November 10, 2022

Spes Medica SRL
Giorgio Facco
Quality Assurance & Regulatory Affairs
Via Europa - Zona Industriale
Battipaglia, 84091
Italy

Re: K211954
Trade/Device Name: Subdural Electrode, Strip/Intraoperative Strip, Grid/Intraoperative Grid, Multi-Strip and Split Grid, Intraoperative Mapping Grid
Regulation Number: 21 CFR 882.1310
Regulation Name: Cortical Electrode
Regulatory Class: Class II
Product Code: GYC

Dated: October 3, 2022
Received: October 11, 2022

Dear Giorgio Facco:

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)*
K211954

Device Name
Recording and stimulating for Central Nervous System electrodes, Spes Medica Subdural Electrodes, Spes Medica Strip/Intraoperative Strip, Spes Medica Grid/Intraoperative Grid, Spes Medica Multi-Strip and Split Grid, Spes Medica Intraoperative Mapping Grid

Indications for Use *(Describe)*
The Recording and stimulating for Central Nervous System electrodes (Strip/lntraoperative Strip, Grid/lntraoperative Grid, Multi-Strip and Split Grid, Intraoperative Mapping Grid) are intended for limited (24 hours) use with recording, monitoring, and stimulation equipment for electrical stimulation, monitoring and recording of the signals on the surface of the brain for intraoperative monitoring, brain mapping and location of epileptogenic foci.

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

Manufacturer's Name:	Spes Medica S.r.l. via Europa (Zona Ind.le), 84091 Battipaglia (SA) – Italy
510(k) number	K211954
Official Correspondent:	Giorgio Facco Quality Assurance and Regulatory Affairs
Telephone Number:	0039 0828 614191
Fax Number:	0039 0828 341788
Device Trade Name:	Subdural Electrode Strip/Intraoperative Strip, Grid/Intraoperative Grid, Multi-Strip and Split Grid, Intraoperative Mapping Grid
Trade Names:	Recording and stimulating for Central Nervous System electrodes
Common or Usual Name:	Subdural Electrode
Classification Name:	Cortical Electrode
Device Class:	Class II
Product Code:	GYC
Classification Regulation:	21 CFR 882.1310

Predicate Device:

Name	Electrode, Cortical
510(K) Number	K191186
Device Name	Subdural Strip/Intraoperative Split Electrode, Subdural Grid/Intraoperative Grid Electrode, Dual-Sided Interhemispheric Subdural Electrode, Multi-Strip And Slit Grid Subdural Electrode, Intraoperative Mapping Grid Subdural Electrode
Applicant	Ad-Tech Medical Instrument Corporation 400 West Oakview Parkway Oak Creek, WI 53154

Device Description:

The Recording and stimulating for Central Nervous System electrodes are used for electrical stimulation, monitoring and recording of the signals on the surface of the brain for intraoperative monitoring, brain mapping and location of epileptogenic foci

The electrodes are multipole arrays of electrodes that are positioned on the surface of the brain.

The electrode must be designed to follow the complex anatomy and they can assume different conformations in relation to the requests of clinical needs. The neurosurgeon is the person recommended for electrode placement.

The electrodes have to be used under the direction of the neurosurgeon and other skilled physicians to support their clinical needs

Intended Use: The Recording and stimulating for Central Nervous System electrodes (Strip/Intraoperative Strip, Grid/Intraoperative Grid, Multi-Strip and Split Grid, Intraoperative Mapping Grid) are intended for limited (≤24 hours) use with recording, monitoring, and stimulation equipment for electrical stimulation, monitoring and recording of the signals on the surface of the brain for intraoperative monitoring, brain mapping and location of epileptogenic foci.

Technological Comparison: The recording and stimulation electrode area is in platinum and is on polyurethane substrate body material. The cables is in PVC with touch proof 1.5 mm connector or with multi connector. The lead wires terminate in a safety connector that cannot be connected to an AC power outlet

The characteristics of Recording and stimulating for Central Nervous System electrodes are substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised, Recording and stimulating for Central Nervous System electrodes employ the same technological characteristics as the predicate device.

Substantial Equivalence: Recording and stimulating for Central Nervous System electrodes is equivalent to the device cleared under K191186 as is presented below in Table.

It has been shown in this 510(k) submission that the differences between the Recording and stimulating for Central Nervous System electrodes and the predicate device K191186 do not raise any questions regarding its safety and effectiveness. Recording and stimulating for Central Nervous System electrodes device is substantially equivalent to the predicate device as it has the same intended use and similar technological characteristics as the previously cleared predicate devices. Recording and stimulating for Central Nervous System electrodes, as designed and manufactured is determined to be substantially equivalent to the referenced predicate devices.

Manufacturer	Ad-Tech Medical Instrument Corporation	Spes Medica S.r.l.	Discussion Differences
Trade Name	**Subdural Strip/Intraoperative Split Electrode, Subdural Grid/Intraoperative Grid Electrode, Dual-Sided Interhemispheric Subdural Electrode, Multi-Strip And Slit Grid Subdural Electrode, Intraoperative Mapping Grid Subdural Electrode**	**Subdural Electrode, Strip/Intraoperative Strip, Grid/Intraoperative Grid, Multi-Strip and Split Grid, Intraoperative Mapping Grid**	
510(k) number	**K191186**	**K211954**	
Product Code	**GYC**	**GYC**	
Intent for use	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 Recording and stimulating for Central Nervous System electrodes (Strip/Intraoperative Strip, Grid/Intraoperative Grid, Multi-Strip and Split Grid, Intraoperative Mapping Grid) are intended for limited (≤24 hours) use with recording, monitoring, and stimulation equipment for electrical stimulation, monitoring and recording of the signals on the surface of the brain for intraoperative monitoring, brain mapping and location of epileptogenic foci.	The contact time duration of Recording and stimulating for Central Nervous System electrodes is ≤24 hours, lower than the predicate device. This range of time is anyway enough long to cover the clinical use described in the intent of use of Recording and stimulating for Central Nervous System electrodes which is of intraoperative monitoring, brain mapping and location of epileptogenic foci. The user is aware of the limited duration of the use thanks to the indication in the instruction for use leaflet. Therefore, the predicate device can be considered as the "worst case" as the time contact is < 30 days. Furthermore, according to the biocompatibility tests, Recording and stimulating for Central Nervous System electrodes result to be fully biocompatible so no new questions of safety or effectiveness are raised.
Regulation Name	Cortical Electrode	Cortical Electrode	The same of the predicate device
Regulation Number	882.1310	882.1310	The same of the predicate device
Device description	The device under review is a family of Subdural Electrodes. These electrodes provide surface brain contact to support recording, monitoring and stimulation from user supplied equipment.	The Recording and stimulating for Central Nervous System electrodes are used for electrical stimulation and recording of the central nervous system signals for intraoperative monitoring, brain mapping and	There is no significant difference between the device description. The electrodes have the same site of contact in the huma body, both the

Manufacturer	Ad-Tech Medical Instrument Corporation	Spes Medica S.r.l.	Discussion Differences
Trade Name	**Subdural Strip/Intraoperative Split Electrode, Subdural Grid/Intraoperative Grid Electrode, Dual-Sided Interhemispheric Subdural Electrode, Multi-Strip And Slit Grid Subdural Electrode, Intraoperative Mapping Grid Subdural Electrode**	**Subdural Electrode, Strip/Intraoperative Strip, Grid/Intraoperative Grid, Multi-Strip and Split Grid, Intraoperative Mapping Grid**	
510(k) number	**K191186**	**K211954**	
Product Code	**GYC**	**GYC**	
	The family of Subdural Electrodes under review are used under the direction of neurosurgeons and other skilled physicians to support their clinical needs for subdural electrodes on the brain. Based upon the needs of their clinical practice and particular patients, various 2-dimensional geometric shapes (length and width) resulting in variations of Subdural Electrode body shapes and orientation configurations are necessary. All variations of Subdural Electrodes under review consist of the same materials and fundamental design as the predicate Subdural Electrodes. Either round discs or rectangular electrode contact material are sandwiched between two layers of silicone substrate electrode body material. The brain contacting side of the silicone substrate body has material removed to expose an amount of electrode contact surface area. The subdural electrode wires between the electrode contact and connector contacts at the most distal end of the subdural electrode tail pass through a tube for interface with the user's equipment.	location of epileptogenic foci. The electrodes are multipole arrays of electrodes that are positioned on the surface of the brain. Recording and stimulating for Central Nervous System electrodes are multipolar arrays of electrodes the surface of the brain. The electrode must be designed to follow the complex anatomy and they can assume different conformations in relation to the requests of clinical needs. The neurosurgeon is the person recommended for electrode placement. The electrodes have to be used under the direction of the neurosurgeon and other skilled physicians to support their clinical needs	electrodes are positioned on the surface of the brain during use. Both the electrodes are used for recording, monitoring and stimulation. Both the electrodes have different shape in relation to the clinical needs. So there is no significant different between the two description, just a different use of the words depending on the writer. No new questions of safety or effectiveness are raised.
Recording/Stimulation area Diameter	4, 5 mm	4, 5 mm	The same of the predicate device
Electrode Body surface area	≤ 138 cm2	≤ 138 cm2	The same of the predicate device
Spacing between the contacts	10 mm	10 mm	The same of the predicate device
Connector	DIN 42802	DIN 42802	The same of the predicate device
Leadwire Length	200 cm	250 cm	No significant difference. The Recording and stimulating for Central Nervous System electrodes

Manufacturer	Ad-Tech Medical Instrument Corporation	Spes Medica S.r.l.	Discussion Differences
Trade Name	**Subdural Strip/Intraoperative Split Electrode, Subdural Grid/Intraoperative Grid Electrode, Dual-Sided Interhemispheric Subdural Electrode, Multi-Strip And Slit Grid Subdural Electrode, Intraoperative Mapping Grid Subdural Electrode**	**Subdural Electrode, Strip/Intraoperative Strip, Grid/Intraoperative Grid, Multi-Strip and Split Grid, Intraoperative Mapping Grid**	
510(k) number	**K191186**	**K211954**	
Product Code	**GYC**	**GYC**	
			is 50 cm longer than the predicate device but this is a no relevant different considering that the predicate device cable is 2 meter long as well. No new questions of safety or effectiveness are raised considering also that the LAL and bioburden tests performed on Recording and stimulating for Central Nervous System electrodes had results in compliance with the standard
Recording/Stimulation area material	Platinum/Iridium or Stainless Steel	Platinum/Iridium	The same of the predicate device for platinum/Iridium. Spes Medica do not supply the Stainless steel version
Substrate material	Silicone	Polyurethane	No significant difference. Both the materials have a large use in medical devices field. Furthermore, the Recording and stimulating for Central Nervous System electrodes result to be fully biocompatible so no new questions of safety or effectiveness are raised
Leadwire	Tinned Copper with PVC Jacket Connector	Tinned Copper with PVC Jacket Connector	The same of the predicate device
Single Use	Yes	Yes	The same of the predicate device
Provided to the user sterile	Yes	Yes	The same of the predicate device
Sterilization	Ethylene Oxide	Ethylene Oxide	The same of the predicate device
Shelf life	2 years	3 years	Spes Medica electrodes have a shelf-life longer than the predicate device,

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510(k) number	**K191186**	**K211954**	
Product Code	**GYC**	**GYC**	
			however the tests about shelf-life validation have been performed by Spes Medica and the results were compliant. So no new questions of safety or effectiveness are raised.
Single Use	Yes	Yes	The same of the predicate device
Duration of Use	< 30 days	≤24 hours	The contact time duration of Recording and stimulating for Central Nervous System electrodes is ≤24 hours, lower than the predicate device. This range of time is anyway enough long to cover the clinical use described in the intent of use of Recording and stimulating for Central Nervous System electrodes which is of intraoperative monitoring, brain mapping and location of epileptogenic foci. The user is aware of the limited duration of the use thanks to the indication in the instruction for use leaflet. Therefore, the predicate device can be considered as the "worst case" as the time contact is < 30 days. Furthermore, according to the biocompatibility tests, Recording and stimulating for Central Nervous System electrodes result to be fully biocompatible so no new questions of safety or effectiveness are raised.

Manufacturer	Ad-Tech Medical Instrument Corporation	Spes Medica S.r.l.	Discussion Differences
Trade Name	**Subdural Strip/Intraoperative Split Electrode, Subdural Grid/Intraoperative Grid Electrode, Dual-Sided Interhemispheric Subdural Electrode, Multi-Strip And Slit Grid Subdural Electrode, Intraoperative Mapping Grid Subdural Electrode**	**Subdural Electrode, Strip/Intraoperative Strip, Grid/Intraoperative Grid, Multi-Strip and Split Grid, Intraoperative Mapping Grid**	
510(k) number	**K191186**	**K211954**	
Product Code	**GYC**	**GYC**	
Maximum Stimulation Charge Density	≤ 30 µC/cm2	≤ 30 µC/cm2	The same of the predicate device
Environment of Use	Operating rooms and temporary	Operating rooms and temporary	The same of the predicate device
Contraindications	The subdural electrodes should not be used on any patient whom the physician/surgeon considers at risk for infection. The subdural electrodes are not intended for continuous stimulation. Stimulation should only be applied to support the brain mapping purpose of the electrodes	The electrode is not recommended for continuous stimulation. Stimulation should be only applied to support brain mapping. The electrodes should not be used on patients with high risk of infection	The same of the predicate device. Spes medica has inserted all these points in the warnings in the instruction for use

Performance Testing Summary

Test	Description	Result	Conclusion
Cytotoxicity (performed on IEP0020)	These methods are designed to determine the biological response of mammalian cells in vitro using appropriate biological parameters.	Test sample results to have a reactivity grade of 0 (=none reactivity)	**NON-CYTOTOXIC** No test extract does not show any reactivity
Skin Irritation (performed on IEP0020)	This method describes the procedure for the assessment of medical devices and their constituent materials with regard to their potential to produce irritation and skin sensitization.	The requirements of the test are met if the final test sample score is 1.0 or less. The final test sample score is 1.0. Very slight erythema (barely perceptible).	**NON-IRRITATING** The test item satisfied the requirements of the test which require a final score

Performance Testing Summary			
Test	**Description**	**Result**	**Conclusion**
Skin sensitization (performed on IEP0020)	This method describes the procedure for the assessment of medical devices and their constituent materials with regard to their potential to produce irritation and skin sensitization.	The results show a % sensitising treated guinea pigs equal to 0% (=no visible change)	**NON-SENSITIZING** On the basis of the results the tested item must be considered not sensitizing.
Systemic toxicity (performed on IEP0008)	This method is a biological evaluation to evaluate the systemic toxicity .	Weight increase: no weight loss was recorded in any treated and control animals. Mortality: in none of the treated and control animals mortality was observed. Clinical symptoms: in none of the treated and control animals toxic signs or symptoms were observed.	**DO NOT CAUSE TOXIC SYMPTOMS** On the basis of the results the tested item doesn't cause toxic symptoms and satisfies the requirements of the test.
Pyrogenicity test (performed on IEP0008)	The aim of the present report is to describe procedure and results obtained for Pyrogen Test.	Two of the eight rabbits showed individual rise of temperature 2 0.5°C and the sum of the eight individual rises is 2.0°C (<3.3° C).	**ABSENCE OF PYROGENS** On the basis of the results the tested item meets the requirement for the absence of pyrogens
Hemolysis test (performed on IEP0020)	The aim of the present report is to evaluate if the test item causes material induced hemolysis for indirect contact, according to ASTM F 756-17	The final hemolytic index for all the three experimental replicates result to be between the range 0-2 which means: non hemolytic grade.	**NOT HEMOLYTIC for indirect contact** On the basis of the results the tested item is not hemolytic for indirect contact.
Packaging Validation Protocol (3 years of shelflife)	The accelerated aging process describes a procedures for developing accelerated aging protocols to rapidly determine the effects, if any, due to the passage of time on sterile integrity of the sterile barrier system.	The results of the tests on medical devices sterile barrier system samples in object not aged [referred as T0] and aged in accelerated conditions for the period corresponding to foreseen shelf life [referred as T3] are as follow: – Visual inspection: compliant – Seals integrity: compliant – Peeling: compliant – Seals width: compliant – Pinholes absence: compliant	For the samples in object, the obtained results conduct to the following conclusions: – Sterile barrier characteristics: the pouches samples have no damage or alteration due to aging process and are coherent with the not aged ones. – Products characteristics: the medical devices were not morphologically and visually damaged when compared to not aged samples. – Sterile barrier system verification: after an accelerated aging process simulating 3 years of shelf - life, the verification data for sterile barrier
Packaging validation test (Sterility test)	The test is performed in order to determine the charge (expressed in Newton/cm2) necessary to separate the two sides of the seal. This test is performed on both dry and wet material.		

Performance Testing Summary			
Test	**Description**	**Result**	**Conclusion**
		– Microorganisms impermeability: compliant – Seals strength: compliant. Average strength internal pouch at T0: 2,22 N/1,5mm. Average strength outer pouch at T0: 2,32 N/1,5mm. Average strength internal pouch at T3: 2,15 N/1,5mm. Average strength outer pouch at T0: 2,42 N/1,5mm. – Sterility tests: compliant, Sterile.	systems result in compliance with requirements and the medical devices samples are sterile; it is also noted that no discrepancies have been found with respect to the results obtained in the tests conducted on the non-ageing referenced samples. So, it can be concluded that the sterile barrier system (double flat pouch in coupled material), used for Spes Medica recording and stimulating for Central nervous system electrodes maintains the integrity, i.e. its efficacy, for the foreseen shelf - life period corresponding to 3 years.
Cable tensile testing	Spes Medica have been tested to get a feedback on the tensile strength of subdural electrodes and to understand the limit value during pull out the cable.	All the results are found to be in compliance with the pass/fail criteria set at the beginning of the test. All the tensile strength evaluates results to be greater than 30N.	The results obtained show that for Recording and stimulating for Central Nervous System electrodes have a very high strength force during the pull-out test. The average is 41.35 N and this value doesn't affect the electrode or the connection part but it is the limit of the cables. The results give to Recording and stimulating for Central Nervous System electrodes the safety of manufacturing process and the strength of the use.
Impedance test and dielectric strength	Spes Medica have been tested to get a feedback on the subdural electrodes use not only for recording but also for stimulation. The aim is to confirm that the devices do not lose their features or worsen their performances after stimulation.	All the results are found to be in compliance with the pass/fail criteria set at the beginning of the test. All the impedance evaluates results to be less than 5kOhm both pre and post simulation.	The results obtained show that for Recording and stimulating for Central Nervous System electrodes stimulation doesn't affect or get worse the electrode performance.
Electrically Safety - Insulation	Evaluate the isolation of the product in the different part at different voltage 250V, 500V and 1000V.	All the different parts of the electrode (connector, case, dielectric) results to be insulated.	The results obtained show that for Recording and stimulating for Central Nervous System electrodes are isolated and are in compliance with requirements for electrical safety.
Climatic Tests	Understand if changing temperature and relative humidity (RH) have effects on	The test samples have been subjected to the following test:	No damage of the product has been observed

Performance Testing Summary			
Test	**Description**	**Result**	**Conclusion**
	packaging and materials which may be related to their field performance.	• Refrigerated storage test • Extreme cold test • Tropical test with positive results. The test sample after that have been subjected to vibration tests	
Shipment Tests	Understand if: • HANDLING TEST, • VEHICLE STACKING TEST, • LOOSE LOAD VIBRATION TEST, • VEHICLE VIBRATION TEST, • CONCENTRATED IMPACT TEST have a impact on packaging and materials.	The result of the following tests • HANDLING TEST, • VEHICLE STACKING TEST, • LOOSE LOAD VIBRATION TEST, • VEHICLE VIBRATION TEST, • CONCENTRATED IMPACT TEST are found to be in compliance with the pass/fail criteria of the tests	No damage of the product has been observed

We specify that the test articles used in all the tests showed in the *Performance Testing Summary* table are identical to the finished, sterilized proposed in the 510(k) submission per formulation, suppliers, processing, packaging, sterilization (including dose and duration), and geometry and no chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents).

Conclusion

All performance testing conducted as outlined above demonstrate that the device met the performance and design specifications.
Based on the results obtained, Spes Medica s.r.l. believes that Recording and stimulating for Central Nervous System electrodes is substantially equivalent and performs as well as the the predicate devices (K191186).