October 31, 2019

Bioness Inc.
Sageev George
Senoir Regulatory Affairs Specialist
25103 Rye Canyon Loop
Valencia, California 91355

Re: K190047
Trade/Device Name: StimRouter Neuromodulation System
Regulation Number: 21 CFR 882.5870
Regulation Name: Implanted Peripheral Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZF
Dated: September 30, 2019
Received: October 1, 2019

Dear Sageev George:

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,

Pamela D. Scott -S

Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine 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)*
K190047

Device Name
StimRouter Neuromodulation System

Indications for Use *(Describe)*
The StimRouter Neuromodulation System is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as an adjunct to other modes of therapy (e.g., medications). The StimRouter is not intended to treat pain in the craniofacial region.

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."

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. Submitter Information

Company: Bioness Inc.
25103 Rye Canyon Loop
Valencia, CA 91355 USA
Phone Number: (661) 902-5324
Fax: (661) 362-4851
Email: mercedes.bayani@bioness.com

Contact: Sageev George
Senior Regulatory Affairs Specialist
Phone Number: (661) 902-5336
Fax Number: (661) 362-4851
Email: sageev.george@bioness.com

Mercedes Bayani
Global Director, Clinical & Regulatory Affairs
Phone Number: (661) 902-5324
Fax Number: (661) 362-4851
Email: mercedes.bayani@bioness.com

Date Prepared: January 7, 2019

II. Name of Device

Device Trade Name: StimRouter Neuromodulation System
Classification Name: Implantable peripheral nerve stimulator for pain relief
Common Name: Implantable Neurostimulator
Product Code: GZF
Regulation Number: 21 CFR §882.5870
Device Class: Class II
Panel Identification: Neurology

III. Predicate Device

Predicate Manufacturer: Bioness Inc.
Predicate Trade Name: StimRouter Neuromodulation System
Predicate 510(k): K142432

Reference Devices:

Predicate Manufacturer:	Medtronic
Predicate Trade Name:	PNS
Predicate 510(k):	K904409/A, K920567, K982902
Predicate Manufacturer:	ANS
Predicate Trade Name:	Renew
Predicate 510(k):	K000582

IV. Device Description

The StimRouter Neuromodulation System consists of two main parts – the implantable lead, and the external (to the body) accessories. Accessories for the StimRouter include a clinician programmer with software (CPS), a patient programmer, disposable hydrogel electrode patch, external pulse transmitter (EPT), and an EPT stimulation tester (EPTT).

The Bioness StimRouter Neuromodulation System is intended to provide electrical stimulation via an implanted lead to a target peripheral nerve, for aid in the management of severe, intractable, chronic pain of peripheral nerve origin in adults, as an adjunct to other modes of therapy (e.g. medications). The StimRouter is not intended to treat pain in the craniofacial region.

The complete StimRouter System consists of three kits: A Lead and Lead Introducer Kit, a Clinician Kit and User Kit. The Lead Kit contains the StimRouter implantable multi-electrode lead with integrated receiver, used for peripheral nerve stimulation. The Lead receives an electrical signal transmitted transcutaneously by the EPT which is mounted on an electrode patch on the skin and delivers that electrical signal down the lead's length to a target peripheral nerve. The Lead is supplied in Lead Loader that is used during intraoperative testing of the lead and to verify proper placement during implantation.

The Lead and lead Introducer Kit consists of two stimulation probes, two stimulation cables, and introducer set, a lead adapter, a Tunneling Needle and a Tunneling Needle Stylet. The included tools and components allow for insertion of the StimRouter Lead and confirmation of optimal location of the stimulation electrode contacts of the StimRouter Lead.

The Clinician Kit is used for the programming of the StimRouter patient programmer and the EPT. The components of the Clinician Kit are a tablet PC with programming software and the accessories for connecting to the Patient Programmer and the EPT.

The User Kit contains the patient-use components of the StimRouter System. The components are the Patient Programmer and the EPT. After the EPT is programmed, the StimRouter electrode interfaces with the EPT and function to delivery stimulation to the implanted lead receiver.

V. Indications for Use

The StimRouter Neuromodulation System is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as an adjunct to other modes of therapy (e.g., medications). The StimRouter is not intended to treat pain in the craniofacial region.

VI. Comparison of Technological Characteristics

The subject device is a modified version of the StimRouter Neuromodulation System previously cleared in K142432. A comparison of the technological characteristics of the two is presented below:

Predicate Device Comparison

	Subject Device (Modified StimRouter)	Predicate (Original StimRouter)	Equivalency Assessment
Manufacturer	Bioness Inc.	Bioness Inc.	**Same**
510(k) number	To be Determined	K142432	-
Intended use	The StimRouter Neuromodulation System™ is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as an adjunct to other modes of therapy (e.g., medications). The StimRouter is not intended to treat pain in the craniofacial region.	The StimRouter Neuromodulation System™ is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as an adjunct to other modes of therapy (e.g., medications). The StimRouter is not intended to treat pain in the craniofacial region.	**Same**
Implantable Lead and Lead Introducer Kit			
Packaging			
Packaged Kit(s)	"Implantable Lead and Lead Introducer Kit"	"Lead Kit" and "Surgical Kit"	**Similar*** New packaging is just consolidation of Lead Kit and Surgical Kit
Inner Tray Material	Blue tinted PETE (Polyethylene Terephthalate): Large history of use in medical device industry	Blue tinted PETG (Polyethylene Terephthalate Glycol): Large history of use in medical device industry	**Similar*** Contract manufacturer confirmed equivalence thru qualification (PETE has better impact resistance)
Tray Lid	1073B Tyvek (DuPont)	1073B Tyvek (DuPont)	**Same**
Tray Lid Adhesive	Heat Seal Coated TPT-021C adhesive: Large history of use in medical device industry	Heat Seal Coated CR-27 adhesive: Large history of use in medical device industry	**Similar*** Contract manufacturer confirmed equivalence thru qualification
StimRouter Lead			
Number of stimulating electrodes	3	Same	**Same**
Electrode shape	Cylindrical	Same	**Same**

Estimated electrode surface area, per electrode	6.3 mm^2	Same	**Same**
Maximum charge per pulse (lead)	3 µC	2 µC	**Similar** Safety is maintained because of limit on max current (30mA) and max pulse duration (500µsec). Max value is lower than that of similar devices, and complies with safety requirements.
Maximum charge density (lead)	15.9 $\mu C/cm^2$	10.6 $\mu C/cm^2$	**Similar** Safety is maintained because of limit on max current (30mA) and max pulse duration (500µsec). Max value is lower than that of similar devices, and complies with safety requirements.
Materials (electrode / Insulator	Platinum Iridium Silicone Rubber	Same	**Same**
Location of stimulation receiver	Implanted, RF lead receiver transmitter	Same	**Same**
Design features	Helical coil design Single silicone insulator sheath	Same	**Same**
Anchors	Yes	Same	**Same**
Lead Length	15 cm	Same	**Same**
Lead body diameter	1.2 mm	Same	**Same**
Implantation / Placer Tools	StimRouter Surgical Tool Kit	Same	**Same**
Introduction method	Percutaneous	Same	**Same**
Tunneling Needle and Tunneling Needle Stylet			
Tunneling Needle Material	304 Stainless Steel (SST 304) (No Nickel warning, unlike predicate)	SST 304 with nickel plating on handles/hubs (Presence of nickel required Nickel allergy warning in labeling)	**Similar** Nickel was used to make soldering easier between needle and handle/hub in predicate. Adequate soldering without nickel was confirmed by vendor in subject device
Tunneling Needle Size	12 Gauge	12 Gauge	**Same**

StimRouter Loader	No changes	Same	**Same**
Stimulation Probe	No changes	Same	**Same**
Stimulation Cable	No changes	Same	**Same**
Introducer Set	No changes	Same	**Same**
Lead Adaptor	No changes	Same	**Same**
Gel Electrodes	No changes	Same	**Same**
Clinician Kit			
Clinician's Programmer			
Hardware	Vanquisher IP67 8-inch tablet (off-the-shelf) with new charger and connector cable with Micro-SD Card storage	Hewlett Packard iPAQ 210 Enterprise Handheld PDA (off-the-shelf) with SD Card storage	**Similar*** IP67 is physically larger than the PDA and runs substantially equivalent software (recompiled for IP67 Operating System)
Clinician Programmer Operating System	Microsoft® Windows 10 Home	Microsoft® Windows Mobile® 5	**Similar*** Same code can run in Windows 10 Home
Location of programmer	External	Same	**Same**
Software driven?	Yes	Same	**Same**
Size of programmer	Hand-held	Same	**Same**
Multiple stim modes?	Yes	Same	**Same**
Graphical User Interface (GUI)	Original GUI adjusted to fit a larger area (8") of screen	Yes	**Similar*** Same GUI contents
Stimulation Frequencies	1, 2, 5, 10, **12**, **15,** 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, 200 Hz	1, 2, 5, 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, 200 Hz	**Simila**r Added frequencies (12, 15 Hz) w/in original stimulation range
Patient Log Export Function in the software	Yes	No	**Similar*** Minor change that just adds a function
Miscellaneous Software Enhancements	Updates to remove obsolete event buffering procedure, to allow co-installation of CPS software with H200 and L300 Go software	Software did not have these enhancements	**Similar*** Minor enhancements to code that do not change function
Tester	No changes	Same	**Same**
User Kit			
External Pulse Transmitter (EPT)			
Power source	One lithium polymer, rechargeable battery	Same	**Same**
Location of transmitter	External	Same	**Same**
Amplitude current	0-5 mA (estimate based on 20% max pick-up ratio, max output of EPT of 30 mA)	Same	**Same**

Communication method	RF	Same	**Same**
Pulse frequency	1-200 Hz	Same	**Same**
Stimulation Frequencies	1, 2, 5, 10, **12, 15**, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, 200 Hz	1, 2, 5, 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, 200 Hz	**Similar** Added frequencies (12, 15 Hz) w/in original stimulation range
Ramp Down Feature	Present Provides smooth transition for patient where pulse amplitude is slowly decreased over time for comfort	Not present	**Similar*** Stimulation pulse with ramp down has same paresthesia effect and may provide more comfort
Maximum Compliance Voltage	100V (higher voltage to treat patients w/ high skin impedance or who need higher current settings to achieve therapeutic effect)	90V	**Similar*** Safety is maintained because of limit on max current (30mA) and max EPT external temperature (41°C)
Pulse width	70-500 µsec	Same	**Same**
Charge per phase limit	15 µC Non-rechargeable batteries are no longer supported so charge limitation is not required	10 µC Included in original design to support non-rechargeable batteries (prevented depletion)	**Similar*** Safety is maintained because of limit on max current (30mA) and max pulse duration (500µsec)
Wave form	Biphasic, charge balanced	Same	**Same**
Stimulation modality	Monopolar	Same	**Same**
Miscellaneous Software Enhancements	Software update to prevent false positive detection of transistor disconnection and improve impedance measurement of electrodes	Original software did not have enhancements	**Similar*** Update provides better detection of conditions and unnecessary termination of stimulation
Patient Programmer			
Stimulation Frequencies	1, 2, 5, 10, **12, 15**, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, 200 Hz	1, 2, 5, 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, 200 Hz	**Similar** 12 Hz and 15 Hz are both within the original stimulation range
Number of programs	8	Same	**Same**
Programs patient selectable?	Yes	Same	**Same**
Programmer communication method with EPT	RF	Same	**Same**
Location of programmer	External	Same	**Same**
Software driven?	Yes	Same	**Same**
Multiple stim modes?	Yes	Same	**Same**

Graphical User Interface (GUI)	Yes	Same	**Same**
Miscellaneous Software Enhancements	Updates to prevent connection with interfering EPTs, to prevent use of buggy RF channels	Original software did not have enhancements	**Similar*** Software updates improve reliability of connection with EPT
StimRouter Electrodes	No change	Same	**Same**

* This technology change does not impact the intended use or the operating principles or mechanism of action of the system

Comparison of Revised Stimulation Parameters

As noted in the above Predicate Device Comparison Matrix, certain stimulation parameters have increased values. However, the subject device uses parameters that are within the safe ranges of the predicates of the original StimRouter cleared in K142432, and which are used as reference devices in this submission. The following table illustrates these parameters and how the subject device falls within these safe ranges:

Receivers and Transmitters	**StimRouter Implantable Neurostimulator (current version)**	**StimRouter Implantable Neurostimulator (as submitted in K142432)**	**REFERENCE 1 Medtronic PNS (K904409/A, K920567, K982902)**	**REFERENCE 2 Renew System (K000852)**
Number of stimulating electrodes	3	3	4	4
Surface area per electrode	6.3 mm^2	6.3 mm^2	12 mm^2	13 mm^2
Total area of stimulating electrodes	18.9 mm^2	18.9 mm^2	48 mm^2	52 mm^2
Amplitude current	0-6mA *(estimate based on 20% max pick-up ratio, max output of EPT of 30 mA)*	0-6mA *(estimate based on 20% max pick-up ratio, max output of EPT of 30 mA)*	Up to 20 mA	24 mA *(estimate based on 12V max output, 500Ω load)*
Pulse frequency	1-200 Hz	1-200 Hz	5-240 Hz (Mattrix)	10-1,500 Hz
Pulse width	70-500 μsec	70-500 μsec	60-450 μsec	50-500 μsec
Maximum average current	1.2 mA	1.2 mA	4.3 mA	Information not publicly available

Receivers and Transmitters	StimRouter Implantable Neurostimulator (current version)	StimRouter Implantable Neurostimulator (as submitted in K142432)	REFERENCE 1 Medtronic PNS (K904409/A, K920567, K982902)	REFERENCE 2 Renew System (K000852)
Maximum current (rms)	2.7 mA	2.7 mA	9.3 mA	Information not publicly available
Maximum average current density	6.3 mA/cm^2	6.3 mA/cm^2	9.0 mA/cm^2	Information not publicly available
Maximum average power density (into 500 Ohm load)	19.2 mW/cm^2	19.2 mW/cm^2	90.1 mW/cm^2	Information is not available
Maximum charge per pulse	3 μC *(estimate based on 20% max pick-up ratio, max output of EPT of 30 mA)*	3 μC *(estimate based on 20% max pick-up ratio, max output of EPT of 30 mA)*	20 μC	12 μC *(estimate based on 12V max output, 500Ω load)*
Maximum charge density	15.9 μC/cm^2 *(estimate based on 20% max pick-up ratio, max output of EPT of 30 mA)*	15.9 μC/cm^2* *(estimate based on 20% max pick-up ratio, max output of EPT of 30 mA)*	160 μC/cm^2 (X-trel)	92.3 μC/cm^2
Wave form	Biphasic, charge balanced	Biphasic, charge balanced	Rectangular, biphasic current outputs	Information not publicly available
Stimulation modality	Monopolar	Monopolar	Bipolar	Bipolar

Performance Data

Risk Analysis methods were used to assess the impact of the modifications of the original StimRouter Neuromodulation System and to determine the verification and validation activities required based on the Risk Analysis. The Risk Analysis methods, the verification and validation activities required, including methods and tests used and their acceptance criteria applied, are provided in the Design Controls section of this submission.

The verification and validation activities required the following bench tests, originally developed under the design control process of the StimRouter Neuromodulation System cleared in K142432:

- **Bioburden**
- **Sterilization & Shelf-life Testing**
- **Biocompatibility Testing**
- **Shelf Life**
- **Shipping Validation**
- **Package Integrity (Bubble Leak Testing, Seal Strength Testing)**
- **Functional Verification and Validation**
- **Label Validation**
- **Printing Verification**
- **MRI Compatibility**
- **Implant Heating**
- **Software Verification and Validation Testing**

VII. Conclusions

The verification and validation activities described above demonstrate that the subject device StimRouter Neuromodulation System, which has modifications as compared to the predicate StimRouter Neuromodulation System (cleared in K142432), is substantially equivalent to the predicate device in terms of safety and effectiveness for its indication of pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as an adjunct to other modes of therapy (e.g., medications). The subject device continues to not be intended to treat pain in the craniofacial region.