February 22, 2022

Bioness Inc.
Sageev George, Ph.D.
Regulatory Affairs Manager, Implantables
25103 Rye Canyon Loop
Valencia, California 91355

Re: K211965
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: January 21, 2022
Received: January 24, 2022

Dear Dr. 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,

Amber Ballard, Ph.D.
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)*
K211965

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.

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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) 388-9303
Fax: (661) 362-4851
Email: sageev.george@bioness.com

Contact:
Sageev George
Senior Regulatory Affairs Manager, Implantables
Bioness Inc.
Phone Number: (661) 388-9303
Fax Number: (661) 362-4851
Email: sageev.george@bioness.com

Sharon Klugewicz
Sr. Vice President, Quality & Regulatory Affairs
Bioventus Inc.
Phone Number: (516) 425-4446
Email: sklugewicz@misonix.com

Date Prepared: January 21, 2022

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): K200482

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 disposable hydrogel electrode patch, an external pulse transmitter, an external pulse transmitter stimulation tester and a device used by the patient to wirelessly control the external pulse transmitter. The StimRouter Neuromodulation System is provided with three labeling documents: the Clinician's Guide, the Procedure Manual and the User's Guide.

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 external pulse transmitter 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 external pulse transmitter. The components of the Clinician Kit are a tablet PC with programming software that is capable of connecting to and configuring the external pulse transmitter.

The User Kit contains the patient-use components of the StimRouter System. The components are the External Electric Field Conductor (E-EFC), an external pulse transmitter, with included charger and the StimRouter Electrode Carrying Case. After the E-EFC is programmed, the E-EFC can be connected to the StimRouter Electrode through which it can deliver stimulation transcutaneously to the implanted lead receiver.

V. Indications for Use

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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 table below compares the principles of operation and operational/technological characteristics for the subject device and the predicate device. These comparisons confirm that the subject and predicate devices have very similar overall principles of operation and operational/technological characteristics, thereby support the substantial equivalence of the subject device to the predicate. Except for three accessories, the subject device is identical to the predicate. The three accessories, the External Electrical Field Conductor, the MAPP Smartphone Application, and a modified version of the Clinician's Programming Software, are newer versions of three accessories of the predicate, the External Pulse Transmitters, the Patient Programmer, and the original Clinician's Programming Software. These new accessories will replace the accessories in the system. The table below confirms that the three new subject device accessories have equivalent functionality to the predicate's accessories that they will replace.

Predicate Device Comparison Matrix

	Subject Device (Modified StimRouter)	**Predicate (StimRouter cleared in K200482)**	**Equivalency Assessment**
Manufacturer	Bioness Inc.	Bioness Inc.	**Same**
510(k) number	K211965	K200482	-
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**

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	Subject Device (Modified StimRouter)	Predicate (StimRouter cleared in K200482)	Equivalency Assessment
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 $\mu C/cm^2$	**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**
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**

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	Subject Device (Modified StimRouter)	Predicate (StimRouter cleared in K200482)	Equivalency Assessment
External Pulse Generator	No changes	Implantation requires the use of a 510(k) cleared External Pulse Generator (such as Dakmed 750 DPNS, cleared in K791047) to verify correct placement of StimRouter lead	**Same**
User Kit			
Externally Worn Device (EWD)			
Name	External Electrical Field Conductor (E-EFC)	External Pulse Transmitter (EPT)	**Similar.** The different product names do not affect safety and effectiveness of intended use.
EWD Description	Generates stimulation signals, transmitting them transcutaneously through StimRouter Electrode to StimRouter Lead. Responds to wireless commands MAPP or CPS, or configuration requests from CPS. Snaps onto StimRouter Electrode; contains a rechargeable lithium battery.	Generates stimulation signals, transmitting them transcutaneously through StimRouter Electrode to StimRouter Lead. Responds to wireless commands from Patient Programmer or CPS, or to configuration requests from CPS. Snaps onto StimRouter Electrode; contains a rechargeable lithium battery.	**Similar.** The E-EFC is substantially equivalent to the EPT for actions including generation of stimulation signals, transmission of signals through Electrode to Lead. Minor differences in hardware are discussed below.
EWD Electronics	E-EFC uses a printed circuit board assembly (PCBA) that includes STMicroelectronics STM32L151 Microcontroller and Nordic Semiconductors nRF52832 Bluetooth LE Module. PCBA-based circuitry generates and transmits electrical stimulation current with embedded waveform parameter settings.	EPT uses a PCBA that includes Texas Instrument TI CC2510F32 DS (26 MHz) and a module that allows for encrypted 2.4 GHz wireless communication. PCBA-based circuitry generates and transmits electrical stimulation current with embedded waveform parameter settings.	**Similar.** The E-EFC PCBA can generate similar electrical stimulation current output as the EPT (symmetrical / asymmetrical, pulse width, pulse frequency, and pulse amplitude). Differences do not affect safety and effectiveness of intended use.

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	Subject Device (Modified StimRouter)	Predicate (StimRouter cleared in K200482)	Equivalency Assessment
EWD Software	STMicroelectronics STM32L151 Microcontroller-specific firmware. In addition to controlling the PCBA-based circuitry, the firmware processes and executes wireless commands sent from MAPP and Clinician Programmer and received by the Nordic Semiconductors nRF52832 Bluetooth LE Module	In addition to controlling the PCBA-based circuitry, the Texas Instrument TI CC2510F32 DS-specific firmware processes and executes wireless commands sent from Patient Programmer and Clinician Programmer	**Similar.** The E-EFC firmware is able to provide substantially equivalent safety, efficacy and functionality as was provided by EPT firmware.
EWD Wireless Protocol	BLE wireless protocol	Proprietary 2.4 GHz wireless protocol	**Similar.** Bluetooth Low Energy (BLE) used by the E-EFC is a widely adopted wireless protocol that can use the 2.4 GHz radio frequency and can provide encryption of transmitted data. The proprietary 2.4 GHz protocol of the EPT was written in-house and also provides encryption of transmitted data.
EWD Wireless Control and Programming	2.4 GHz BLE communication used for control of E-EFC by Wireless Remote (MAPP) and control and programming of E-EFC by CPS.	Proprietary 2.4 GHz RF communication used for control of EPT by Wireless Remote (Patient Programmer) and control and programming of EPT by Clinician Programmer Software (CPS)	**Similar.** The functionality of the EPT (control by wireless remote and control and programming by CPS) has been duplicated in the E-EFC using BLE. The differences do not affect safety and effectiveness of intended use.
EWD Electrical Signal Transmitter	E-EFC has PCBA-based circuitry that is functionally equivalent to that of the EPT	EPT has PCBA-based circuitry that generates and transmits the therapeutic electrical signal	**Similar.** The E-EFC circuitry is functionally equivalent to the EPT circuitry. The differences do not affect safety and effectiveness of intended use.

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	Subject Device (Modified StimRouter)	Predicate (StimRouter cleared in K200482)	Equivalency Assessment
EWD Charger Port	E-EFC uses USB-C charging port	EPT uses Barrel Charging port	**Similar.** The USB-C-type charging port is functionally equivalent to the EPT barrel port. The differences do not affect safety and effectiveness of intended use.
EWD Built-in Control Interface	E-EFC has integrated controls (buttons) that allow the user to turn the device on/off, turn the stimulation on/off, increase or decrease therapy levels.	EPT has no onboard buttons for controlling EPT.	**Similar.** With the exception of the On/Off button, all other functions provided by the E-EFC integrated button controls were previously provided by the EPT's Patient Programmer. Therefore, the addition of integrated button controls does not affect safety and effectiveness of intended use
EWD Status Indicators	E-EFC has an LED built into one of the multi-functional built-in buttons. The LED can indicate charging, standby mode, stimulation mode, low battery, error, action required and pairing mode.	EPT has an integrated LED indicator to indicate when charging is occurring.	**Similar.** The new functions of the E-EFC were previously provided by the Patient Programmer. Therefore, these differences do not affect safety and effectiveness of intended use
EWD Enclosure: Externally Contacting Materials	E-EFC: Housing: Tritan™ Copolyester MX731 Button overlay: Polycarbonate polyform Snap connector: CDA 260 Brass 200 Series S.S	ABS/PC-PBT	**Similar.** As with the EPT ABS/PC-PBT externally contacting enclosure material, the E-EFC enclosure material was confirmed to be biocompatible for the type and duration of contact as per ISO 10993-1.
EWD Enclosure: Size and Weight	E-EFC: 5.7 x 3.7 x 1.2 cm, 28g	EPT: 5.7 x 3.2 x 1.2 cm, 20g	**Similar.** The E-EFC is slightly larger and slightly heavier than the EPT, but the differences do not affect safety and effectiveness of intended use.

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	Subject Device (Modified StimRouter)	Predicate (StimRouter cleared in K200482)	Equivalency Assessment
EWD Delivery of Energy	E-EFC delivers transcutaneous electrical pulses via hydrogel patch attached to the skin over the implanted receiver.	EPT delivers transcutaneous electrical pulses via hydrogel patch attached to the skin over the implanted receiver.	**Same.** The delivery of energy remains unchanged.
EWD Stimulation	E-EFC Max output: 30mA Monopolar, Biphasic, Charge Balanced, Pulse Freq: 1-200 Hz, **Max Compliance Voltage: 130V**, Charge per phase limit:15 µC Ramp Up/Down feature Amplitude at Lead: 0-5mA (20% max pick-up ratio) Stimulation Signal: Monopolar	EPT Max output: 30mA Monopolar, Biphasic, Charge Balanced, Pulse Freq: 1-200 Hz, **Max Compliance Voltage: 100V**, Charge per phase limit:15 µC Ramp Up/Down feature Amplitude at Lead: 0-5mA (20% max pick-up ratio) Stimulation Signal: Monopolar	**Similar** E-EFC max compliance voltage increased to 130V. Since both the EPT and E-EFC are current controlled stimulators, the maximal delivered current or other stimulation parameters did not change. Increase in max compliance voltage allows delivery of the required current into higher impedance, thus providing the therapy to a wider range of patient skin impedances. This difference in hardware does not affect safety and effectiveness of the intended use.

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	Subject Device (Modified StimRouter)	Predicate (StimRouter cleared in K200482)	Equivalency Assessment
EWD Phase Duration	Pulse Width: 100-500 µsec (Positive Phase Duration Values: 100, 200, 300, 400, 500 µsec) Negative Phase Duration for Asymmetric Waveforms: Three times positive phase duration	Pulse Width: 70-500 µsec (Positive Phase Duration Values: 70, 100, 150, 200, 250, 300, 350, 400, 450, 500 µsec) Negative Phase Duration for Asymmetric Waveforms: Four times positive phase duration	The reduction in number of positive phase duration values (due to a simplified code base) does not affect safety and effectiveness of the intended use because minor adjustments can be made to other parameters to create therapeutic programs equivalent to those provided by the EPT. The change in relative duration of the negative phase of asymmetric waveforms does not affect the safety or effectiveness because of the following: 1. Because E-EFC stimulation is still charged balanced ,the physiological response range/impact is equivalent to that of the predicate. 2. The positive phase remains physiologically dominant. 3. Fine tuning of amplitude parameters to create therapeutic programs is equivalent to those provided by EPT.
EWD 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**
Wireless Remote Control: Accessory for Controlling EWD			
Name	MAPP	Patient Programmer	

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	Subject Device (Modified StimRouter)	Predicate (StimRouter cleared in K200482)	Equivalency Assessment
Electronic Platform	Smartphone operating system running MAPP software with a graphical user interface to change E-EFC therapy programs and parameters via 2.4 GHz BLE protocol. E-EFC therapy programs are retrieved by the MAPP from the E-EFC in case E-EFC needs to be replaced.	PCBA running firmware and button interface to change EPT therapy programs and parameters via 2.4 GHz proprietary wireless protocol. EPT therapy programs are loaded by CPS into Patient Programmer in case EPT needs to be replaced.	**Similar.** MAPP software uses a graphical user interface to allow changes to the E-EFC therapy programs via a BLE protocol that reproduces the functions of the EPT. Differences do not affect safety and effectiveness of the intended use.
Wireless Protocol	Smartphone running MAPP software uses 2.4 GHz BLE protocol to communicate with E-EFC	Patient Programmer uses 2.4 GHz proprietary wireless protocol to communicate with EPT	**Similar.** The BLE protocol provides the same functionality as the 2.4 GHz proprietary protocol (i.e., effective wireless communication and encrypted data). Differences do not affect safety and effectiveness of the intended use.
Software / Firmware Capabilities	Smartphone running MAPP can select one of 8 pre-set therapy programs, start/stop therapy on E-EFC, increase / decrease amplitude of therapy signal and provide status readout for paired E-EFC.	Patient Programmer can select one of 8 pre-set therapy programs, start/stop therapy on EPT, increase / decrease amplitude of therapy signal and provide status readout for paired EPT.	**Similar.** Smartphone running MAPP software replicates all of Patient Programmers capabilities. Differences do not affect safety and effectiveness of the intended use.
Remote Control Required?	Optional	Required	**Similar.** Because of the integrated control buttons of the E-EFC, the use of MAPP is optional, but it is as functional as the Patient Programmer. Differences do not affect safety and effectiveness of the intended use.
Reusable Electrodes for Transmitting EWD signal to StimRouter Lead			

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	Subject Device (Modified StimRouter)	Predicate (StimRouter cleared in K200482)	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.**
Clinician Kit			
Clinician's Programmer			
Electronic Platform	Clinician Programmer Software (CPS) runs on Vanquisher IP67 8-inch tablet running Window 10 Home. Built-in Bluetooth functionality is used.	Clinician Programmer Software (CPS) runs on Vanquisher IP67 8-inch tablet running Window 10 Home. Built-in Bluetooth functionality is not used.	**Similar.** The new version of the CPS runs on the same electronic platform, although now the Bluetooth functionality of the tablet is used. Differences in software do not affect safety and effectiveness of the intended use.
Wireless Protocol	2.4 GHz Bluetooth Low Energy (BLE) protocol used to program E-EFC directly	CPS uses attached Patient Programmer and proprietary 2.4 GHz RF protocol to program EPT	**Similar. The** CPS can now program the E-EFC directly where previously, it needed to be connected to the Patient Programmer. Differences do not affect safety and effectiveness of intended use.
Software	Updated Clinician Programmer Software can perform the same functions as the original CPS but uses BLE to send wireless commands directly to the E-EFC.	The Clinician Programmer Software is used for storing patient info, session data, logs, patient stimulation profile, programming, testing, and saving of stimulation programs on tablet. In addition, the CPS allows for downloading of programs to the EPT using wireless commands sent via the Patient Programmer using proprietary 2.4 GHz RF protocol.	**Similar,** but differences do not affect safety and effectiveness of intended use: 1. BLE vs. 2.4 GHz proprietary protocol: Equivalent capabilities. 2. Although fewer positive phase duration values are available in new CPS, substantially equivalent therapies can be created using other available parameters.

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	Subject Device (Modified StimRouter)	Predicate (StimRouter cleared in K200482)	Equivalency Assessment
EWD Tester	No changes	The EPT Tester is used to confirm that the EPT is delivering stimulation by providing audio feedback when stimulation is applied.	**Same.** The same EPT Tester can be used, unchanged, to confirm that the E-EFC is delivering stimulation via audio feedback.

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Performance Testing

The StimRouter Neuromodulation System was qualified through the following :

- **Electrical compatibility and safety**
- **Wireless coexistence**
- **Biocompatibility Testing**
- **Shipping and storage**
- **Shelf life**
- **Functional Verification**
- **Usability**
- **Software Verification and Validation Testing**

VII. Conclusions

Bioness concludes that the StimRouter Neuromodulation System is substantially equivalent to its predicate, the StimRouter Neuromodulation System cleared in K200482, and does not raise any new issues or concerns of safety or effectiveness.

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