February 10, 2021

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

Re: K202174
Trade/Device Name: Digital NeuroPort Biopotential Signal Processing System
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological Signal Amplifier
Regulatory Class: Class II
Product Code: GWL, GWK
Dated: December 21, 2020
Received: December 28, 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,

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)*
K202174

Device Name
Digital NeuroPort Biopotential Signal Processing System

Indications for Use *(Describe)*
The Digital NeuroPort Biopotential Signal Processing System supports recording, processing, and display of biopotential signals from user-supplied electrodes. Biopotential signals include: Electrocorticography (ECoG), electroencephalography (EEG), electromyography (EMG), electrocardiography (ECG), electrooculography (EOG), and Evoked Potential (EP).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# I. Submitter, Device, Predicate

| | |
|---|---|
| **Sponsor/Applicant** | Blackrock Microsystems<br>630 Komas Drive, Suite 200<br>Salt Lake City, UT 84108 |
| **Primary Contact** | Rachelle Frischknecht<br>Regulatory Affairs Specialist<br>(801) 994-5668<br>rfrischknecht@blackrockmicro.com |
| **Date Summary Prepared** | January 20, 2021 |
| **510(k) Submission Type** | Special |
| **Device Name** | Digital NeuroPort Biopotential Signal Processing System |
| **Common/Usual Name** | Physiological signal amplifier; Physiological signal conditioner |
| **Classification Name** | Physiological signal amplifier (21 CFR 882.1835) |
| **Regulatory Class** | II |
| **Product Code** | GWL; GWK |
| **Predicate Device** | K090957, Blackrock NeuroPort Biopotential Signal Processing System |

# II. Device Description

The Digital NeuroPort Biopotential Signal Processing System is used to acquire, process, visualize, archive/record signals as acquired from user-supplied electrodes for biopotential monitoring. Signals are acquired using a headstage relay that attaches to the pedestal interface and digitizes the signal through the hub. The Digital NeuroPort System uses preamplifiers, analog to digital converters, a signal processing unit, and software running on a personal computer to visualize and record biopotentials from electrodes in contact with the body. Components include:

- **Central Software Suite**: Used to receive, display and store data, configure signal processing characteristics.
- **Neural Signal Processor**: Used for signal processing.
- **Digital Hub**: Used to connect digital headstage accessories and perform digital to optical conversion to pass data over fiberoptic cable to Signal Processor.

The Digital Headstage Accessory Devices are devices that interface with the electrodes connected to the patient. Headstage devices and accessories include:

- **NeuroPlex E Headstages:** Interface to percutaneous connector of NeuroPort Electrode. Acquires signal from connected electrode and performs signal processing before sending to output connector, which connect to Digital Hub via Digital Data Cable. Provided in both sterile and non-sterile configurations.
- **Digital Data Cable:** 1.5M Digital Data Cables connected to Digital Hub. Hub powers Digital Headstages (4.8VDC), and Headstages provide digitized biopotential signals to Hub. Provided in both sterile and non-sterile configurations.

# III. Indications for Use

The Digital NeuroPort Biopotential Signal Processing System supports recording, processing, and display of biopotential signals from user-supplied electrodes. Biopotential signals include:

Electrocorticography (ECoG),
Electroencephalography (EEG),
Electromyography (EMG),
Electrocardiography (ECG),
Electrooculography (EOG), and
Evoked Potential (EP)

# IV. Comparison of Technological Characteristics with the Predicate Device

At a high level, the following technological differences exist between the subject and predicate devices:

- Electrical/EMC:
  - Change in power supply configuration (moved into Digital Hub)
  - Change in headstage device and accessory (NeuroPlexE and Digital data cable, versus patient and blue ribbon cables)
  - Change in simulator (Digital Simulator replaces Analog Simulator)
  - Digitization of signals to reduce signal atentuation
  - Stage of signal conversion (pre-amplifier/headstage level) to improve system synchronization and reduce noise
  - Change in patient protection circuitry: Patient Cable in K090957 uses capacitor and resistor;

whereas, ASIC in NeuroPlex E uses diodes.

- Higher frequency data transmission over new 1.5m Digital Data Cable.
- Expansion of band pass to detect neural signals
- Digital Hub clock communicates over 1.5m Digital Data Cable to headstage instead of all on internal printed circuit boards.
- NeuroPlex E has option for wideband hardware filter that Patient Cable does not.
- NeuroPlex E has a Delrin wheel; whereas, Patient Cable has a 300 SS wheel.
- Digital Data Cable uses common connector type.
- Digital Data Cable is a commercially available cable type (HDMI A to D connector).
- Longer cable.
- Labeling of reference selection switches changed from A, B, C, D to Ref 1, Ref 2, and Gnd.

- Shelf Life/Packaging
  - 1 year to 18 months.
  - Single to double pouch configuration as a sterile barrier.
- Software
  - Update to patient cable programming to handle increase in channels (E96 vs. 128)
  - New calculation for impedance detection.

| **Comparison of the Predicate and Subject Device** | | |
|---|---|---|
| | **Predicate Device: NeuroPort Biopotential Signal Processing System (K090957)** | **Subject Device: Digital NeuroPort Biopotential Signal Processing System** |
| **FDA Regulatory Information** | | |
| **Manufacturer** | Blackrock Microsystems | Same as predicate |
| **FDA Product Code** | GWL, GWK | Same as predicate |
| **Classification** | Class II - 21 CFR 882.1835, 882.1845 | Same as predicate |
| **Classification Name** | Physiological signal amplifier | Same as predicate |
| **Indications for Use** | | |

| Comparison of the Predicate and Subject Device | | |
|---|---|---|
| | **Predicate Device: NeuroPort Biopotential Signal Processing System (K090957)** | **Subject Device: Digital NeuroPort Biopotential Signal Processing System** |
| **Indications for Use** | The Digital NeuroPort Biopotential Signal Processing System supports recording, processing, and display of biopotential signals from user-supplied electrodes.<br>Biopotential signals include:<br>Electrocorticography (ECoG), electroencephalography (EEG), electromyography (EMG), electrocardiography (ECG),<br>electrooculography (EOG), and Evoked Potential (EP). | Same as predicate |
| **Device Design** | | |
| **Principles of Operation** | Preamplification, amplification, analog to digital conversion, digital to optical<br>conversion, signal processing, visualization, and archiving/recording | Same as predicate |
| **Connection Mechanism** | Pedestal | Same as predicate |
| **Sterility** | The cables may be supplied sterile or non-sterile. | Same as predicate. |
| **Fast Settle** | 5V TTL Input | Same as predicate |
| **Noise** | < 3 µVrms | Same as predicate |
| **Sampling Rate** | Up to 30,000 Hz | Same as predicate |
| **Electrical Safety/EMC Testing** | Testing in accordance with:<br>IEC 60601-1:1998<br>IEC 60601-1-2:2001<br>IEC 60601-2-26:2002 | Testing in accordance with:<br>IEC 60601-1:2005/A1:2012<br>IEC 60601-1-2:2014<br>IEC 60601-2-26:2002 |
| **Sterility and Shelf Life** | | |
| **Provided Sterile Barrier Packaging Configuration** | Tyvek | Same as predicate |
| **Provided Sterile Packaging Unit** | 1 unit per box | Same as predicate |

| Comparison of the Predicate and Subject Device | | |
|---|---|---|
| | **Predicate Device: NeuroPort Biopotential Signal Processing System (K090957)** | **Subject Device: Digital NeuroPort Biopotential Signal Processing System** |
| **Sterility Assurance Level (SAL)** | $10^{-6}$ | Same as predicate |
| **Sterilization Method** | Ethylene oxide | Same as predicate |
| **Sterile Shelf Life** | 1 year | 18 months |

# V. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

| Table 1. Test Results Summary | |
|---|---|
| **Test** | **Standard/Methods** |
| Safety | IEC 60601-1:2005/A1:2012 |
| EMC | IEC 60601-1-2:2014 |
| EEG | IEC 60601-2-26:2002 |
| Usability | IEC 60601-1-6/A1:2013 |
| Biocompatibility | ISO 10993-1:2018 |
| Sterilization | ISO 10993-7 Second Edition 200810/15<br>ISO 11135-1 Second Edition 2014/07/15 |
| Cleaning | No pitting, spotting, discoloration, or corrosion with IPA, ethanol, or CaviWipes |
| Packaging | ISO 11607-1:2019 ASTM D4169-09<br>ASTM D4332-14 ASTM F88/F88M-15<br>ASTM F1886-09/(R)2013 ASTM F1980-16<br>ASTM F2096-11 |

## Electrical Safety/Electromagnetic Compatibility

The Digital NeuroPort Biopotential Signal Processing System was evaluated for electrical safety and electromagnetic compatibility in accordance with IEC 60601-1:2005/A1:2012, Edition 3.1 and IEC 60601-1-2:2014, Edition 4.0, with results demonstrating that the Digital NeuroPort Biopotential Signal Processing System continues to be compliant upon field deployment.

## Design Verification, Software Verification and Validation and Usability

The Digital NeuroPort Biopotential Signal Processing System was evaluated with respect to design verification and validation, software verification and validation, and usability.

| Table 2. Functional Testing for NeuroPlex E | | |
|---|---|---|
| **Test** | **Acceptance Criteria** | **Result** |
| **Mating** | Screws down on pedestal and LED turns green | Pass |
| **Crosstalk** | Isolation resistance of 1kohms at 500 V DC | Pass |

| Table 2. Functional Testing for NeuroPlex E | | |
|---|---|---|
| **Label Durability** | IEC 60601-1:2005/A1:2012, Edition 3.1 7.1.3 | Pass |
| **Digital Accuracy** | Appropriate voltages for different filters.<br><br>Filtering:<br>.02-10 kHz (Wide)<br>.3-7.5 kHz (Standard)<br><br>Peak-to-peak of 500mV ±10% | Pass |
| **Input Impedance** | ≥10MΩ | Pass |
| **Impedance Measurement** | 820 ± 15% kOhms and 170 ± 15% kOhms | Pass |
| **Current Rating** | <1A | Pass |
| **Stability** | All channels have neural data from a simulator after 90 attachments and detachments | Pass |
| **Attachment** | Two-Finger Tightness | Pass |
| **Input Noise** | ≤3 RMS | Pass |
| **Crosstalk** | <44mV | Pass |
| **Leakage** | IEC 60601-1:2005/A1:2012, Edition 3.1 | Pass |
| **Breakaway** | <14lbf | Pass |

| Table 3. Functional Testing for Digital Hub | | |
|---|---|---|
| **Test** | **Acceptance Criteria** | **Result** |
| **Input Power Supply** | External, medical-grade | Pass |
| **FPGA Testing from Headstage** | Accommodates up to 128 channels and channel priority starts with first channel and ends with fourth channel. | Pass |
| **Output Power Supply to Headstage** | 4.8V | Pass |
| **Full-Scale Analog Input** | ±8.192mV. | Pass |
| **Burn in Test:** | Hub can run continuously for 12 hours. | Pass |
| **Compatibility Test** | Validated data packets received at hub and NeuroPlex E is powered. | Pass |

| Table 4. Functional Testing for Digital Neural Signal Simulator (DNSS) | | |
|---|---|---|
| **Test** | **Acceptance Criteria** | **Result** |
| **Rechargeable Battery** | Battery life is ≥10 hours. | Pass |

| Table 4. Functional Testing for Digital Neural Signal Simulator (DNSS) | | |
|---|---|---|
| **Power** | Charge battery by Digital Data Cable or USB | Pass |
| **Digital** | Digital Hub recognizes DNSS connected through Data Cable. | Pass |

| Table 5. Functional Testing for System | | |
|---|---|---|
| **Test** | **Acceptance Criteria** | **Result** |
| **Synchronization** | Timestamps aligned within 100 microseconds with maximum capacity of four 128-channel Es, four 128-channel hubs, (only one digital data cable from one E to one hub), and two 256 NSPs. | Pass |
| **Channel Count** | Facilitates up to 512 channels. | Pass |

| Table 6. Usability Testing | | |
|---|---|---|
| **Test** | **Acceptance Criteria** | **Result** |
| **IFU Readability** | Users are able to configure intended settings, assemble the system, and perform maintenance activities all from instruction in the IFU. | Pass |
| **Impedance, Reference, and Ground Switching** | Users are able to achieve each possible configuration prompted by the facilitator. | Pass |
| **Cleaning** | Users do not damage the device during cleaning. Users identify the proper cleaning solutions. Users indicate that the instructions are sufficiently clear. | Pass |

## Biocompatibility

Of the subject device system components, the NeuroPlexE and pedestal components have some extent of patient contact during intraoperative use, with both components being used in sterile configurations.

Specific to the NeuroPlexE which is new to the subject device system, while not intended to be a patient-contacting device there is potential for incidental contact with skin intraoperatively when a patient or surgeon touches the device. It was evaluated in accordance with ISO 10993-1 Fifth Edition 2018/18 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process. Given the contact classification and cumulative duration of contact, the endpoints assessed were cytotoxicity, irritation, or sensitization.

## Sterility and Shelf Life

Components of the system that are available in both sterile and non-sterile configurations are the NeuroPlex E and Digital Data Cable. NeuroPlex E briefly contacts the percutaneous portion of the electrode before implantation, and the Digital Data Cable attaches to the NeuroPlex E.

The devices are sterilized with 100% ethylene oxide (EtO) in accordance with ISO 11135-1 Second Edition 2014/07/15 Sterilization of Health Care Products – Ethylene Oxide – Part I: Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices to a Sterility Assurance Level of $10^{-6}$ using Overkill Method with three half cycles.

**Residuals:** The NeuroPlex E and Digital Data Cable are no more difficult to sterilize than PCD NeuroPort Electrode (as cleared in K042384, K070272, and K110010) which meets the requirements of ISO 10993-7 Second Edition 2008/10/15 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals for the limit of toxic sterilant residuals and has been adopted into the NeuroPort Electrode sterilization validation per AAMI TIR28:2016 Product Adoption and Process Equivalence for Ethylene Oxide Sterilization. An exhaustive extraction procedure was performed and the ethylene oxide levels are <4mg and the ethylene chlorohydrin levels are <9mg per 24 hours and both residuals were <60mg per 30 days.

### Packaging

#### *Sterile:*

**NeuroPlex E and Digital Data Cables:** The NeuroPlexE and Digital Data Cable devices are packaged separately**.** The sterile barrier is double-pouched in 1073B uncoated Tyvek/.00048 PET .002 LDPE film. The transportation/shelf-life barrier is an inner and outer pouch, then a foam base, ring, and lid in a chipboard box in a 51 ECT cardboard overshipper. The packaging conforms to ISO 11607-1:2019. Conditioning per ASTM D4332- 14 and Distribution Simulation per ASTM D4169-16 was performed on representative device CerePlex E. Accelerated aging testing was conducted per ASTM F1980-16 on representative device Patient Cable to validate an 18- month shelf-life. Following conditioning and distribution simulation and accelerated aging, samples were tested for Visual Inspection per ASTM F1886-09/(R)2013, Bubble Emissions per ASTM F2096-11, Seal Strength per F88/F88M-15, and functionality. The devices met the requirements of the applicable standards and functional testing following conditioning, distribution simulation, and accelerated aging studies.

#### ***Non-Sterile*:**

**NeuroPlex E:** The non-sterile NeuroPlex E is in a three-piece foam enclosure with a Plastazote foam conductive polyethelene primary base, Plastazote foam conductive polyethelene small base, and PE Black Conductive LD30 XLPE device holder and placed in a necklace box. The necklace box is then placed into a black photoreactive resin foam and then into a small UPS box.

**Digital Data Cables:** The non-sterile Digital Data Cables are placed in a poly bag.

**Digital Hub:** The non-sterile Digital Hub is placed in a 32 ECT/B Flute corrugated box in a suspension packaging insert of cardboard with cellophane.

# VI. CONCLUSIONS

The non-clinical data support the safety and effectiveness of the device, with the testing performed demonstrating that the Digital NeuroPort Biopotential Signal Processing System device performs comparably to the predicate device that is currently marketed for the same intended use and should perform as intended in the specified use conditions.