April 18, 2023

Sensomedical Labs LTD
Sama Tarazi
Regulatory Affairs
Nazareth Industrial Park
Nazareth, 1612102
Israel

Re: K213170
Trade/Device Name: SENSOSEEG Depth Electrodes
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth Electrode
Regulatory Class: Class II
Product Code: GZL
Dated: March 20, 2023
Received: March 20, 2023

Dear Sama Tarazi:

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

Patrick Antkowiak
Assistant Director (Acting)
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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
SENSO SEEG Depth Electrodes

Indications for Use *(Describe)*
Device Name: SENSO SEEG Depth Electrodes

INDICATION FOR USE:
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.

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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510K Summary

Premarket Notification 510(k) Summary as required by Section 807.92

General Company Information as required by 807.92 (a)

Submitter's Name	Sensomedical Labs LTD
Address:	Nazareth Industrial Park, Mount Precipice Nazareth 1612102, Israel +972 (0) 4 6800668
Contact Person Name:	Sama Tarazi
Title:	Regulatory Affairs
Phone Number:	+972 (0) 4 6800668
Dated:	Apr 14 2023

Throughout the submission " SENSO SEEG Depth Electrodes" is covered under 510 (k) Submission.

Proprietary Name:

SENSO SEEG Depth Electrodes

Assigned K number:

K213170

Common or Usual Name:

- Electrode, depth

Classification Name:

Depth electrode (21 CFR 882.1330)

Product Code:
GZL

Device Class: II

Review Panel: Neurological and Physical Medicine

Regulation Number: 21 CFR 882.1330

Identification of the Predicate Device:

DIXI Medical Microdeep Depth Electrode (K170959), Primary Predicate
Predicate Device Ad-tech depth electrodes (K964644), Secondary Predicate
PMT Depthalon Electrodes (K802152), Secondary Predicate

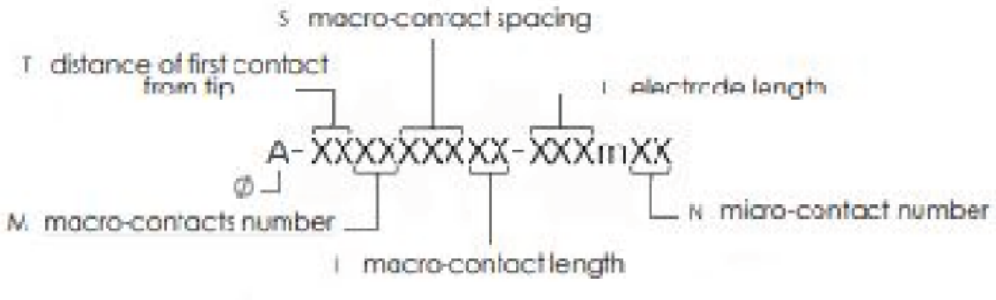
Device Description:

The SENSO SEEG Electrode is a smooth electrode with a diameter of 0.8 – 2 mm with a rounded tip. Different configurations exist with diameters of 0.8, 1.1, 1.27, and 2.0 mm. The electrode contacts are made from stainless-steel that can be 1.5mm, 2.0, and 3.0 mm long, with a total exploration length varying from (22 - 82 mm) according to the electrode reference. The total length of the electrodes range from 360 mm to 410 mm long depending on the number of contacts and total exploration length of the electrodes. The electrodes come in 3 main configurations, but can be customized to the parameters mentioned above based on the application need.

Three standard configurations of the electrodes can be generated according to the following code:

P/N coding:

	Diameter
B	Ø 0.8 mm
C	Ø 1.1 mm
D	Ø 1.27mm
E	Ø 2.0 mm



The codes are as follows:

Product code	Contact #	Electrode diameter (mm)	Electrode contact lengths (mm)	Electrode contact spacing (mm)	Electrode total length (mm)
B-20042524-400m00	4	0.8	2.4	2.5	400
B-20082524-400m00	8	0.8	2.4	2.5	400
B-20162524-400m00	16	0.8	2.4	2.5	400

*SENSO SEEG Depth Electrodes are also available within the parameters mentioned earlier.

Senso Medical SEEG 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.

SENSO SEEG 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

Device Indications for Use:

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

Predicate Comparison Table

Table 1 Shows the predicate comparison table of the SENSO SEEG Depth Electrode

Features	**New Device SEEG depth electrodes**	**Predicate Device DIXI Medical depth electrode(K170959)**	**Predicate Device Ad-tech depth electrodes (K964644)**	**Predicate Device PMT Depthalon Electrodes (K802152)**	**Comments**
Indications for Use	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 DIXI Medical Microdeep Depth Electrodes are intended for temporary (< 30 days) use with recording, monitoring and stimulation of electrical signals at the subsurface level of the brain	The Ad-Tech Depth Electrodes (Depth Electrodes, Foramen Ovale Depth Electrodes, Macro Micro Depth Electrodes, Spencer Probe Depth Electrodes, Wyler Sphenoidal 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 recording of electrical activity supports definition of the location of epileptogenic foci and brain mapping.	The 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	Identical

Clinical Application	Placed in the subsurface level of the brain to support recording, monitoring and stimulation.	Placed in the subsurface level of the brain to support recording, monitoring and stimulation.	Placed in the subsurface level of the brain to support recording, monitoring and stimulation.	Not available online	Identical
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.	Not available online	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	Identical
Single patient use, Disposable	Yes	Yes	Yes	Yes	Identical
Provided Sterile	Yes	Yes	Yes	Yes	Identical
Environmen t of	Intraoperative and Neurological	Intraoperative and Neurological	Intraoperative and Neurological	Intraoperative and Neurological	Identical
Use	monitoring locations	monitoring locations	monitoring locations	monitoring locations	Identical
Duration of Use	< 30 days	< 30 days	< 30 days	< 30 days	Identical
Electrode Contact Material	Stainless steel	Platinum / Iridium	Platinum / Iridium	Stainless steel	Different with primary predicate but identical with secondary one*
Maximum Stimulation Charge Density	< 30 µC/cm2	N/A	< 30 µC/cm2	Not available online	Identical with secondary predicate
Number of electrode contacts	4-16	From 5 to 18 contacts	Up to 16	Up to 16 contacts	Similar
Electrode Material	Stainless Steel	Platinum Iridium	Platinum Iridium and Stainless Steel	Stainless steel	Different with primary predicate but identical with secondary ones*

Electrode jacket	TPU	TPU	TPU	Not available online	Identical
Electrode body diameter (brain contact)	0.8 mm to 2 mm	0.8 mm	1.57 mm (Macro)	0.8 mm to 1.8 mm	Equivalent - Design Verification Testing proves the equivalency. A comparative testing with Ad depth electrodes proves the equivalency.
Stylet	Yes	Yes	Yes	Yes	Identical
Electrode contact length (along body of the electrode)	1.5 - 3[mm] Macro	2 mm long	Not available online	Contact sizes of 2.0mm and 5.0mm	Similar. SENSO SEEG has a smaller electrode contact, but does not raise concern over safety similarly to other depth electrode marketed devices, such as the SPENCER® PROBE DEPTH ELECTRODES K041604, with similar smaller contact lengths of less1.5 mm
Overall length	360 - 400[mm]	500 mm and 1000 mm	< 660 mm	27 mm	A longer electrode accommodates additional contacts and user preference. Safety and performance has

					been evaluated in the design verification testing.
Electrode contact surface	Ring contact built from a folded (coiled) exposed wire on top of lead body	Ring contact	Ring contact	Ring contact	**Different: the electrode contact is built from folding (coiling) an exposed wire on top of the lead in the appropriate place; this coiled wire together forms a ring contact.

**A difference in the manufacturing technology of predicates devices vs. SENSOMEDICAL SEEG contributes to a difference in the way the electrode contacts are formed. The SENSO SEEG depth electrode are built by weaving and braiding techniques (same materials as used in predicate devices and in almost most of brain implant leads), whereas predicate devices contacts are built by crimping and welding stainless steel pieces to the body of the electrode. However, the difference in technology does not raise concern over the safety of this device.

Substantial equivalence including comparison with predicate devices

The Senso Medical Depth Electrodes are substantially equivalent to the primary predicate device,the DIXI Medical depth electrode (K170959) as they have the similar intended use in the same patient population, utilize similar performance specifications and have comparable technological features to achieve the same mechanism of action: therefore, the Senso Medical Depth Electrodesdo not raise any different issues of safety or effectiveness. Additional predicate devices have been selected for comparison to technological characteristics, the Ad-tech electrodes (K964644), and PMT Depthalon Electrodes (K802151).

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. [807.92(b)(1)] The nonclinical, bench testing performed included:

- Verification testing (mechanical, electrical, and functional testing)
- Biocompatibility Testing
- Packaging, shelf life and transit testing; and
- EO Sterilization Validation

CONCLUSION:

Table 2 Identifies the proposed device's features relative to the predicate device features

S.No.	Parameter of Conclusion	Proposed Device	Predicate Devices
1	Product Code	GZL	Same
2	Regulation Number	21 CFR 882.1330	Same
3	Regulatory Class	II	Same
4	Intended Use	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.	Identical
5	Sterilization	EO Sterilization	Same
6	Performance Test	Functional, mechanical and electrical	Same
7	Contact material	Stainless-steel	Same

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.