DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 18, 2016

SI-BONE, Inc.
Roxanne Dubois
VP, Regulatory Affairs and Quality Assurance
3055 Olin Ave, Suite 2200
San Jose, California 95128

Re: K161893
Trade/Device Name: Neuromonitoring Kit
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: PDQ
Dated: September 15, 2016
Received: September 16, 2016

Dear Ms. Dubois:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -A

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161893

Device Name
Neuromonitoring Kit

Indications for Use *(Describe)*
The Neuromonitoring Kit is indicated for stimulation of peripheral motor nerves, including spinal nerve roots, for localization and identification during surgery.

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 – K161893
Neuromonitoring Kit

I. SUBMITTER

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Date Prepared: October 14, 2016

II. DEVICE

Name of Device:	Neuromonitoring Kit
Common or Usual Name:	Neuromonitoring Kit
Classification Name:	Surgical nerve stimulator/locator (21 CFR 874.1820)
Regulatory Class:	II
Product Code:	PDQ

III. PREDICATE DEVICE

Rhythmlink International Monopolar Stimulating Instrument (K072736).
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Neuromonitoring Kit is designed to use stimulation to locate, identify and monitor peripheral motor nerves and spinal nerve roots during surgery. The kit contains a Probe, Guide Pin Sleeve, and cable electrodes (Guide Pin Cap, and Guide Pin Clip). The Neuromonitoring Kit can be used with the iFuse Implant System.

The design of the Probe is similar to existing stainless steel stimulating instruments. The Probe consists of a stainless steel wire with biocompatible electrical insulation applied to selected portions, and a proximal connector provided to attach the probe to a monopolar stimulator. The distal surface of the Probe is non-insulated stainless steel to provide for tissue stimulation.

The Neuromonitoring Kit meets the requirements of IEC 60601-1:2012 reprint and IEC 60601-1-2:2007 Clause 56.3(c) per 21 CFR 898.12. The Neuromonitoring Kit is sterile (ETO) and for single use only.

V. INDICATIONS FOR USE

The Neuromonitoring Kit is indicated for stimulation of peripheral motor nerves, including spinal nerve roots, for localization and identification during surgery.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The design of the Probe is similar to the design of the predicate device. Both the Probe and the predicate device consists of a stainless steel wire with biocompatible electrical insulation applied to selected portions, and a proximal connector provided to attach the Probe to a monopolar stimulator. For both, the distal surface of the Probe is non-insulated stainless steel to provide for implant and tissue stimulation. In addition, the subject device and predicate device are manufactured the same way and at the same facility.

The following is a comparison of the technological characteristics of the Neuromonitoring Kit where compared to the predicate device.

Table 1 – Substantial Equivalence Comparison Table

Characteristic	Proposed Neuromonitoring Kit	Rhythmlink International Monopolar Stimulating Instrument Predicate Device
510k number	K161893	K072736
Principles of Operation	Same	Monopolar nerve stimulation
Sterile (EtO)	Same	EtO Sterilization
Single Use	Same	Single Use
Biocompatible	Same	Biocompatible
Biocompatible Electrical insulation	PVDF	PTFE or PVDF
Distal stainless steel patient contact surface	Same	316 SS
Proximal stimulator connector	Same	DIN 42802-1 Touch-proof
IEC 60601 - 1 Protected Pin design	Same	IEC 60601 - 1 Protected Pin design
Shaft Material	Same	316 SS
Handle Material	Same	Acrylonitrile butadiene styrene (ABS)
Maximum Charge Density which will be generated by the probe	374 $\mu C/cm^2$	Exhibits a range of Charge Densities depending on Probe. Maximum Charge Density is greater than the subject device
Probe Length	225mm	Exhibits a range of probe lengths depending on probe. The probe length is within the range of the subject device
Cable/ Lead Wire Length	2.5m	Exhibits a range of Cable/Lead wire lengths depending on probe. The Cable/Lead Wire Length is within the range of the subject device.
Uncoated Conducting Surface Area	$27mm^2$	Exhibits a range of Conducting Surface Areas. Smallest Conducting Surface Area is less than the subject device .
Tip Diameter/ Exposure	3.0mm	Exhibits a range of Tip Diameter/Exposures depending on probe. The Tip Diameter/Exposure is within the range of the subject device.

There are no changes to the technological characteristics of the Probe.

VII. PERFORMANCE DATA

Electrical safety, electromagnetic compatibility and mechanical performance data were provided in support of the substantial equivalence determination.

Electrical Safety and Electromagnetic Compatibility (EMC) testing were conducted on the Neuromonitoring Kit and demonstrated that the Neuromonitoring Kit, including the Probe within the kit, meets the requirements of IEC 60601-1:2012 reprint and IEC 60601-1-2:2007 Clause 56.3(c) per 21 CFR 898.12.

Electrical safety, electromagnetic compatibility and mechanical performance test results demonstrate that the subject Probe is substantially equivalent to the predicate.

VIII. CONCLUSIONS

The Neuromonitoring Kit that is the subject of this 510(k) is substantially equivalent to the predicate device.