November 22, 2022

WISE S.r.l.
% Terri Bogucki
Regulatory Consultant
Decus Biomedical
2342 Shattuck Ave #333
Berkeley, California 94704

Re: K221123
Trade/Device Name: WISE Cortical Strip (WCS)
Regulation Number: 21 CFR 882.1310
Regulation Name: Cortical Electrode
Regulatory Class: Class II
Product Code: GYC
Dated: October 24, 2022
Received: October 26, 2022

Dear Terri Bogucki:

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)*
K221123

Device Name
WISE Cortical Strip

Indications for Use *(Describe)*
The WISE Cortical Strip is intended for intraoperative (≤ 24 hours) use with recording, monitoring and stimulation equipment for the recording, monitoring, and stimulation of electrical signals on the surface of the brain.

The WCS is indicated as an aid to IntraOperative Neurophysiological Monitoring (IONM) during brain surgeries.

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.

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510(k) Summary

Submitter's Name:	WISE S.r.l.
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Title:	Regulatory Consultant
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Date Summary Prepared:	10 November 2022
Device Proprietary Name:	WISE Cortical Strip
Model Number:	WCS04S10A-00-001
Common Name:	Cortical electrode
Regulation Number:	21 CFR 882.1310
Product Code:	GYC
Device Class:	II
Predicate Devices	Manufacturer: Ad-Tech Medical Instrument Corporation Address: 400 West Oakview Parkway Oak Creek, Wisconsin 53154 Regulation Number: 21 CFR 882.1310 Regulation Name: Cortical electrode Device Class: Class II Product Code: GYC <u>Primary Predicate</u> Trade name: Ad-Tech Intraoperative Strip Electrode 510(k) Number: K191186 510(k) Clearance Date: 15 January 2020 <u>Secondary Predicate</u> Trade name: Ad-Tech Intraoperative Subdural Electrode 510(k) Number: K053363 510(k) Clearance Date: 30 May 2006

1 Description of the Device

The WISE Cortical Strip is medical device composed of:

- A strip containing 4 electrodes that is positioned during surgery on the exposed surface of the brain
- A cable composed of 4 conductive channels intended to transfer electrical signals to and from a commercial connecting cable.

The device is intended to be used only for intraoperative monitoring during brain surgery and is not implanted.

The WCS is a sterile, single-use device, individually packaged with a shelf life of 18 months.

Manufacture of the device uses a WISE proprietary patented technology called “Supersonic Cluster Beam Implantation” (SCBI). This technology produces flexible conductors by enabling thin conducting metal layers to be deposited on a silicone substrate. This enables the strip to be flexible and conform to the brain’s surface.

The WCS is intended to be used with FDA-cleared IONM equipment and a reusable connecting cable. The device does not include (as an accessory or component) these separate devices.

2 Indications for Use

Both the WISE Cortical Strip (subject device) and Ad-Tech Intraoperative Strip Electrode (predicate device) are designed to be used intraoperatively for the recording, monitoring and stimulation of electrical signals on the surface of the brain. The Indications for Use for the subject and predicate devices are:

WISE Cortical Strip Subject Device	AD-TECH Subdural Electrodes Predicate Device, K191186	AD-TECH Subdural Electrodes Predicate Device, K053363
The WISE Cortical Strip is intended for intraoperative (≤ 24 hours) use with recording, monitoring and stimulation equipment for the recording, monitoring, and stimulation of electrical signals on the surface of the brain. The WCS is indicated as an aid to IntraOperative Neurophysiological Monitoring (IONM) during brain surgeries.	The Ad-Tech Subdural Electrodes (Strip/Intraoperative Strip, Grid/Intraoperative Grid, Dual-Sided Interhemispheric, Multi-Strip and Split Grid, Intraoperative Mapping Grid) are intended for temporary (< 30 days) use with recording, monitoring, and stimulation equipment for the recording, monitoring, and stimulation of electrical signals on the surface of the brain. The recording of electrical activity supports definition of the location of epileptogenic foci and brain mapping.	The Ad-Tech Subdural Electrodes (Dual-Sided Interhemispheric, Grid, Intraoperative, Strip, Wyler) are intended for temporary (< 30 days) use with recording, monitoring, and stimulation equipment for the recording, monitoring, and stimulation of electrical signals on the surface of the brain. The recording of electrical activity supports definition of the location of epileptogenic foci and brain mapping.

3 Summary of Technological Characteristics Comparison

The primary and secondary predicate devices have regulatory clearance as part of a family of electrodes provided in multiple shapes and configurations that support a range of intraoperative and subdural (implanted <30 day) use. Specifically, the Ad-Tech Intraoperative Strip Electrode is claimed as the primary predicate device.

The technologic characteristics of the subject and predicate devices are similar in the following ways:

- They are subdural cortical electrodes used intraoperatively to transfer electrical signals to and from the brain for the same duration of use, in the same environment of use, by the same users.
- They are sterilized using EO and provided sterile, for single-use only.
- They come in configurations that have four numbered 2.3 mm diameter electrodes spaced 10 mm apart in a silicone substrate ending in a.
- The strips end in a 1.5 mm diameter electrode cable that attaches to a separate connecting cable for use.
- Consistent with the clinical practice safety limit, they support a maximum stimulation charge density of ≤ 30 $\mu C/cm^2$.

The main technological differences between the subject and predicate devices are:

- The contact materials are similar but not identical; the subject device electrodes are Platinum only, whereas the predicate device electrodes are made of 90:10 Platinum:Iridium or stainless steel.
- The subject device is labeled “non-pyrogenic” while the predicate is not.
- The subject device is manufactured using a unique Supersonic Cluster Beam Implantation process which produces a very flexible electrode strip that conforms with the cortex surface.

4 Non-Clinical Performance Data

Testing was performed with the WCS to support substantial equivalence to the predicate device. Testing included performance testing, biocompatibility, and shelf-life testing.

Bench testing was conducted on WCS devices that were exposed to 2x sterilization, 18 months of accelerated aging, environmental conditioning and transport simulation prior to testing. In addition to ensure their integrity even under conditions of misuse, many of the tests were conducted after the devices were exposed to soaking, linear elongation, and bending conditioning.

The following standards were utilized in the evaluation:

- ASTM D1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM D4332-14 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
- ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems

Test Case Name	Purpose	Conclusion
Labelling and packaging integrity verification	Prove integrity of device labeling, retail box and sterile barrier system following conditioning	Pass
Label indelibility test	Prove that product labels preserve their integrity and readability after conditioning	Pass
Dielectric strength test	Prove the device cable insulation is able to withstand high voltage electrical stresses beyond what would be encountered during normal use	Pass
Device integrity verification	Prove that the device keeps its integrity before and after exposure to stress conditions	Pass

Test Case Name	Purpose	Conclusion
AC impedance test	Prove the device is able to conduct signals between the electrodes on the strip and the corresponding electrodes on the cable with a total impedance ≤ 10 kΩ @ 10 Hz*	Pass
	Prove the device is compatible with the Cabrio L-SRL-4DIN connecting cable	Pass
	Prove the performance of the device with the Cabrio L-SRL-4DIN and WCS Link connecting cables is equivalent	Pass
Insulation test	Prove that the device insulation resistance meets requirements following 1 hour immersion in saline solution	Pass
Compatibility with recorders test	Prove the device is compatible with EEG/ECoG recorders measuring the values of offset voltage and combined offset instability and internal noise	Pass
Compatibility with stimulators test	Prove the device is compatible with commercially available neurostimulators (compliant with IEC60601-1 and IEC60601-2-40) by demonstrating the electrode's ability to deliver worst-case condition stimulating pulses	Pass
Stimulation and metal release test	Prove the device is able to deliver stimulation pulses for 48 hours in simulated conditions	Pass
	Prove the electrodes keep integrity following 48 hours of stimulation	Pass
	Prove that the platinum released from the electrodes during 48 hours stimulation is within safe limits	Pass
Bias current tolerance test	Prove the device is compatible with EEG/ECoG recorders measuring the values of the DC offset voltage does not exceed the limits of the input voltage when a DC bias current is applied to a pair of electrodes for 24 hours	Pass

Direct comparison testing of the subject device and the secondary predicate demonstrates that both devices meet the ≤ 10 kΩ acceptance criteria at 10 Hz. In addition, the subject device maintains this performance level even after exposure to worst-case stimulation conditions.

5 Biocompatibility Testing

Biocompatibility testing was performed based on the nature and duration of patient contact outlined in ISO 10993-1: "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and the FDA guidance document: *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* (September 2020). The device was tested per the ISO 10993-1 requirements for an externally communicating device with tissue contact and cerebrospinal contact for a limited duration (≤ 24 hours).

Test	**Result**	**Conclusion**
Cytotoxicity	The full strength EMEM10 test article extract showed no cytotoxic potential to L-929 mouse fibroblast cells	Non-cytotoxic
Sensitization	Topical application of the 0.9% NaCl extract and the sesame extract did not induce delayed sensitization in the guinea pig	Non-sensitizer
Intracutaneous reactivity	The 0.9% NaCl extract of the test article and the sesame extract did not induce any erythema or edema reactions after injection by intracutaneous route in the rabbit	Non-irritant
Pyrogenicity	Sum of temperature rises = 0.69°C No rabbit showed an individual temperature rise higher or equal to 0.5°C above its initial temperature	Non-pyrogenic
Acute Systemic Toxicity	There was no evidence of significant systemic toxicity or mortality after test article extracts injection	Non-toxic
Indirect Hemolysis	Based on the hemolytic index of the assay sample above the negative control, the WCS is demonstrated to be non-hemolytic for indirect contact	Non-hemolytic

Results of testing demonstrate that the materials used in the construction of the WCS are safe for their intended use.

6 Sterilization and Shelf-Life Testing

Sterilization of the subject device using Ethylene Oxide was validated following ANSI/AAMI/ISO 11135:2014 and demonstrated a SAL of 10^{-6}. A shelf-life of 18 months has been established based on accelerated aging.

7 Substantial Equivalence Conclusion

The WCS is substantially equivalent to the Ad-Tech Intraoperative Strip Electrode based on the intended use and technological characteristics as well as the intended users and intended use environment. Both devices have similar physical characteristics and stimulation parameters. The manufacturing differences are demonstrated through the testing to not adversely impact the subject device's safety or effectiveness. Therefore, one can conclude that the WISE Cortical Strip is substantially equivalent to the Ad-Tech Intraoperative Strip Electrode predicate device and is safe for its intended use.