February 14, 2020

Blackrock Microsystems
Rachelle Frischknecht
Regulatory Affairs Specialist
630 Komas Drive, Suite 200
Salt Lake City, Utah 84108

Re: K191346
Trade/Device Name: Blackrock NeuroCoG Subdural Cortical Electrodes (Strips and Grids)
Regulation Number: 21 CFR 882.1310
Regulation Name: Cortical Electrode
Regulatory Class: Class II
Product Code: GYC
Dated: January 12, 2020
Received: January 15, 2020

Dear Rachelle Frischknecht:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191346

Device Name
Blackrock NeuroCoG Subdural Cortical Electrodes (Strips and Grids)

Indications for Use *(Describe)*
Blackrock NeuroCoG 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 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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Traditional 510(k) Summary

1. Summary Date: February 13, 2020

2. Applicant Name: Blackrock Microsystems, LLC
630 Komas Drive, Suite 200
Salt Lake City, UT 84108
USA
Establishment Registration Number: 3007323246

3. Correspondent: Rachelle Frischknecht

4. Trade Name: Blackrock NeuroCoG Subdural Cortical Electrodes (Strips and Grids)

5. Common Name: Cortical Electrode, Subdural Strips and Grids

6. Description: Cortical Electrode (Per FDA Classification)

7. Manufacturing Site: Blackrock Microsystems, LLC
E-mail: rfrischknecht@blackrockmicro.com
FDA Establishment Number: 3007323246

8. Sterilization Site: Sterilization Site: Life Science Outsourcing, Inc.
FDA Establishment Number: 2031093

9. Classification Regulation, Class, Product Code, and Panel:
21 CFR 882.1310 Neurology
Class II
Product Code: GYC
Panel: Neurology

10. Reason for Traditional 510(k):
New submission

11. 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

12. Compliance to Special Controls / Performance Standards
There are no special controls/performance standards associated with Product Code GYC. However, conformance to the following recognized consensus standards is declared:
- **AAMI TIR12:2010** Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Medical Device Manufacturers
- **AAMI TIR30:2011(R)2016** A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices
- **ANSI/AAMI/ISO 10993-1:2009/(R)2013** Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process
- **ANSI/AAMI/ISO 11737-1:2018** Sterilization of Health Care Products –Microbiological Methods – Part 1: Determination of a Population of Microorganisms on Products

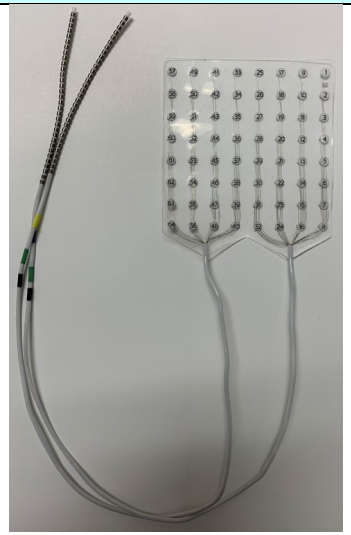
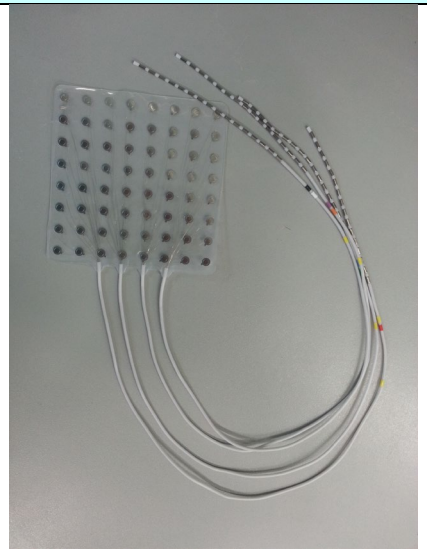
- **ANSI/AAMI/ST72:2011/(R)2016** Bacterial Endotoxins – Test Methods, Routine Monitoring, and Alternatives to Batch Testing
- **ASTM D4169-16** Standard Practice for Performance Testing of Shipping Containers and Systems
- **ASTM D4332-14** Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
- **ASTM F88/F88M-15** Standard Test Method for Seal Strength of Flexible Barrier Materials
- **ASTM F756-17** Standard Practice for Assessment of Hemolytic Properties of Materials
- **ASTM F1886-16** Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- **ASTM F1980-16** Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- **ASTM F2096-11** Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization
- **ASTM F2901-19** Standard Guide for Selecting Tests to Evaluate Potential Neurotoxicity of Medical Devices
- **BS/EN/ISO 11607-1:2017** Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier System, and Packaging Systems
- **BS/EN/ISO 11737-2:2009** Sterilization of Medical Devices – Microbiological Methods – Part 2: Tests of Sterility Performed in the Definition, Validation, and Maintenance of a Sterilization Process
- **IEC 62366-1 Edition 1.0 2015-02** Medical devices - Part 1: Application of Usability Engineering to Medical Devices [Including CORRIGENDUM 1 (2016)]
- **ISO 10993-4 Third Edition 2017-04** Biological Evaluation of Medical Devices – Part 4: Selection of Test for Interactions with Blood
- **ISO 10993-5 Third Edition 2009-06-01** Biological Evaluation of Medical Devices – Part 5: Tests for in Vitro Cytotoxicity
- **ISO 10993-6 Third Edition 2016-12-01** Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects After Implantation
- **ISO 10993-7 Second Edition 2008-10-15** Biological Evaluation of Medical Devices: Ethylene Oxide Sterilization Residuals
- **ISO 10993-10 Third Edition 2010-08-01** Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization
- **ISO 10993-11 Third Edition 2017-09** Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity
- **ISO 11135-1 Second Edition 2014-07-15** Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for Development, Validation, and Routine Control of a Sterilization Validation for Medical Devices
- **ISO 11138-1 Third Edition 2017-03** Sterilization of Health Care Products – Biological Indicators – Part 1: General Requirements
- **ISO 11138-2 Third Edition 2017-03** Sterilization of Health Care Products – Biological Indicators – Part 2: Biological Indicators for Ethylene Oxide Sterilization Processes

13. Indications for Use
    The Blackrock NeuroCoG 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 of the brain. The recording of electrical activity supports definition of the location of epileptogenic foci and brain mapping.

14. Technological Characteristics
    Both devices are nearly identical in size and materials to the predicate and both essential serve as “electrical conductors” of either EEG signals or stimulation currents. The differences are minor and do not affect safety or efficacy.

15. Comparison to Predicates
    The main differences between the NeuroCoG Subdural Cortical Electrodes (Strips and Grids) device under review and the predicate are as follows:
    - Both companies include a means to show the user the layout and color-coding of the electrode. Differences exist based on layout, font sizes, marketing issues, etc. These issues do not affect the safety or effectiveness of the device.
    - The proposed device is labeled as non-pyrogenic, the predicate device is not. Labeling the devices as non-pyrogenic is not a regulatory requirement. Doing so is done for marketing purposes and does not raise any new questions of safety or effectiveness.
    - The proposed device includes additional cautions statements for user performance issues only. They do not raise any questions on safety or efficacy.
    - The proposed device is available with electrode exposures of 2.3 mm diameter. The predicate device has electrode exposures of 1.5 mm x 1.5 mm, 1.5 mm x 3.0 mm, 2.3 mm diameter, 4.0 mm diameter per K053363 submission and 1.17, 1.8 mm, 5 mm dia. (exposed) currently marketed. The proposed exposure of 2.3 mm is within the boundaries of the predicate.
    - The proposed device can accommodate 32 contacts per pigtail instead of 16. Doing so reduces the number of incisions needed to tunnel the pigtails away from the surgical site. Less pigtails implies fewer block connectors under the wrap leading to better patient comfort. Although this aspect of the electrodes is viewed to be a feature of the design process, and in theory reduces the potential for infection, it does not affect the overall design intent/indications for use of the device. Additionally, having more contacts per pigtail reduces the likelihood of making an electrical misconnection, but this feature does not affect the overall design intent/indication for use of the device.
    - The proposed device uses different manufacturing methods in comparison to the predicates, but the overall design intent is identical.
    - The proposed device cites numerous applicable testing and performed numerous documented tests in compliance of their requirements while the predicate device did not.

16. Substantial Equivalence Table

Item	Proposed Device: Blackrock NeuroCoG Subdural Cortical Electrodes (Strips and Grids)	Predicate Device: Ad-Tech Medical Subdural Cortical Electrodes (K053363)	Comments
BASIC INFORMATION AND USES			
Picture			The pictures show that the Proposed Device is nearly identical in size to the predicate. The model shown (64 contact grid) for the proposed device is 78 mm x 90 mm with 400 - 450 mm pigtails; the predicate device is 80 mm x 80 mm with 375 mm pigtails. They are made with similar materials (silicone body and pigtails and platinum:iridium or stainless steel recording /stimulating pad electrodes). The differences are minor and do not affect safety or efficacy. Therefore, Substantially Equivalent
Description	Cortical Electrode	Cortical Electrode	Identical to the predicate. Therefore, Substantially Equivalent
Product Code	GYC (cortical electrodes)	GYC (cortical electrodes)	Identical to the predicate. Therefore,

			Substantially Equivalent
Class	II	II	Identical to the predicate. Therefore, Substantially Equivalent
Regulation	CFR 882.1310	CFR 882.1310	Identical to the predicate.
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 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.	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 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.	Nearly identical to the predicate. The proposed device is available sterile only, while the predicate device was originally available as either sterile or non-sterile. They are no longer available sterile only. Therefore, Substantially Equivalent.
Family Members	Strips, Grids	Dual-Sided, Interhemispheric, Grid, Intraoperative, Strip, Wyler	Grids and strips are contained within the cleared electrode types of the predicate. Therefore, Substantially Equivalent.
Indication for Use	The Blackrock NeuroCoG 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 of the brain. The recording of	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	Except for branding and the more limited subset of family members, the proposed device is nearly identical to the

	electrical activity supports definition of the location of epileptogenic foci and brain mapping.	signals on the surface of the brain. The recording of electrical activity supports definition of the location of epileptogenic foci and brain mapping.	predicate. Therefore, Substantially Equivalent.
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.
Intended User	Neurosurgeons, Neurologists, Epileptologists, Clinical Neurophysiologists, EEG / Neurodiagnostic Technicians, OR Staff Members	Not stated formally, but clinically known to include: Neurosurgeons, Neurologists, Epileptologists, Clinical Neurophysiologists, EEG / Neurodiagnostic Technicians, OR Staff Members	Although not known to be formally stated in the predicate's submission, the intended users are assumed to be identical to the predicate.
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.
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, Substantially Equivalent.
LABELING & PACKAGING INFORMATION			
NeuroCoG Product Identification	NNN-XXM- YYF-ZZC NNN = Electrode type, where STR = Strip Electrode w / 4-16 contacts GRD = Grid electrode w/ 4-99 contacts GRC = Grid electrode w/ 100-128 contacts XX = Number of Contacts M = Metal Type, where P = Platinum S = Stainless Steele YY = Uniqueness of Electrode (Defined in Product Registry) F = Feature, where N = Non-reinforced, R = Reinforced ZZ = Spacing of Contacts Center to Center(10mm) C = Contact Diameter, where S = Standard 4mm, 2.3mm Exposed	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. These issues do not affect the safety or effectiveness of the device. Therefore, Substantially Equivalent.

<table>
<tr>
<td>NeuroCoG Patient Cable Identification</td>
<td>
<table>
<tr><th>NPC Configuration</th><th>Channels in NPC</th><th>Quick Connect Band Color/s</th><th>Bend Relief Color/s</th><th>Channels in Conductor Cable</th><th>Block Connector Size</th><th>Block Connector Qty</th><th>Number of DIN leads</th></tr>
<tr><td>NPC-004D-XX</td><td>4</td><td>Yellow</td><td>Black</td><td rowspan="3">8</td><td rowspan="3">8-channel</td><td rowspan="6">1</td><td>4</td></tr>
<tr><td>NPC-006D-XX</td><td>6</td><td>Green</td><td>Black</td><td>6</td></tr>
<tr><td>NPC-008D-XX</td><td>8</td><td>Blue</td><td>Black</td><td>8</td></tr>
<tr><td>NPC-010D-XX</td><td>10</td><td>Black</td><td>Red</td><td rowspan="3">16</td><td rowspan="3">16-channel</td><td>10</td></tr>
<tr><td>NPC-012D-XX</td><td>12</td><td>White</td><td>Red</td><td>12</td></tr>
<tr><td>NPC-016D-XX</td><td>16</td><td>Green</td><td>Red</td><td>16</td></tr>
<tr><td>NPC-020D-XX</td><td>20</td><td>Black</td><td>White</td><td rowspan="9">32</td><td rowspan="9">32-channel</td><td>20</td></tr>
<tr><td>NPC-024D-XX</td><td>24</td><td>Yellow</td><td>White</td><td>24</td></tr>
<tr><td>NPC-032D-XX</td><td>32</td><td>White</td><td>Orange</td><td>32</td></tr>
<tr><td>NPC-048D-XX</td><td>48</td><td>Yellow Blue</td><td>White Yellow</td><td rowspan="2">2</td><td>48</td></tr>
<tr><td>NPC-064D-XX</td><td>64</td><td>White Yellow</td><td>Orange Green</td><td>64</td></tr>
<tr><td>NPC-096D-XX</td><td>96</td><td>White Yellow Green</td><td>Orange Green Grey</td><td>3</td><td>96</td></tr>
<tr><td>NPC-128D-XX</td><td>128</td><td>White Yellow Green Blue</td><td>Orange Green Grey White</td><td>4</td><td>128</td></tr>
<tr><td>NPC-032Q-XX</td><td>32</td><td>White</td><td>Orange</td><td>1</td><td rowspan="4">0</td></tr>
<tr><td>NPC-048Q-XX</td><td>48</td><td>Yellow Blue</td><td>White Yellow</td><td rowspan="2">2</td></tr>
<tr><td>NPC-064Q-XX</td><td>64</td><td>White Yellow</td><td>Orange Green</td></tr>
<tr><td>NPC-096Q-XX</td><td>96</td><td>White Yellow Green</td><td>Orange Green Grey</td><td>3</td></tr>
<tr><td>NPC-128Q-XX</td><td>128</td><td>White Yellow Green Blue</td><td>Orange Green Grey White</td><td>4</td><td></td></tr>
</table>
</td>
<td>NPC-XXXC-YY
<table>
<tr><td>NPC</td><td>Acronym for NeuroCoG Patient Cable</td></tr>
<tr><td>XXX</td><td>Number of channels (004-128)</td></tr>
<tr><td>C</td><td>Type of connector (D=DIN leads, Q=Q-Connector</td></tr>
<tr><td>YY</td><td>Length of NPC in feet (06 or 10)</td></tr>
</table>
</td>
<td>Ad-Tech did not qualify a Patient Cable as device-specific in their submission.</td>
</tr>
<tr>
<td>Directions for use</td>
<td>A directions for use that includes a generic picture and description of the numbering and color coding scheme is included with each electrode.</td>
<td>A directions for use and separate “Code Chart” identifying the numbering and color coding scheme is included with each electrode.</td>
<td>Both companies include a means to show the user the layout and color-coding of the electrode. Differences exist based on layout, font sizes, marketing style, etc. These differences do not affect the safety or effectiveness of the</td>
</tr>
</table>

			device. Therefore, Substantially Equivalent.
NeuroCoG Cautionary Statements	For Single Patient Use Only. Do not Re-Sterilize or Reuse. Not intended of Implantation (21 CFR 860.3(d): > 30 days. CAUTION: Federal Law (U.S.A.) restricts this Device to sale by or on the order of a 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. CAUTION: Do not use NeuroCoG if packaging is damaged. CAUTION**:** Handle the electrode with care to prevent damage. Avoid pulling or stressing the pigtail, rings or electrodes, which could result in loss of contact recordings. CAUTION**:** If suturing the electrode, avoid suturing contacts, wires, and/or pigtail, as damage may result. CAUTION: Handle the electrode with care to prevent damage. Avoid pulling or stressing the pigtail, rings or electrodes, which could result in loss of contact recordings.	For Single Patient 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 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.	Additional Cautions statement for user performance issues only and do not raise any questions on safety or efficacy. Therefore, Substantially Equivalent.
NeuroCoG Cautionary Statements	Do not use NeuroCoG Patient Cable if pogo pins are recessed or aggressively clean Pogo Pins such that they recess. Use with recessed pogo pins may result in damaging the devices or incomplete signal path.		Ad-Tech did not qualify a Patient Cable as device-specific in their submission.

Sterility status of the electrodes	Sterile only	Both sterile and non-sterile devices were originally offered. Only sterile electrodes are offered currently	Identical sterility status of the currently marketed devices of the predicate.
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Identical to the predicate.
Sterility status of patient cable	Non-Sterile	--	Ad-Tech did not qualify a Patient Cable as device-specific in their submission.
Non-Pyrogenic	Labeled as non-pyrogenic	Not so labeled	Labeling the devices as non-pyrogenic is not a regulatory requirement. Doing so is done for marketing purposes and does not raise any new questions of safety or effectiveness. Therefore, Substantially Equivalent.
Single Patient Use, Disposable	Yes	Yes	Identical to the predicate.
Shelf Life	Currently 1 year (per accelerated aging) and 1-year and 5-year real-time aging studies are ongoing)	5 years (Launched with 1 year accelerated aging)	After 5 years, identical to the predicate.
Packaging Configuration	The Blackrock NeuroCoG Subdural Cortical Electrode (Strips and Grids) is double (Tyvek) pouched and placed in a chipboard box. The NeuroCoG Patient Cable is placed in a poly bag and then cleaned and disinfected by the end-user.	The device is double (Tyvek) pouched and placed in a chipboard box.	Identical to the predicate.

ELECTRODE CONTACT INFORMATION			
Number of Electrode Contacts	Strips: 4 to 16, Inclusive Grids: 4 to 128, inclusive	1 to 128, inclusive	Within the boundaries of the predicate.
Electrode Contact Spacing	10 mm, 5 mm Other variations can be requested by the customer.	10 mm Other variations can be requested by the customer.	Identical to the predicate.
Electrode Contact Material	90:10 Platinum:iridium or Stainless Steel	90:10 Platinum or Stainless Steel	Identical to the predicate.
Electrode Contact Size (exposed surface area)	2.3 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 K053363 submission 1.17, 1.8 mm, 5 mm dia. (exposed) currently marketed	Within the boundaries of the predicate.
ELECTRODE PIGTAIL INFORMATION			
Maximum contacts per pigtail	32	16	The proposed device offers more potential contacts per pigtail than the predicate. Doing so reduces the number of incisions needed to tunnel the pigtails away from the surgical site. Less pigtails implies fewer block connectors under the wrap leading to better patient comfort. Although this aspect of the electrodes is viewed to be a feature of the design process, and in theory reduces the potential for infection, it does not affect the overall design intent/indication for use of the device. Additionally, having more contacts per pigtail reduces the likelihood of making an electrical misconnection but this feature does not affect the overall

			design intent/indication for use of the device. Therefore, Substantially Equivalent
Connection Cable (510(k) Exempt)	The connection cable terminates in a safety female DIN leads connector or Q-Connector. It connects the electrode cable per 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 per the connector to the amplifier / stimulator	Although per 21 CFR 890.1175, the electrode-to-EEG/Stimulator cables are 510(k) exempt, 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 the applicable safety standards and share the same overall design intent. Therefore, Substantially Equivalent.
MANUFACTURING & PERFORMANCE CHARACTERICS			
Stimulation Parameters	As stated on the instructions for use, a safe level of stimulation is below 30 μC/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 30 μC/cm^2. This is a function of exposed electrode contact size, pulse duration and stimulation current.	Identical to the predicate.
Electrode Manufacturing Technique	NeuroCoG subdural cortical electrodes are hand-made. The device consists of a silicone mat into which the pad electrodes comprising of platinum:iridium or stainless steel contacts are embedded. The electrode contacts' conducting paths are electrically connected to their contact rings per insulated stainless steel wires encapsulated in the pigtail.	Ad-Tech electrodes are hand-made. The electrodes' contacts are sandwiched in between layers of liquid silicone and trimmed to size. Insulated wires extend from each electrode through a flexible silicone or polyurethane tube to a connector for EEG monitoring	Manufacturing methods may vary in comparison to the predicates, but the overall design intent and materials are identical.

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.	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. Therefore, Substantially Equivalent.
STANDARDS			
Standards Cited	• AAMI TIR12:2010 Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Medical Device Manufacturers • AAMI TIR30:2011(R)2016 A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices • ANSI/AAMI/ISO 10993-1:2009/(R)2013 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process • ANSI/AAMI/ISO 11737-1:2018 Sterilization of Health Care Products – Microbiological Methods – Part 1: Determination of a Population of Microorganisms on Products • ANSI/AAMI/ST72:2011/(R)2016 Bacterial Endotoxins – Test Methods, Routine Monitoring, and Alternatives to Batch Testing • ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems	None cited	Citing the applicable standards does not raise any new questions of safety or effectiveness. Therefore, Substantially Equivalent.

	• ASTM D4332-14 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing • ASTM F88/F88M-15 Standard test Method for Seal Strength of Flexible Barrier Materials • ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials • ASTM F1886-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection • ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices • ASTM F2096-11 Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization • ASTM F2901-19 Standard Guide for Selecting Tests to Evaluate Potential Neurotoxicity of Medical Devices • BS/EN/ISO 11607-1:2017 Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier System and Packaging Systems • BS/EN/ISO 11737-2:2009 Sterilization of Medical Devices – Microbiological Methods – Part 2: Tests of Sterility Performed in the Definition, Validation, and Maintenance of a Sterilization Process • IEC 62366-1 Edition 1.0 2015-02 Medical Devices - Part 1: Application of Usability Engineering to Medical Devices [Including CORRIGENDUM 1 (2016)]		

	• ISO 10993-4 Third Edition 2017-04 Biological Evaluation of Medical Devices – Part 4: Selection of Test for Interactions with Blood • ISO 10993-5 Third Edition 2009-06-01 Biological Evaluation of Medical Devices – Part 5: Tests for in Vitro Cytotoxicity • ISO 10993-6 Third Edition 2016-12-01 Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects After Implantation • ISO 10993-7 Second Edition 2008-10-15 Biological Evaluation of Medical Devices: Ethylene Oxide Sterilization Residuals • ISO 10993-10 Third Edition 2010-08-01 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization • ISO 10993-11 Third Edition 2017-09 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity • ISO 11135-1 Second Edition 2014-07-15 Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for Development, Validation, and Routine Control of a Sterilization Validation for Medical Devices • ISO 11138-1 Third Edition 2017-03 Sterilization of Health Care Products – Biological Indicators – Part 1: General Requirements • ISO 11138-2 Third Edition 2017-03 Sterilization of Health Care Products – Biological Indicators – Part 2: Biological		

	Indicators for Ethylene Oxide Sterilization Processes		
Electrical Performance Testing	As part of the manufacturing process, the Blackrock NeuroCoG Subdural Electrodes (Strips and Grids) are checked for electrical continuity and resistance. The devices were physically tested for dielectric strength, impedance, resistance and charge injection capacity on new and aged products. The NeuroCoG Patient Cable was tested for channel mapping, resistance, shorts, dielectric strength, and impedance.	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.
Mechanical Performance Testing	The Blackrock NeuroCoG Subdural Electrodes (Strips and Grids) were physically tested for tensile strength, bending, and chemical compatibility on new and aged products as well as underwent extensive verification of their mechanical properties. The NeuroCoG Patient Cable was tested for tensile strength, mating, bending, dropping, and chemical compatibility.	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. Therefore, Substantially Equivalent.
MRI Testing	The Blackrock NeuroCoG Subdural Electrodes and NeuroCoG Patient Cable (Strips and Grids) are MR Unsafe.	Not Stated	Labeling the device as not being evaluated for safety and compatibility in the MR environment while the predicate device does not raise any new questions of safety or effectiveness. Therefore, Substantially Equivalent
Contains Software/Firmware	No	No	Identical to the predicate.

Electrical Safety Testing	Not Conducted. Not Applicable	Not Conducted. Not Applicable	Identical to the predicate.
EMC Testing	Not Conducted. Not Applicable	Not Conducted. Not Applicable	Identical to the predicate.

Blackrock NeuroCoG Subdural Cortical Electrodes (Strips and Grids) Biocompatibility Evaluation			
Test	**Standard**	**Method**	**Results**
Hemolysis	ISO 10993-4:2017 ASTM F756-17 ASTM F2901:2019	Indirect Contact	Non-hemolytic
Cytotoxicity	ISO 10993-5:2009	L929 MEM Elution	Non-cytotoxic
Implantation	ISO 10993-6:2016	Subdural Rabbit Brain	Non-demyelinating, Non-neurodegenerative, Non-astrocytotic, and Non-microglial-proliferative
Irritation	ISO 10993-10:2010	Intracutaneous Reactivity	Non-irritant
Sensitization	ISO 10993-10:2010	Kligman Maximization	Non-sensitizer
Acute Systemic Toxicity	ISO 10993-11:2017	Systemic Injection	Non-toxic

Blackrock NeuroCoG Subdural Cortical Electrodes (Strips and Grids) Biocompatibility Evaluation			
Test	**Standard**	**Method**	**Results**
BET/LAL	ANSI/AAMI ST72:2011/(R)2016	Kinetic Chromogenic Technique The Endotoxin limit applied to the NeuroCoG is 2.15 EU/Device (0.06 EU/ml). The selected endotoxin limit is based on the potential contact with Cerebrospinal Fluid.	Non-pyrogenic
Patient Cable			
Test	**Standard**	**Method**	**Results**
Cleaning	AAMI TIR12:2010 AAMI TIR30:2011(R)2016	British soil, CaviWipes and CaviCide	Protein Marker: <6.4µg/cm^2 Carbohydrate Marker: <1.8µg/cm^2
Disinfection	AAMI TIR12:2010	Low-level disinfection with CaviWipes and CaviCide	6-log reduction in bacteria

17. Conclusions

Blackrock Microsystems believes the proposed Blackrock NeuroCoG Subdural Cortical Electrodes (Strips and Grids) and their predicate, Ad-Tech Medical Subdural Cortical Electrodes, are substantially equivalent in their intended use, intended users, intended use environment, and indications for use. Furthermore, both systems have the same/equivalent technological characteristics, physical characteristics, and stimulation parameters. The difference that exists between the devices—namely the aspect that pertains to the number of contacts per pigtail—does not affect the relative safety and/or effectiveness.