March 12, 2019

CorTec GmbH
Mara Assis
Regulatory Affairs & Quality Management
Neuer Messplatz 3
79108 Freiburg i. Br., Germany

Re: K183437
Trade/Device Name: AirRay Subdural Cortical Electrodes
Regulation Number: 21 CFR 882.1310
Regulation Name: Cortical Electrode
Regulatory Class: Class II
Product Code: GYC
Dated: November 30, 2018
Received: December 12, 2018

Dear Mara Assis:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jay R. Gupta -S

For Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183437

Device Name
AirRay Subdural Cortical Electrodes

Indications for Use *(Describe)*
The °AirRay® Subdural Cortical Electrodes (Strips and Grids) 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 level of the brain. The recording of electrical activity supports definition of the location of epileptogenic foci and brain mapping.

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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K183437 Traditional 510(k) Summary
°AirRay® Subdural Cortical Electrodes

Submitter	CorTec GmbH Neuer Messplatz 3 79108 Freiburg i. Br., Germany Tel: +49 (0)761 70 888 100 Fax: +49 (0)761 70 888 399 E-mail: sales@cortec-neuro.com
Contact Person	Mara Assis Regulatory Affairs & Quality Management E-mail: mara.assis@cortec-neuro.com
Date	March 12, 2019
Device Name	°AirRay® Subdural Cortical Electrodes
Common Name	Strip and Grid Subdural Electrodes
Classification	Cortical Electrode 21 CFR 882.1310, Class II
Product Code	GYC, Cortical Electrode
Predicate Device(s):	510(k) Number: K053363 Manufacturer: Ad-Tech Medical Instrument Corporation Trade Name: AD-TECH Subdural Cortical Electrodes (Dual-Sided Interhemispheric, Grid, Intraoperative, Strip, Wyler) Product Code: GYC Classification: 21 CFR 882.1310

Intended Use
The °AirRay® Subdural Cortical Electrodes Subdural electrodes are single patient use, disposable, sterile devices.

The electrodes are invasive as they are placed in contact with the brain.

The electrodes provide the patient contact device. The electrodes connect to the user's recording, monitoring and stimulation/response equipment. The electrodes are used under the supervision of a physician. Physicians in the areas of biopotential recording, monitoring and stimulation/response studies understand the use of subdural electrodes.

Indication for Use
The °AirRay® Subdural Cortical Electrodes (Strips and Grids) 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 level of the brain. The recording of electrical activity supports definition of the location of epileptogenic foci and brain mapping.

Conformance to Special Controls / Performance Standards/ Recognized Consensus Standards
There are no special controls/performance standards associated with Product Code GYC. However, conformance to the following recognized consensus standards is declared:

FDA #	Standard Name
5-87	IEC 62366 Consolidated Version Medical Devices - Application of Usability Engineering to Medical Devices:2014, Version 1.1
2-156	ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within A Risk Management Process: 2009(R)2014
14-452	ISO 11135-1 Sterilization of Health-Care Products - Ethylene Oxide - Requirements for The Development, Validation and Routine Control of ASterilization Process for Medical Devices: 2014
14-454	ISO 11607-1 Packaging for Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems [Including: Amendment 1(2014)]
14-455	ISO 11607-2 Packaging for Terminally Sterilized Medical Devices - Part 2: Requirements for Materials, Sterile Barrier Systems and Packaging Systems [Including: Amendment 1(2014)]

Comparison to Predicates

The primary differences between the AirRay® Subdural Cortical Electrodes (subject device) and the predicate are:

- The proposed device offers fewer variants than the predicate.
- The proposed device can accommodate 32 contacts per electrode connector instead of 16 contacts.

Biocompatibility Summary Table

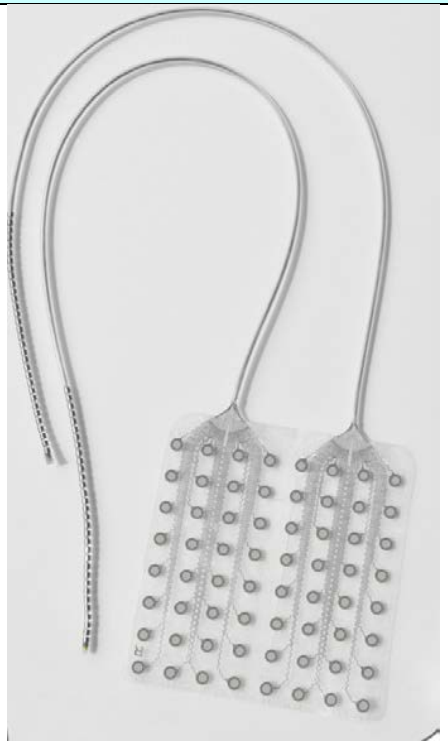
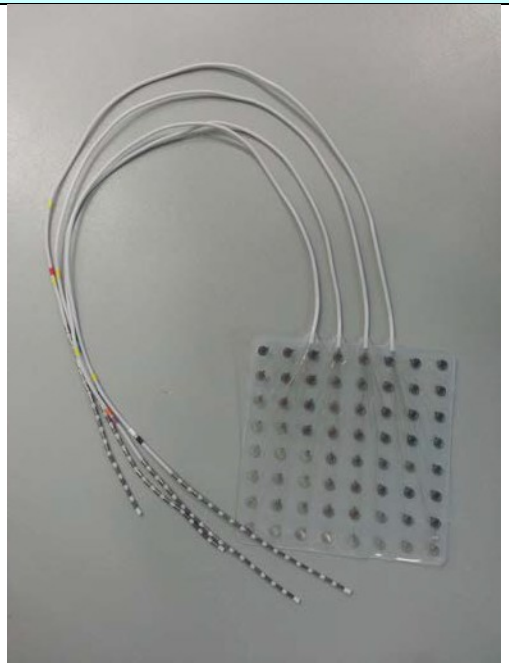
The AirRay Subdural Cortical Electrodes is categorized as an implant device in prolonged (up to 30 days) contact with neural tissue/bone, cerebrospinal fluid (CSF) and blood (indirect blood contact through CSF as CSF is reabsorbed into the venous system). Based on this classification, tests relevant to the device were selected and conducted on the finished, sterilized device in accordance with ISO 10993-1 and 2016 FDA Biocompatibility Guidance. All biocompatibility studies were conducted in compliance with Good Laboratory Practices (GLP), 21 CFR Part 58. The results of the biocompatibility testing are summarized in the Table below. All prespecified acceptance criteria were met and all tests passed.

Test (Applicable ISO 10993 Part No.)	Test Method	Results	Conclusion
Cytotoxicity (10993-5)	BCA Protein Cytotoxicity Assay with Test Extract using L-929 Mouse Fibroblast Cells	Pass	Non-cytotoxic
Sensitization (10993-10)	Guinea Pig Maximization Sensitization Test	Pass	Non-sensitizer
Irritation (ISO 10993-10)	Intracutaneous Reactivity Test	Pass	Non-irritant
Acute Systemic Toxicity (ISO 10993-11)	Acute Systemic Injection Test	Pass	No acute systemic toxicity
Material- mediated Pyrogenicity (ISO 10993-11)	Rabbit Pyrogen Test	Pass	Non-pyrogenic

Test (Applicable ISO 10993 Part No.)	Test Method	Results	Conclusion
Hemocompatibility (ISO 10993-4)	Indirect Hemolysis Test (extract test)	Pass	Non-hemolytic
Subchronic Toxicity (ISO 10993-11)	4-week Systemic Toxicity Study following Subcutaneous Implantation in Rats	No systemic or local toxicities were observed in this study. Clinical observations, body weights, organ weights, organ/body weight ratios, hematology and clinical chemistry values, and necropsy results were acceptable. Microscopic evaluation of the collected organs revealed no evidence of systemic toxicity related to the test article. Microscopic evaluation of the implantation sites indicated no difference in the local tissue response between the control and test articles.	No subchronic systemic toxicity
Genotoxicity (ISO 10993-3)	• Bacterial Mutagenicity Test (Ames Assay) • In Vitro Mouse Lymphoma Assay	Pass Pass	Non-mutagenic Non-mutagenic / clastogenic

Test (Applicable ISO 10993 Part No.)	Test Method	Results	Conclusion
Implantation (ISO 10993-6)	A 4-week brain implantation study was conducted in rabbits. The test article and negative control article (HDPE) were implanted in separate animals. Both male and female animals were used in the study. Throughout the study, assessments of general health, neurological examinations, and body weight measurements were performed. There were two termination points in the study – 1 week and 4 weeks. At each termination timepoint, the cranium with the brain were collected. The implant sites and the cervical draining lymph nodes were macroscopically evaluated, collected, histologically processed, and microscopically evaluated. Following stains were used for histopathology - hematoxylin and eosin (H&E), Iba-l for microglia, luxol fast blue (LFB) for myelin, anti-glial fibrillary acid protein (GFAP) antibody for astroglia, and fluoro-jade B (FJB) for neuronal degeneration/necrosis. The macroscopic and microscopic evaluations were performed by a board certified veterinary pathologist.	Overall, there were no adverse local effects attributed to the implanted articles. All implanted animals survived the study with no clinical or neurological findings that were attributable to the test article or the negative control article. There was no evidence of cerebrospinal fluid leakage or infection for the test article or the negative control article. At both 1 and 4 weeks timepoints, the test article was considered to elicit no or minimal reaction in comparison to the negative control article.	No adverse local effects in neural tissues, no neurotoxicity

K183437 Traditional 510(k) Summary

Characteristic	Proposed Device: CorTec AirRay® Subdural Cortical Electrodes K183437	Predicate Device: Ad-Tech Medical Subdural Cortical Electrodes K053363	Comments
BASIC INFORMATION AND USES			
Picture			The pictures show that the Proposed Device models shown (64 contact grid) for the proposed device is 80 mm x 86 mm with 370 mm electrode cables; the predicate device is 80 mm x 80 mm with 375 mm electrode cables. They are made with similar materials (silicone body and cables with platinum:iridium contacts). The manufacturing techniques of the proposed device allows for 32 contacts per cable, while the predicate only allows 16. The differences are minor and do not affect safety or effectiveness. Acceptable
FDA Device Type	Cortical Electrode	Cortical Electrode	Acceptable
FDA Product Code	GYC (cortical electrodes)	GYC (cortical electrodes)	Acceptable
FDA Class	II	II	Acceptable
FDA Regulation	CFR 882.1310	CFR 882.1310	Acceptable
Intended Use	Subdural electrodes are single patient use, disposable, sterile devices. The electrodes are invasive as they are placed in contact with the brain. The electrodes provide the patient contact device. The electrodes connect to the user's recording, monitoring and	Subdural electrodes are single patient use, disposable, sterile and non-sterile devices. The electrodes are invasive as they are placed in contact with the brain. The electrodes provide the patient contact device. The electrodes connect to the user's recording, monitoring and	Acceptable

K183437 Traditional 510(k) Summary

Characteristic	Proposed Device: CorTec AirRay® Subdural Cortical Electrodes K183437	Predicate Device: Ad-Tech Medical Subdural Cortical Electrodes K053363	Comments
	stimulation/response equipment. The electrodes are used under the supervision of a physician. Physicians in the areas of biopotential recording, monitoring and stimulation/response studies understand the use of subdural electrodes	stimulation/response equipment. The electrodes are used under the supervision of a physician. Physicians in the areas of biopotential recording, monitoring and stimulation/response studies understand the use of subdural electrodes.	
Device Family Members	Strips, Grids	Dual-Sided, Interhemispheric, Grid, Intraoperative, Strip, Wyler	Grids and strips are contained within the cleared electrode types of the predicate. Offering fewer product variants does not raise any new questions of safety or effectiveness. Therefore, acceptable.
Indication for Use	The °AirRay® Subdural Cortical Electrodes (Strips and Grids) 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 level 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.	Except for branding and the more limited subset of family members, the proposed device is identical to the predicate. Branding issues and offering fewer product variants does not raise any new questions of safety or effectiveness Therefore, acceptable.
Contraindications	The subdural electrodes should not be used on any patient who 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 subdural electrodes should not be used on any patient who 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	Identical to the predicate. Therefore, acceptable.
Intended User	Physicians, Surgeons, Epileptologists, Electrophysiologists, Neurosurgeons, Neurologists	Not stated formally, but clinically known in the industry to be: Physicians, Surgeons, Epileptologists, Electrophysiologists, Neurosurgeons, Neurologists	Although not known to be formally stated in the predicate's submission, the intended users are assumed to be identical to the predicate. Therefore, acceptable.
Intended Environment of Use	Operating rooms and epilepsy monitoring facilities	Not stated formally but clinically known to be: Operating rooms and epilepsy monitoring facilities	Although not known to be formally stated in the predicate's submission, the intended Environment of Use are assumed to be identical to the predicate. Therefore, acceptable.

K183437 Traditional 510(k) Summary

Characteristic	Proposed Device: CorTec AirRay® Subdural Cortical Electrodes K183437	Predicate Device: Ad-Tech Medical Subdural Cortical Electrodes K053363	Comments
Targeted Patient Population	Not stated formally	Not stated formally	Neither the proposed device nor the predicate device states the targeted patient population (nor do any other similar devices cleared under the same product code). In clinical practice the use of the device is up to the applicable physician. Not stating a targeted patient population does not raise any new questions of safety or effectiveness. Therefore, acceptable.
LABELING & PACKAGING INFORMATION			
Product Identification	XXXX.XXXX.XX e.g. 2011.1020.01 **201**X.XXXX.XX general product definition (group), here: 201 = ECoG electrode; XXX**1**.XXXX.XX product type regarding manufacturing, here: 1 = final product XXXX.**1**XXX.XX product application, here: 1 = clinical product XXXX.X**020**.XX consecutive number, here: 020 XXXX.XXXX.**01** product variant, here: 01 = defined color coding	AANNR-YYMS-000 AA = The electrode type where IS=Numbered Strip, TS=non-numbered strip or FG=Grid NN= Number of contacts R = The type of contact (various options exist for small, indented, square, etc. electrodes) YY = the spacing between contacts M= Metal Type, where P=Platinum, S=Stainless Steel S = Sterility Status where X= Sterile, N=Non-Sterile 000 = Uniqueness of electrode	Both companies use a formulaic catalog numbering system to encode for the applicable variants. Minor differences exist to reflect marketing preferences and fewer choices/options for the proposed device. These issues do not affect the safety or effectiveness of the device. Therefore, Substantially Equivalent
Schematic	The proposed device includes a “Code Chart” identifying the layout of the electrode as well as the color coding identification of the electrode cable(s) [aka tail(s)] of the electrode.	The predicate device includes a “Code Chart” identifying the layout of the electrode as well as the color coding identification of the electrode cable(s) [aka tail(s)] of the electrode.	Both companies include a code chart to show the user the layout and color-coding of the electrode. Minor differences exist based on layout, font sizes, marketing issues, etc. These issues do not affect the safety or effectiveness of the device. Therefore, Substantially Equivalent
Cautionary Statements	Comment: See the instructions for use for a full list. MR UNSAFE	For Single Use Only. Do not Re-Sterilize or Reuse. Not intended of Implantation (21 CFR 860.3(d): > 30 days. For Surgical Use Only. Do not use if packaging is damaged. CAUTION: Federal Law (U.S.A.) restricts this Device to sale by or on the order of a	To comply with CE marking requirements, the proposed device includes additional caution/warning statements than the predicate, but doing so does not raise any new questions of safety or effectiveness. Identical to the predicate. Therefore,

K183437 Traditional 510(k) Summary

Characteristic	Proposed Device: CorTec AirRay® Subdural Cortical Electrodes K183437	Predicate Device: Ad-Tech Medical Subdural Cortical Electrodes K053363	Comments
		physician CAUTION: Reuse of this Device is prohibited as it may malfunction and cause contamination and risk to the patient, CAUTION: Disconnect from monitoring equipment during cardiac defibrillation.	acceptable.
Sterility status of the electrodes	Sterile only	Both sterile and non-sterile devices are offered.	Sterile only devices are within the boundaries of the predicate and offering only sterile devices does not raise any new questions of safety or effectiveness. Therefore, acceptable.
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Identical to the predicate. Therefore, acceptable.
Packaging Configuration	Individually packaged in a labeled pouch that ships in its own labeled box along with directions for use and a code chart.	Individually packaged in a labeled pouch that ships in its own labeled box along with directions for use and a code chart.	Identical to the predicate. Therefore, Substantially Equivalent
Non-Pyrogenic	not so labeled, but bacterial endotoxin testing demonstrates that the subject device meets ≤ 2.15 EU/device endotoxin limit requirement; endotoxin levels on the device are less than 2.15 EU/device, which is the endotoxin limit for the CSF-contacting device.	Not so labeled	Identical to the predicate. Therefore, acceptable.
Single Patient Use, Disposable	Yes	Yes	Identical to the predicate. Therefore, acceptable.
ELECTRODE CONTACT INFORMATION			
Number of Electrode Contacts	Strips: 4 to 8, Inclusive Grids: 4 to 64, inclusive	Strips: 1 to 16, Inclusive Grids: 3 to 128, inclusive	The number of contacts for the proposed devices is within the boundaries of the predicate, offering a narrower range of contacts does not raise any new questions of safety or effectiveness. Therefore, acceptable.
Electrode Contact Spacing	10 mm Other variations can be requested by the customer.	10 mm Other variations can be requested by the customer.	The number of contacts for the proposed devices is within the boundaries of the predicate. Offering a narrower range of contacts does not raise any new questions of

K183437 Traditional 510(k) Summary

Characteristic	Proposed Device: CorTec AirRay® Subdural Cortical Electrodes K183437	Predicate Device: Ad-Tech Medical Subdural Cortical Electrodes K053363	Comments
			safety or effectiveness Therefore, acceptable.
Electrode Contact Material	90:10 Platinum:iridium	90:10 Platinum:iridium or Stainless Steel	90:10 Platinum:Iridium is within the boundaries of the predicate. Offering a fewer electrode contact materials does not raise any new questions of safety or effectiveness Therefore, acceptable.
Electrode Contact Size (exposed surface area)	2.7 mm diameter	1.5 mm x 1.5 mm, 1.5 mm x 3.0 mm, 2.3 mm diameter, 4.0 mm diameter – per the K053363 submission 1.17, 1.8 mm, 5 mm dia. (exposed) currently marketed	The diameter of the contacts for the proposed devices is within the boundaries of the predicate. Offering a narrower range of contact diameters does not raise any new questions of safety or effectiveness. Therefore, acceptable.
ELECTRODE CABLE (aka electrode tail) INFORMATION			
Maximum contacts per electrode cable	32	16	The proposed device offers more potential contacts per electrode cable than the predicate. Doing so reduces the number of incisions needed to tunnel the cables away from the surgical site. Although this aspect of the electrodes is viewed to be a feature of the design process, and in theory reduces the risk of infection, it does not affect the overall design intent/indication for use of the device or its safety or effectiveness. Therefore, acceptable.
Diameter of the electrode cable	1.8 mm	1.5 to 2.1 mm	The diameter of the electrode cable for the proposed devices is within the boundaries of the predicate and does not raise any new questions of safety or effectiveness. Therefore, acceptable.
CONNECTION CABLE (Electrode to EEG) INFORMATION			
Connection Cable (510(k) Exempt)	The connection cable terminates in a safety female DIN connector. It connects the electrode cable via the connector to the amplifier / stimulator.	TECH-ATTACH and Cabrio™ Connection Systems which connect to a patient cable that terminates in a safety female Din connector. It connects the electrode cable via the connector to the amplifier / stimulator	Although per 21CFR890.1175, the electrode-to-EEG/Stimulator cables are exempt from 510(k) submissions, their use is still vital to connect the proposed/predicate devices to a third-party EEG. Although the specific manufacturing methods vary, both the proposed and predicate device comply with

K183437 Traditional 510(k) Summary

Characteristic	Proposed Device: CorTec AirRay® Subdural Cortical Electrodes K183437	Predicate Device: Ad-Tech Medical Subdural Cortical Electrodes K053363	Comments
			the applicable safety standards and share the same overall design intent. Therefore, acceptable.
PRINCIPLES OF OPERATION			
Interactions with Third Party EEGs/ Stimulators	Subdural electrodes themselves are non-active and serve simply as conductors for the EEG signals produced by the CNS and/or for the currents produced by the stimulators. In a sense, they simply serve as electrical pathways. Nonetheless formal compatibility testing was done on commercially-available ECoG systems and stimulators.	While not formally stated in the predicate's 510(k) summary statement or labeling, it is known that the predicate 510(k) submission maintained that the devices are non-active and serve simply as conductors for the EEG signals produced by the CNS and/or for the currents produced by the stimulators. In a sense, they simply serve as electrical pathways	Both devices are essentially "wires' that simply conduct electricity. However, the formal testing that the proposed device undertook does not raise any new questions of safety or effectiveness. Therefore, acceptable.
Stimulation Parameters	As stated on the instructions for use, a safe level of stimulation is below 50 $\mu C/cm^2$ and an acceptable stimulation is between 50 $\mu C/cm^2$ and 108 $\mu C/cm^2$ This is a function of exposed electrode contact size, pulse duration and stimulation current.	As stated on the instructions for use, a safe level of stimulation is below 50 $\mu C/cm^2$ and an acceptable stimulation is between 50 $\mu C/cm^2$ and 150 $\mu C/cm^2$ This is a function of exposed electrode contact size, pulse duration and stimulation current.	Both devices claim an identical safe level of stimulation to be less than 50 $\mu C/cm^2$. The proposed device claims an acceptable range that is more conservative (108 $\mu C/cm^2$ versus 150 $\mu C/cm^2$ than the predicate. However, being more restrictive does not raise any new questions of safety or effectiveness. Therefore, acceptable.

K183437 Traditional 510(k) Summary

Characteristic	Proposed Device: CorTec AirRay® Subdural Cortical Electrodes K183437	Predicate Device: Ad-Tech Medical Subdural Cortical Electrodes K053363	Comments
Contains Software/Firmware	No	No	Identical to the predicate. Acceptable.
STANDARDS & TESTING			
Conformance to Standards	• IEC 62366 Consolidated Version Medical Devices - Application of Usability Engineering to Medical Devices:2014, Version 1.1 • ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within A Risk Management Process: 2009(R)2014 • ISO 11135-1 Sterilization of Health-Care Products - Ethylene Oxide - Requirements for The Development, Validation and Routine Control of A Sterilization Process for Medical Devices: 2014 • ISO 11607-1 Packaging for Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems [Including: Amendment 1 (2014)] • ISO 11607-2 Packaging for Terminally Sterilized Medical Devices - Part 2: Requirements for Materials, Sterile Barrier Systems and Packaging Systems [Including: Amendment 1 (2014)]	None stated in the public summary for the device.	The proposed device declares compliance to the current, applicable standards pertaining to human factors, biocompatibility, sterilization and packaging while the predicate does not. However, doing so does not raise any new questions of safety or effectiveness. Acceptable.
Electrical Performance Testing	As part of the manufacturing process, the electrodes are checked for electrical continuity and lack of cross-talk between channels. The devices were physically tested for dielectric strength, impedance and corrosion on new and aged products.	As part of the manufacturing process, the electrodes are checked for electrical continuity and lack of cross-talk between channels. It is known that the submission contained theoretical calculations for dielectric breakdown of the insulation and the current-carrying capacity of the internal electrode wires. No formal test results were submitted.	The proposed device underwent formal electrical testing while the predicate did not. However, being more rigorous does not raise any new questions of safety or effectiveness. Therefore, Substantially Equivalent
Electrical Safety Testing	Not Conducted – Not Applicable	Not Conducted – Not Applicable	Identical to the predicate. Therefore, Substantially Equivalent

K183437 Traditional 510(k) Summary

Characteristic	Proposed Device: CorTec AirRay® Subdural Cortical Electrodes K183437	Predicate Device: Ad-Tech Medical Subdural Cortical Electrodes K053363	Comments
EMC Testing	N/A	N/A	N/A
Mechanical Performance Testing	The devices were physically tested for tensile strength, hardness and bending on new and aged products as well as underwent testing for their mechanical properties.	Not Stated – it is known that the submission did not include formal mechanical testing	The proposed device underwent formal mechanical testing while the predicate did not. However, being more rigorous does not raise any new questions of safety or effectiveness. Acceptable
MRI Testing	MR UNSAFE; Not testing The AirRay Subdural Cortical Electrodes is MR Unsafe	Not Stated	Labeling the device in an identical manner to the predicate does not raise any new questions of safety or effectiveness. Acceptable.
Human Factors Testing	The devices are in conformance with the requirements of IEC 62366 (Usability Engineering)	Not Stated – it is known that the submission did not include formal Human Factors testing	The proposed device underwent formal human factors / usability engineering testing while the predicate did not. However, being more rigorous does not raise any new questions of safety or effectiveness. Acceptable.

Conclusion

The proposed AirRay® Subdural Cortical Electrodes and its predicate, the Ad-Tech Medical Subdural Cortical Electrodes, are substantially equivalent based on their intended use and technological characteristics as well as their intended users, intended use environment, and indications for use. Furthermore, both systems have similar physical characteristics and stimulation parameters. The differences between the devices, namely the aspects that pertain to the number of variants, the number of contacts per electrode connector, and the manufacturing and testing methods do not adversely impact the safety and/or effectiveness.