May 22, 2018

Neural Analytics, Inc.
% Javad Seyedzadeh
Cheif QA/RA
2440 S. Sepulveda Blvd., Suite 115
LOS ANGELES CA 90064

Re: K180455
Trade/Device Name: NeuralBot
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, ITX, OQQ
Dated: April 17, 2018
Received: April 19, 2018

Dear Javad Seyedzadeh:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*

K180455

Device Name
NeuralBot

Indications for Use *(Describe)*

The NeuralBot when used with the Lucid M1 System is a medical ultrasound device which assists the user in the setup and acquisition of cerebral blood flow velocity via the patient's temporal windows. It is intended for use as an adjunct to standard clinical practices for measuring and displaying cerebral blood flow velocity and the occurrence of transient emboli within the blood stream.

The NeuralBot is intended to be used by healthcare professionals qualified by training in its safe and effective use. The device is not intended to replace other means of evaluating vital patient physiological processes, is not intended to be used in fetal applications and is not intended to be used inside the sterile field.

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

Date Prepared	February 16, 2018
Manufacturer	Neural Analytics, Inc. 2440 S Sepulveda Blvd, Suite 115 Los Angeles, CA 90064 *Phone:* (914) 473-1678 *Facsimile:* (877) 638-7251 *Internal Contact: Javad Seyedzadeh* *Email:* javad@neuralanalytics.com
Official Correspondent	Javad Seyedzadeh Chief of QA/RA (914) 473-1678 javad@neuralanalytics.com
Trade Name	NeuralBot
Common Name(s)	NeuralBot System, NeuralBot Guided Headmount Accessory, NeuralBot Guided Headmount Accessory for the Lucid M1 System
Project Name	Apollo Beta
Model Number(s)	NA-RBT-1 NeuralBot NA-DSP2 NeuralBot Procedural Set
Federal Regulation Number	21 CFR 892.1550 21 CFR 892.1570
Product Codes	IYN, ITX, OQQ
Class	Class II Device

Predicate Devices	K122710 Shenzhen Delicate Electronics Co., Ltd. Transcranial Doppler with Robotic Probe Headband, EMS-9UA Class II 21 CFR 892.1550, IYN 21 CFR 892.1570, ITX and OQQ K160442 NEURAL ANALYTICS, INC. Lucid M1 Transcranial Doppler Ultrasound System (Lucid M1 System) With 2MHz Transducers Class II 21 CFR 892.1550, IYN 21 CFR 892.1570, ITX
Performance Standards	There are no required performance standards under the Federal Food, Drug and Cosmetic Act. Voluntary standards to which we will conform include: IEC 60601-1, IEC 60601-1-2, IEC, IEC 60601-2-37, IEC 62133 (RCU rechargeable battery and ACU internal battery), ISO 10993-1, and ISO 62304.
Special Controls	There are no special controls as a special report is no longer required. The guidance referenced is "*Guidance for Industry and FDA Staff - Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers*" dated September 9, 2008.

Submission Focus:

The submission will focus on the NeuralBot System.
The NeuralBot System consists of the following elements:

- Accessory Control Unit (ACU)
- Robotic Control Unit (RCU)
- Patient Headmount Unit (PHU)
- Cart

This system connects to the Lucid M1 System as an accessory.
Information from the Lucid M1 System (K160442) is provided in this submission for the purpose of clarification where deemed appropriate.

Device Description

The NeuralBot System is a cart mounted, robotic transcranial Doppler (TCD) probe positioning accessory for the previously cleared Lucid M1 System (K160442) which assists the user in the acquisition of cerebral blood flow velocity (CBFV) data via the patient's temporal acoustic windows.

The NeuralBot System consists of the following three subsystems mounted on a cart

1. Accessory Control Unit (ACU)
   a. The main accessory software including the, TCD signal search algorithm, and graphical user interface are installed on this subsystem.
2. Robotic Control Unit (RCU)
   a. Contains the electronics and embedded software that control the robotic actuators of the patient headmount unit.
3. Patient Headmount Unit (PHU)
   a. Comprised of the patient head interface, 2 MHz transducers, and the robotic probe positioning mechanism.

The NeuralBot System guides the operator in positioning the transducers in the PHU, one on each side of a patient's head, at their temporal regions. The 2 MHz transducers used in the NeuralBot System are the same transducers previously cleared for use with the Lucid M1 System (K160442). The NeuralBot System's probe positioning is accomplished using robotic actuators that adjust the translational and angular position of each transducer independently using TCD signal search algorithms. The accessory is designed to locate TCD signals at depths between 45 and 60 mm allowing the operator to monitor the CBFV of the vessels via the patient's temporal acoustic windows. The NeuralBot System identifies several candidate TCD signals and displays multiple signals from each side of the patient's head. At the end of the search, the NeuralBot System will then retrieve and track the best located signal.

Communication between the Lucid M1 System (K160442) and the NeuralBot System occurs via a USB to Ethernet cable that connects the ACU to the Lucid M1 System using its digital streaming feature. The 2 MHz transducers of the PHU are connected to the Lucid M1 System's TCD probe connections (K160442).

Indications for Use

The NeuralBot when used with Lucid M1 System is a medical ultrasound device which assists the user in the setup and acquisition of cerebral blood flow velocity via the patient's temporal windows. It is intended for use as an adjunct to standard clinical practices for measuring and displaying cerebral blood flow velocity and the occurrence of transient emboli within the blood stream.

The NeuralBot is intended to be used by healthcare professionals qualified by training in its safe and effective use. The device is not intended to replace other means of evaluating vital patient physiological processes, is not intended to be used in fetal applications, and is not intended to be used inside the sterile field.

Equivalence Discussion:
The NeuralBot System and Lucid M1 System (K160442):
A full comparison of the technological characteristics of the NeuralBot System when connected to the Lucid M1 System and the Lucid M1 System was made. Both are TCD ultrasound flow systems with monitoring functions. Both systems monitor cerebral blood flow velocity and the occurrence of transient emboli within the blood stream via the temporal windows.

Both systems have equivalent modes and use pulsed wave Doppler (PWD) using color M-Mode for location of the vessel of interest.

Additionally, both devices:

- Are transcranial Doppler ultrasound systems used for cerebral blood flow analysis
- Monitor the cerebral blood flow velocity and the occurrence of transient emboli within the blood stream via the temporal windows
- Utilize two transducers which are attached via a headset for cephalic monitoring
- Use substantially equivalent operating modes
- Measure equivalent hemodynamic indices
- Have equivalent monitoring functions
- Transducers are substantially equivalent
- Are manufactured to meet applicable physical, mechanical, and electrical safety requirements
- Display TIC, velocity spectrum, M-Mode, velocity envelope, Mean velocity, Minimum velocity, Maximum velocity, Pulsatility index, and emboli count (in emboli and bubble exams of the Lucid M1 System)

The NeuralBot System and the Transcranial Doppler with Robotic Probe Headband, EMS-9UA (K122710):
A full comparison of the technological characteristics of the NeuralBot System when connected to the Lucid M1 System and the Transcranial Doppler with Robotic Headband was made. Both are Robotic Probe systems intended for obtaining the information of CBFV by using a non-invasive ultrasonic technique. This method of measurement is particularly useful for examining the major arteries supplying blood to the brain via the temporal window.

Both systems have equivalent modes and use pulsed wave Doppler (PWD) using color M-Mode for location of the vessel of interest. Both systems can automatically adjust the position of the ultrasonic transducers during monitoring according to the signal intensity of CBFV via the patient's temporal windows.

Summary of Non-Clinical Testing and Reliance on Standards

The NeuralBot System when used with the Lucid M1 system is evaluated for acoustic output, biocompatibility, and accuracy, as well as thermal, electrical, electromagnetic, and mechanical safety. Non-clinical testing to support thermal, mechanical, electromagnetic, and mechanical safety is conducted per the FDA *Guidance Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers*, using applicable sections of the following voluntary standards:

- IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, Edition 3.1
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests, Edition 3.1
- IEC 60601-2-37:2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, Edition 2.1
- NEMA Standards Publication UD 2-2004(R2009) Acoustic Output Measurement Standard For Diagnostic Ultrasound Equipment Revision 3
- NEMA Standards Publication UD 3-2004(R2009) Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment Revision 2
- ISO 10993-1:2010 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process, Fourth Edition

Conclusion

The documentation provided demonstrates that:

- The NeuralBot System is substantially equivalent to the predicate devices.
- There are no new questions of safety and effectiveness concerning the NeuralBot System.
- The NeuralBot System is designed to be as safe and effective as the predicate devices.
- The NeuralBot System is designed to perform as well as the predicate devices.

Accordingly, the NeuralBot System is believed to be substantially equivalent to the predicate devices of the same type which are lawfully distributed in interstate commerce in the United States.