August 18, 2023

SPARK Neuro Inc.
% John Doucet
Vice President, Neurology Regulatory Affairs
MCRA, LLC
803 7th Street NW
Washington, DC 20001

Re: K231457
Trade/Device Name: SPARK Scan
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ
Dated: May 18, 2023
Received: May 19, 2023

Dear John Doucet:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Patrick Antkowiak -S

for
Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

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

Device Name
SPARK Scan

Indications for Use *(Describe)*
The SPARK Scan is intended to acquire, display, and store the electrical activity of a patient's brain obtained by placing two or more electrodes on the head to aid in diagnosis.

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.

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510(K) SUMMARY

Device Trade Name:	SPARK Scan
Manufacturer:	SPARK Neuro Inc. 212 W. 18th Street #17A New York, NY 10011 USA
Contact:	John Doucet Vice President, Neurology Regulatory Affairs MCRA, LLC 803 7th Street NW Washington, DC 20001 Office: 202.552.5835 Jdoucet@mcra.com
Prepared by:	MCRA, LLC 803 7th St NW Washington, DC 20001 Office: 202.552.5800
Date Prepared:	May 18, 2023
Regulation:	21 CFR 882.1400
Class:	II
Product Code:	GWQ
Classification Name:	Full-Montage Standard Electroencephalograph
Common Name:	Electroencephalograph
Primary Predicate:	K143233 Mitsar-EEG

Indications For Use:

The SPARK Scan is intended to acquire, display, and store the electrical activity of a patient's brain obtained by placing two or more electrodes on the head to aid in diagnosis.

Device Description:

The SPARK Scan is intended for the acquisition, display, and storage of electroencephalogram (EEG) data. The SPARK Scan is intended to be used by EEG technicians, or appropriately trained Nurses and Medical Assistants practicing in any medical setting where EEG data collection may be required.

The SPARK Scan is an SaMD product that consists of the Edge Software and Data Storage and Communication Platform.

The Edge software runs locally on the user's device and consists of a User interface and the EEG hardware interface, including the electroconductive gel (K111717). The User Interface is a desktop application that (a) manages interaction with the EEG hardware interface, (b) facilitates set up and recording of EEG data, and (c) provides limited access to review of patient records according to the user's permissions.

The Data Storage and Communication Platform (Cloud Software): The Cloud software runs on a server managed by SPARK Neuro and contains no user interface. The Cloud Software is responsible only for managing (a) authorization and authentication of users and (b) storage, validation, and access to all data collected on the system.

The SPARK Scan is compatible with three 3rd-party accessory devices: an FDA-cleared EEG hardware system, a standard off-the-shelf-laptop, and FDA-cleared EEG Recording Viewing Platforms.

Comparison to the Predicate Device:

	Subject Device	**Primary Predicate**	**Comparison**
Trade Name	SPARK Scan	Mitsar-EEG	N/A
Company	SPARK Neuro	Mitsar Co., LTD	N/A
K Number	K23xxxx	K143233	N/A
Regulation Number	21 CFR 882.1400	21 CFR 882.1400	Identical
Product Codes	GWQ	GWQ	Identical
Indications for Use Statement	The SPARK Scan is intended to acquire, display, and store the electrical activity of a patient's brain obtained by placing two or more electrodes on the head to aid in diagnosis.	The Mitsar-EEG is intended to acquire, display, and store the electrical activity of a patient's brain obtained by placing two or more electrodes on the head to aid in diagnosis.	Identical
Intended User	Medical Staff	Medical Staff	Identical
Target Population	Adults	Adults	Identical
Use Environment	Healthcare Facilities	Healthcare Facilities	Identical
System Components	Edge Software Data Storage and Communication Platform Off-The-Shelf EEG Amplifier (K172312) Off-The-Shelf EEG Cap (K110223)	EEG Amplifier USB-Cable USB-Dongle EEG Studio Software	Similar. The subject and the predicate devices each comprise components that allow for its proper functionality.
Acquires signals	Yes, EEG	Yes, EEG	Identical

Number of Signals Recording Channels Compatibility	up to 32	up to 21	Similar. Subject device is similar to the number of recording channels of the predicate device.
Impedance Test	Yes	Yes	Identical
Sampling Rate	500Hz	500Hz	Identical.
Interface	PC	PC	Identical

Performance Testing Summary:

Non-Clinical Testing

- Software verification and validation testing
- Cybersecurity Risk Analysis and Testing
- Human Factors Use Related Risk Analysis

Biocompatibility

The subject device does not come into direct or indirect contact with the patient. This is not applicable.

Electrical Safety and Electromagnetic Compatibility

The subject device does not contain hardware. This is not applicable.

Animal Testing

Animal testing is not required to support substantial equivalence.

Clinical Testing

Clinical testing is not required to support substantial equivalence.

Conclusion: The subject device and the predicate device have the same intended use and have similar technological characteristics. The data included in this submission demonstrate substantial equivalence to the predicate device listed above. SPARK Scan is substantially equivalent to the predicate device.