



March 27, 2020

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

Re: K200482

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: February 25, 2020
Received: February 27, 2020

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 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

Indications for Use

510(k) Number (if known)

K200482

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.

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3. 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

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Date Prepared:

February 25, 2020

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): K190047

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 StimRouter Neuromodulation System is provided with three labeling documents: the Clinician’s Guide, the Procedure Manual and the User’s Guide. Only the Procedure Manual has been modified to include an alternative implantation procedure for situations in which an open implantation of the implantable StimRouter Lead is indicated

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 K190047. A comparison of the technological characteristics of the two is presented below. As noted in the Predicate Device Comparison Matrix below, other than the update of the Procedure Manual to include an alternative implantation procedure for situations in which an open implantation of the implantable StimRouter Lead is indicated, there are no other modifications with respect to the K190047 predicate all other technological characteristics are equivalent.

Predicate Device Comparison

	Subject Device (Modified StimRouter)	Predicate (StimRouter cleared in K190047)	Equivalency Assessment
Manufacturer	Bioness Inc.	Bioness Inc.	Same
510(k) number	To be Determined	K190047	-
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			
Packaging	No changes	Tray Material: PETG Lid Material: 1073B Tyvek Lid Adhesive: TPT-021C	Same
StimRouter Lead			
StimRouter Lead	No changes	Implanted Lead: Length: 15cm, Diameter: 1.2mm, Helical coil design, Anchors, silicone insulator sheathe	Same
StimRouter Lead Receiver End	No changes	12mm receiver electrode, captures portion of signal generated by EPT	Same
StimRouter Lead Stimulating End	No changes	3 cylindrical stimulating electrodes: Materials: Platinum Iridium, Surface Area: 6.3 mm ² , Max charge per pulse: 3 μC, Max charge density: 15.9 μC/cm ²	Same
Introduction method	No changes	Percutaneous	Same
Tunneling Needle and Tunneling Needle Stylet	No changes	Stainless steel hollow needle and solid stylet used to implant receiver end of Lead	Same

	Subject Device (Modified StimRouter)	Predicate (StimRouter cleared in K190047)	Equivalency Assessment
StimRouter Loader	No changes	Stainless Steel Tube with Reed Connector	Same
Stimulation Probe	No changes	Stainless steel wire coated w/ titanium nitride and insulated tubing	Same
Stimulation Cable	No changes	2m long Cable for connecting external peripheral nerve stimulator with Stimulation Probe, StimRouter Loader or StimRouter Lead Adaptor	Same
Introducer Set	No changes	11cm long dilator & sheath used for routing stimulation end of Lead from incision to target stimulation point	Same
Lead Adaptor	No changes	5.5 cm stainless steel cylinder which connects to Lead, allowing connection of Stimulation cable	Same
Gel Electrodes	No changes	Nonsterile gel electrodes (5cm diameter) used when stimulation applied to Stimulation Probe or Stimulation Lead. Comes with 1.5m long electrode cable	Same
Clinician Kit			
Clinician's Programmer			
Hardware	No changes	Vanquisher IP67 8-inch tablet running Window 10 Home	Same
Software	No changes	Clinician Programmer Software used for storing patient info, session data, logs, patient stimulation profile, and programming, testing and saving of stimulation programs on tablet, and downloading of programs to Patient Programmer and EPT	Same
Stimulation Frequencies available for Patient Programmer and EPT stimulation programs	No changes	1, 2, 5, 10, 12, 15, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, 200 Hz	Same

	Subject Device (Modified StimRouter)	Predicate (StimRouter cleared in K190047)	Equivalency Assessment
Tester	No changes	Used to confirm EPT is delivering stimulation by providing audio feedback when stimulation is applied	Same
User Kit			
External Pulse Transmitter (EPT)			
External Pulse Transmitter Description	No change	Generates stimulation signals, transmitting them transcutaneously through StimRouter Electrode to StimRouter Lead. Responds to wireless commands from Patient Programmer. Snaps onto StimRouter Electrode, Rechargeable lithium battery	Same
EPT Stimulation	No Change	EPT Max output: 30mA, Amplitude at Lead: 0-5mA (20% max pick-up ratio) Stimulation Signal: Monopolar, Biphasic, Charge Balanced, RF-based, Pulse Freq: 1-200 Hz, Max Compliance Voltage: 100V, Pulse Width: 70-500 µsec, Charge per phase limit: 15 µC Ramp Up/Down feature	Same
EPT Stimulation Frequencies	No change	1, 2, 5, 10, 12, 15, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, 200 Hz	Same
Patient Programmer			
Patient Programmer Description	No change	Communicates wirelessly (RF) with EPT to do the following: start/stop stimulation, adjust stimulation intensity, selection of one of 8 possible stimulation programs	Same
Patient Programmer Stimulation Frequencies	No change	1, 2, 5, 10, 12, 15, 20, 30, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, 200 Hz	Same

	Subject Device (Modified StimRouter)	Predicate (StimRouter cleared in K190047)	Equivalency Assessment
StimRouter Electrodes	No change	Reusable electrodes with gel pad that adhere to skin and transmit EPT stimulation signal to StimRouter Lead, Includes 2 snaps for EPT attachment	Same
Labeling: Update to Procedure Manual (MODIFIED FROM PREDICATE)			
Addition of New Section Detailing Alternative Implantation Procedure for StimRouter Lead			
Summary: The new section provides details on the implantation of the StimRouter Lead when open implantation of the Lead is indicated and treating physician believes that the StimRouter System would be useful in treating the pain associated with target nerve.			
Implantation of Lead Procedure	The updated Procedure Manual still includes the minimally invasive procedure for Lead implantation but includes an alternate implant procedure for situations where open implantation of the Lead is indicated, for example when the area around the target nerve has been exposed (e.g., nerve decompression procedures). The new procedure details how the Lead can be placed and fixated next to target nerve and how the Tunneling Needle and Stylet can be used to place receiver end of Lead.	The Procedure Manual details a minimally invasive procedure for implanting the StimRouter Lead using a single stab incision, Stimulator Probe for target point identification, insertion of the Lead stimulating end using Introducer Set, and insertion of Lead receiver end using Tunneling Needle and Stylet.	Similar: The new procedure is being provided for situations in which the surgical field has been previously opened and does not introduce additional risks to the patient. Also, the new method of placing the Lead allows for similarly effective stimulation of target nerve and receipt of stimulation from EPT.

Design Control Activities

Bioness Inc. established, and continues to document and maintain, a system for identifying and addressing hazards associated with the design, manufacture and use of a medical device throughout its lifecycle. This system includes procedures for estimating, evaluating, controlling, and/or reducing risk such that the medical benefit outweighs the residual risk associated with the use of the devices that are marketed by Bioness Inc. These procedures address the risk management requirements of ISO 13485, ISO 14971:2012, the Medical Device Directive (MDD) and the Quality System Regulation (QSR).

This system was used to assess the impact of the modifications of the original StimRouter Neuromodulation System and to determine what verification and validation activities may be

required based on this assessment. The methods and results of the Risks vs. Benefits Assessment are provided in the Design Controls section of this submission. The results of the analysis are as follows:

- Verification activities are not required, as there is no change to the design of the StimRouter.
- Validation activities are not required – lead placement using this alternate approach is visible to the implanting physician due to the open nature of the procedure. The novel component involved during StimRouter lead implantation using this alternate technique is the process of using sutures and/or surgical glue to anchor the lead and prevent migration. These are commonly used surgical procedures employed by trained physicians and are not unique to the StimRouter implantation. As such, these process steps do not require usability testing.
- The potential hazardous situation resulting from the alternate surgical approach has been identified as “Undesired motor neuron stimulation, due to poor placement of the lead during implant or migration after implant”. The specific harm associated with this failure mode has the same end effect (severity) as overstimulation of contra-indicated nerves – a failure mode which is currently listed within the risk documentation (HA-00011) and the current state of the art information. As such, the Risk vs. Benefits assessment remains unchanged, where the benefits accrued from the use of the device outweigh any identified residual risk.

VII. Conclusions

Based on the system maintained by Bioness Inc. for identifying and addressing hazards associated with the design, manufacture and use of a medical device throughout its lifecycle, Bioness Inc. concludes that the Risks vs. Benefits assessment remains unchanged, where the benefits accrued from the use of the device outweigh any identified residual risk. Therefore, the subject device StimRouter Neuromodulation System, which has modifications as compared to the predicate StimRouter Neuromodulation System (cleared in K190047), 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.