate:	PMT Depthalon Electrode — 510(k) K151790 (PMT Medical)
Date of Summary:	March 18, 2026

2. Device Description

The Wovyn Depth Electrode is a single-use, pre-sterilized, implantable depth electrode designed for stereoelectroencephalography (SEEG). It is used by neurosurgeons to record, monitor, and stimulate electrical signals at the subsurface level of the brain in patients undergoing evaluation for epilepsy surgery or other neurological procedures.

The Wovyn Depth Electrode is a smooth electrode, the device is available in configurations of 4 to 16 macro electrode contacts, with contact lengths of 1.5 mm to 3 mm along the electrode body and various inter-contact spacing configurations. The electrode body diameter in the brain contact region ranges from 0.8 mm to 2.0 mm, and the overall electrode length ranges from 360 mm to 400 mm. A stylet is included to facilitate placement. The device is supplied sterile (Ethylene Oxide sterilization) and is labeled for single-patient use with a maximum duration of use of 30 days.

The Wovyn Depth Electrodes are intended for temporary use with recording, monitoring and stimulation equipment for the recording, monitoring and stimulation of electrical signals at the subsurface level of the brain.

The Wovyn Depth Electrodes are connected to the user under the guidance and instruction of a supervising physician (physicians in the areas of biopotential recording, monitoring and stimulation/response studies, knowledgeable in the use of depth electrodes). Environment of use: This device is intended to be implanted into a patient's brain by a trained clinician in a professional healthcare facility only. It is NOT intended for MR use and is MR unsafe.

3. Indications for Use

Sensomedical Wovyn Depth Electrodes are intended for temporary (<30 days) use with recording, monitoring, and stimulation equipment for the recording, monitoring, and stimulation of electrical signals at the subsurface level of the brain.

4. Summary of Technological Characteristics

The technological characteristics of the Wovyn Depth Electrode were compared against those of the primary predicate (SENSO SEEG Depth Electrode, K213170) and secondary predicate (PMT Depthalon Electrode, K151790). The comparison is presented below for each characteristic.

Features	New device Wovyn Fabric Depth Electrode (Under Review)	Senso SEEG depth Electrode (K213170) Primary Predicate	PMT DEPTHALON Electrode K151790 Secondary Predicate	Comments
Indications for Use	Senso Medical Wovyn Depth Electrodes are intended for temporary (< 30 days) use with recording, monitoring and stimulation equipment for the recording, monitoring and stimulation of electrical signals at the subsurface level of the brain	Senso Medical Depth Electrodes are intended for temporary (< 30 days) use with recording, monitoring and stimulation equipment for the recording, monitoring and stimulation of electrical signals at the subsurface level of the brain.	The Platinum /Stainless Steel Depthalon Electrodes are intended for temporary (<30days) use with recording, monitoring, and stimulation equipment for the recording, monitoring, and stimulation of electrical signals in the subsurface of the brain	Same
Clinical Application	Placed in the subsurface level of the brain to support	Placed in the subsurface level of the brain to support recording,	Not available online	Same

	recording, monitoring and stimulation.	monitoring and stimulation.		
Contraindications	These depth electrodes should not be used on any patient who the physician/surgeon considers at risk for infection or for whom the surgical recording and stimulation procedure cannot be performed safely and effectively.	These depth electrodes should not be used on any patient who the physician/surgeon considers at risk for infection or for whom the surgical recording and stimulation procedure cannot be performed safely and effectively.	Not available online	Same
Single patient use, Disposable	Yes	Yes	Yes	Same
Provided Sterile	Yes	Yes	Yes	Same
Environment of use	Intraoperative and Neurological	Intraoperative and Neurological		Same
Use	monitoring locations	monitoring locations		Same
Duration of Use	< 30 days	< 30 days		Same
Electrode Contact Material	Platinum/Iridium	Stainless-Steel	Stainless steel or platinum	Different than 1st predicate, but same as second predicate
Maximum Stimulation Charge Density	< 30 µC/cm2	< 30 µC/cm2		Same
Number of electrode contacts	4-16	4-16	Not available online	Equivalent
Electrode jacket	TPU	TPU	TPU	Equivalent
Electrode body diameter (brain contact)	0.8 mm to 2 mm	0.8 mm to 2 mm	0.8mm	Equivalent - Variations of electrode body diameter is provided
Stylet	Yes	Yes	Yes	Same
Electrode contact length (along body of the electrode)	1.5mm – 3mm Macro, Other different configuration available.	1.5mm –3mm Macro	Standard 2mm, however; Different spacing configuration available	Similar
Overall length	360 - 400[mm]	360 - 400[mm]	235.24 to 291 mm	Same

Sensomedical concludes that the Wovyn Depth Electrode (K253970) is substantially equivalent to the primary predicate device, the SENSO SEEG Depth Electrode (K213170), for the following reasons:

- **Same intended use:** Both devices are intended for temporary (<30 days) recording, monitoring, and stimulation of electrical signals at the subsurface level of the brain, in the same patient population, in the same clinical settings.
- **Same or equivalent technological characteristics for all features except electrode contact material:** The devices share identical or equivalent indications, clinical application, contraindications, use environment, duration of use, electrode jacket material, body diameter, contact length, overall length, stylet design, number of contacts, stimulation charge density limits, and single-use sterile supply.
- **Different electrode contact material does not raise new safety or effectiveness questions:** The use of Pt90/Ir10 alloy contacts in place of stainless steel is the sole technological difference. This difference is well-supported by the secondary predicate (K151790), which uses the same Platinum material as many other Depth electrodes, and does not alter intended use, mechanism of action, or device design. Nonclinical testing confirms the safety and performance of the Pt90/Ir10 contacts under the intended conditions of use.

5. Brief Discussion of Nonclinical Tests

Non-clinical testing performed

Performance testing was performed to assure safety and effectiveness of the Senso Medical Depth Electrodes. All necessary bench testing was conducted on the Senso Medical Depth Electrodes to ensure conformance to design specifications and to support a determination of substantial equivalence to the predicate devices. The nonclinical, bench testing performed included:

- Verification testing (mechanical, electrical, and functional testing), verifying design output meets design input
- Biocompatibility Testing including Cytotoxicity, Skin Sensitization, Intracutaneous test, Material-Mediated Pyrogenicity, Acute Systemic Toxicity,Subacute systemic toxicity, Bacterial Reverse Mutation, Chromosomal aberration, Hemolysis test, Brain Implantation Study .
- Packaging, shelf life and shipment and transit testing; and
- EO Sterilization Validation in accordance with ISO 11135. Demonstrating achievement of a Sterility Assurance Level (SAL) of 10^{-6}.
- Performance testing including electrical (impedance, recording, and stimulation), mechanical, and electrochemical testing.

6. Clinical Tests

No clinical studies specific to the Wovyn Depth Electrode were conducted or are required to support these 510(k) submissions. The substantial equivalence determination is supported entirely by

nonclinical testing data and predicate device comparison, consistent with the 510(k) regulatory pathway for this device type and classification.

7. Conclusion:

From the data available we can justify that the " Senso Medical Depth Electrodes " has the same intended use and the same technological characteristics as the already marketed predicate devices identified above. Hence our device can be considered substantially equivalent to the predicates.