July 16, 2025

Bioventus LLC
Sageev George
Director, Regulatory Affairs
4721 Emperor Boulevard
Suite 100
Durham, North Carolina 27703

Re: K243782
Trade/Device Name: StimTrial 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: June 16, 2025
Received: June 16, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 T. Ballard -S

Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243782

Device Name
StimTrial Neuromodulation System

Indications for Use *(Describe)*
The StimTrial System is indicated for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for the StimRouter Neuromodulation System's permanent (long term) implant indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as an adjunct to other modes of therapy used in a multidisciplinary approach and 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

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Date Prepared: July 9, 2025

II. Name of Device

Device Trade Name:	StimTrial 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 Devices

Predicate #1 Manufacturer:	Nalu Medical Inc.
Predicate #1 Trade Name:	Nalu Neurostimulation System for Peripheral Nerve Stimulation
Predicate #1 510(k):	K183579
Predicate #2 Manufacturer:	Bioness Inc.
Predicate #2 Trade Name:	StimRouter Neuromodulation System
Predicate #2 510(k):	K211965

Predicate #3 Manufacturer: SPR Therapeutics
Predicate #3 Trade Name: Smartpatch PNS System
Predicate #3 510(k): K161154

IV. Device Description

The StimTrial Neuromodulation System is to be used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) implant for a system indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as an adjunct to other modes of therapy used in a multidisciplinary approach and not intended to treat pain of craniofacial nerve origin.

The StimTrial Neuromodulation System is intended to help determine patient candidacy for a permanent implant to help manage pain of peripheral nerve origin. The StimTrial System works by sending electrical impulses from an external stimulator to a lead that is percutaneously placed next to a target nerve. These impulses are intended to interrupt or change the pain signals, inducing the feeling of tingling or numbness (paresthesia), and possibly reducing or replacing the feeling of pain.

The StimTrial Neuromodulation System consists of three main parts - the percutaneous StimTrial Lead, the StimTrial Lead Adaptor Cable, and the StimTrial External Stimulator. The StimTrial Lead is percutaneously placed with the distal, stimulating end located at or near the targeted peripheral nerve and with the proximal end remaining outside of the body for the trial duration. The StimTrial Lead Adaptor Cable is an external cable that directly connects the StimTrial Lead to the StimTrial External Stimulator providing a direct electrical pathway from the External Stimulator to the Lead. The StimTrial External Stimulator is a device which, when connected to the Lead Adaptor Cable and the StimRouter Electrode (a hydrogel patch electrode) attached to the skin near the implant site, generates electrical stimulation pulses that travel to the StimTrial Lead. Accessories for the StimTrial System include the StimRouter Electrode (a disposable electrode patch, cleared most recently in K211965), the StimTrial Clinician Programmer with Software (CPS) and the optional StimTrial Mobile Application (MAPP) installed on a Smartphone.

The StimTrial System incorporates both commercially available and specially designed components. The materials used in the StimTrial Lead have a long history of use in implanted devices; the insertion tools are also constructed from materials with a long history of surgical use. Materials in the external accessories are commonly used in both medical and non-medical applications. The powered components of the StimTrial System use commercially available IEC and UL approval rechargeable batteries. There are no components which are plugged into a wall socket during the use of the system by the patient.

V. Indications for Use

The StimTrial System is indicated for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for the StimRouter Neuromodulation

System's permanent (long term) implant indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as an adjunct to other modes of therapy used in a multidisciplinary approach and 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 StimTrial System and its predicate devices. These comparisons confirm that all of these PNS systems have very similar overall principles of operation and operational/technological characteristics, thereby supporting the substantial equivalence of the StimTrial System to these previously cleared predicates. Comparison is listed per following aspects:

- System Characteristics
- Leads
- Externally Worn Devices
- Clinician Programmer
- Patient Remote Control

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Comparison of Subject Device and Predicate Device Systems

	Subject Device	Primary Predicate Device	Secondary Predicate Device	Tertiary Predicate Device	Equivalency discussion
510(k) Number	K243782	K183579	K211965	K161154	
Device Name	StimTrial Neuromodulation System	Nalu Neuromodulation System for Peripheral Nerve Stimulation	StimRouter Neuromodulation System	Smartpatch PNS System	
Regulation and Product Codes	21 CFR 882.5870 GZF	21 CFR 882.5870 GZF	21 CFR 882.5870 GZF	21 CFR 882.5890 NHI	
Indications for Use	The StimTrial System is indicated for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for the StimRouter Neuromodulation System's permanent (long term) implant indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as an adjunct to other modes of therapy used in a multidisciplinary approach and not intended to treat pain in the craniofacial region.	This system is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent or as an adjunct to other modes of therapy used in a multidisciplinary approach. The system is not intended to treat pain in the craniofacial region. The trial devices are solely used for trial stimulation (no longer thank 30 days) to determine efficacy before recommendation for a permanent (long term) device.	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 Smartpatch Peripheral Nerve Stimulation (PNS) System is indicated for up to 30 days in the back and/or extremities for: · Symptomatic relief of chronic, intractable pain, post-surgical and post-traumatic acute pain; · Symptomatic relief of post-traumatic pain; · Symptomatic relief of post-operative pain. The Smartpatch PNS System is not intended to treat pain in the craniofacial region.	
Implant Site	Subcutaneous, stimulating electrode(s) of the lead are at peripheral nerves, excluding craniofacial region.	Peripheral nerves, excluding craniofacial region.	Not publicly available	Percutaneous electrode placed in proximity to a target peripheral nerve.	Similar. The subject device and predicates target the peripheral nerves.
Mode of action	Wearable external stimulator delivering electrical stimulation to a percutaneous electrode placed in proximity to a target peripheral nerve.	Not publicly available	Not publicly available	External stimulator delivers stimulation therapy to percutaneous electrode placed in proximity to a target peripheral nerve.	Similar. All devices deliver energy to implanted receiver.

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Stimulation Parameters

	Subject Device	Primary Predicate Device	Secondary Predicate Device	Tertiary Predicate Device	Equivalency discussion
Stimulator battery type	One Lithium ion Polymer, rechargeable	One Lithium ion Polymer, rechargeable	One Lithium ion Polymer, rechargeable	Replaceable batteries	The differences do not affect safety and effectiveness of intended use
Current / Voltage regulated	Current	Current	Current	Not publicly available	The differences do not affect safety and effectiveness of intended use
Amplitude of Stimulator current (max)	10mA	10.2 mA (300Ω load)	30 mA	20 mA	Subject device within range of predicates
RMS value of Stimulator current (max)	3.16 mA	7.2 mA (300Ω load) Assuming continuous stimulation, positive phase rectangle, negative is decaying exponential	Not publicly available	Not publicly available	The differences do not affect safety and effectiveness of intended use
Pulse frequency	1 – 200 Hz	2 – 1,500 Hz	1 – 200 Hz	5 – 100 Hz	Subject device within range of predicates
Pulse width (positive phase)	100 – 500 µsec	12 – 1,000 µsec	100 – 500 µsec	Up to 200 µsec	Subject device within range of predicates
Maximum charge per pulse	5.0 µC	10.2 µC (300Ω load)	Not publicly available	Not publicly available	The differences do not affect safety and effectiveness of intended use
Maximum charge density (at stimulating electrode)	26.5 µC /cm^2	83.3 µC /cm^2 (300Ω load)	Not publicly available	40 µC /cm^2	Subject device within range of predicates

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	Subject Device	**Primary Predicate Device**	**Secondary Predicate Device**	**Tertiary Predicate Device**	**Equivalency discussion**
Maximum current density at (stimulating electrode)	52.9 mA/cm^2	83.3 mA/cm^2 (300Ω load)	Not publicly available	Not publicly available	Subject device within range of predicates.
Net charge	0 µC	0 µC	Not publicly available	Not publicly available	Subject device within range of predicates.
Max average phase power	0.030 W / phase (300Ω load)	0.031 W / phase (300Ω load)	Not publicly available	Not publicly available	Subject device within range of predicates
Max average phase power density	0.16 W/cm^2 / phase (300Ω load)	0.25 W/cm^2 / phase (300Ω load)	Not publicly available.	Not publicly available.	Subject device within range of predicates
Waveform	Charge balanced, biphasic, rectangular, symmetrical or asymmetrical	Charge balanced (delayed) biphasic asymmetrical	Charge balanced, biphasic, rectangular, symmetrical or asymmetrical	Biphasic rectangular with a positive and negative phase that is charge balanced	The differences do not affect safety and effectiveness of intended use
Pulse shape	Rectangular	Decaying exponential	Not publicly available	Rectangular	The differences do not affect safety and effectiveness of intended use.
Stimulation modality	Monopolar	Bipolar	Not publicly available	1 pair (1 percutaneous electrode and 1 surface electrode)	The differences do not affect safety and effectiveness of intended use.
Main materials in long term contact with intact skin (see biocomp report for complete list)	Santoprene® 8281-75MED PELLETHANE 2363-80A TRITAN MX731	PC ABS housing. Textile material of belt / cuff may be worn over clothing. Hydrocolloid adhesive applied to skin.	Santoprene® 8281-75MED PELLETHANE 2363-80A TRITAN MX731	Not publicly available	The differences do not affect safety and effectiveness of intended use.
Wireless Communications	Bluetooth Low Energy (BLE)	Bluetooth Low Energy (BLE)	Bluetooth Low Energy (BLE)	Not publicly available	The differences do not affect safety and effectiveness of intended use.

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Comparison of Subject Device and Predicate Device Leads

	Subject Device	Primary Predicate Device	Secondary Predicate Device	Tertiary Predicate Device	Equivalency discussion
Number of stimulating electrodes	1 (divided into 3 segments)	8	1 (divided into 3 segments)	1 pair (1 percutaneous electrode and 1 surface electrode)	The differences do not affect safety and effectiveness of intended use.
Electrode shape	Cylindrical	Cylindrical	Cylindrical	Straight with tine	The differences do not affect safety and effectiveness of intended use.
Individual Electrode surface area	6.3 mm^2	12.25 mm^2	6.3 mm^2	Not publicly available.	StimTrial individual electrode surface is the same as StimRouter predicate. Differences with Nalu predicate do not affect safety and effectiveness of the intended use.
Electrode array length	5 mm	52 mm	Not publicly available	Not publicly available.	Differences with predicates do not affect safety and effectiveness of the intended use.
Individual electrode length	1 mm	3 mm	Not publicly available.	15.2mm	Differences with predicates do not affect safety and effectiveness of the intended use.
Electrode spacing	Spacing between electrode segments 1mm	4 mm	Not publicly available.	Not publicly available.	Differences with predicates do not affect safety and effectiveness of the intended use.
Electrode material	Platinum – Iridium (90:10)	Platinum – Iridium (90:10)	Platinum – Iridium (90:10)	316L Stainless Steel	The differences do not affect safety and effectiveness of intended use.
Lead body insulation material	Silicone	Pellethane 2363-55D	Silicone	Not publicly available.	The differences do not affect safety and effectiveness of intended use.
Wire features	Multi-strand, non-insulated, helical	Multilumen tube	Not publicly available.	Fine wire	The differences do not affect safety and effectiveness of intended use.

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	Subject Device	**Primary Predicate Device**	**Secondary Predicate Device**	**Tertiary Predicate Device**	**Equivalency discussion**
Anchor	No anchor. Lead is secured at skin level with a wound bandage.	Optional molded silicone anchor with Ti locking mechanism	Not publicly available.	Tine	The differences do not affect safety and effectiveness of intended use.
Lead + Lead Adaptor length	~45 cm	40cm, 60cm	Not publicly available.	Lead is either 20cm or 40cm with 10cm introducer needle	The differences do not affect safety and effectiveness of intended use.
Lead body diameter	1.2 mm	1.3 mm	1.2 mm	Not publicly available.	The differences do not affect safety and effectiveness of intended use.
Biocompatibility	Yes	Yes	Yes	Yes	Substantially equivalent
Sterilization method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Provided sterile. Sterilization method not publicly available	The differences do not affect safety and effectiveness of intended use.

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Comparison of Subject Device and Predicate Device Externally Worn Devices

	Subject Device	**Primary Predicate Device**	**Secondary Predicate Device**	**Tertiary Predicate Device**	**Equivalency discussion**
Name	External Stimulator	Trial Therapy Disc	StimRouter External Electrical Field Conductor (E-EFC)	Not publicly available.	N/A
Electronics	A printed circuit board Assembly (PCBA) that generates therapeutic stimulation currents and buttons for power and adjusting parameter settings as needed by the user.	A printed circuit board Assembly (PCBA) that generates therapeutic stimulation currents and buttons for power and adjusting parameter settings as needed by the user.	A Printed Circuit Board Assembly (PCBA) that generates therapeutic stimulation currents and buttons for power and adjusting parameter settings as needed by the user.	Not publicly available.	The differences do not affect safety and effectiveness of intended use.
User interface	Integrated controls and visual and audio indicators that allow the user to turn the device on/off, increase or decrease therapy levels, select from configured therapy profiles and monitor device status.	Integrated controls and indicators that allow the user to turn the device on/off, increase or decrease therapy levels, select from configured therapy profiles and monitor device status	Integrated controls and visual and audio indicators that allow the user to turn the device on/off, increase or decrease therapy levels, select from configured therapy profiles and monitor device status.	Button controls for turning device on/off and for decreasing/increasing therapy intensity. Text prompts provided on LCD screen	The differences do not affect safety and effectiveness of intended use.
Delivery of energy	External Stimulator delivers electrical stimulation directly (via connectors and cables) to the percutaneously implanted trial lead.	Trial Therapy Disc delivers electrical stimulation directly (via connectors and cables) to the percutaneously implanted trial lead.	Not publicly available.	Wearable external stimulator delivers stimulation therapy to the percutaneous electrode	The differences do not affect safety and effectiveness of intended use.
Area of hydrogel skin electrode for return.	28 cm^2	N/A (not used for Nalu System)	Not publicly available.	Not publicly available.	The differences do not affect safety and effectiveness of intended use.
Max current density (at hydrogel electrode)	0.226 mA/cm^2 (RMS)	N/A	Not publicly available.	Not publicly available.	The differences do not affect safety and effectiveness of intended use.

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	Subject Device	**Primary Predicate Device**	**Secondary Predicate Device**	**Tertiary Predicate Device**	**Equivalency discussion**
Wearing	External Stimulator is plugged into hydrogel electrode patch. The patch is attached to the skin. The subcutaneous lead is connected through the Lead adaptor to the USB output of Stimulator. Hydrogel patch serves as a mechanical attachment to the skin and as an electrical conductor for monopolar return to close the circuit between stimulating electrode of the implanted trial lead.	Trial Therapy Disc is positioned over IPG via two options: • Adhesive clip (hydrocolloid adhesive) • Elastic Belt / Cuff	StimRouter E-EFC is plugged into a hydrogel electrode patch. The patch is positioned on the skin over the implanted receiver. Hydrogel patch serves as a mechanical attachment to the skin and as an electrical conductor to deliver transcutaneous stimulation.	Hand-held	The differences do not affect safety and effectiveness of intended use.
Size / Weight	External Stimulator: 5.7cm x 3.7cm x 1.2cm 28g Hydrogel patch: 10.6 x 3.4 x 0.26cm 6g	Trial Therapy Disc: ~1.5cm thick, 7.5cm diameter Weight: ~80g	StimRouter E-EFC: 5.7 x 3.7 x 1.2cm 28g	24g	The differences do not affect safety and effectiveness of intended use.
Externally contacting materials	External Stimulator: Housing - Tritan™ Copolyester MX731 Button overlay: Polycarbonate polyform Snap connector: CDA 260 Brass 200 Series S.S Patch: Hydrogel, Non- woven fabric (Ml)	PC ABS housing. Textile material of belt / cuff may be worn over clothing. Hydrocolloid adhesive applied to skin.	StimRouter E-EFC: Housing - Tritan™ Copolyester MX731 Button overlay: Polycarbonate polyform Snap connector: CDA 260 Brass 200 Series S.S	Not publicly available.	The differences do not affect safety and effectiveness of intended use.
Battery charging	Medical grade USB charger with a USB-A to USB-C cable plugging to the External Stimulator.	Electrically isolated cradle charger.	E-EFC uses USB-C charging port	Not publicly available.	The differences do not affect safety and effectiveness of intended use.

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Substantial Equivalence Table – Clinician Programmer

	Subject Device	Primary Predicate Device	Secondary Predicate Device	Tertiary Predicate Device	Equivalency discussion
Configuration	Software installed on a Windows tablet.	Software installed on an Android tablet.	Software installed on a Windows tablet.	Not publicly available.	The differences do not affect safety and effectiveness of intended use.
Purpose	Allows healthcare provider to set desired therapy levels and device settings across External Stimulator and optional Mobile App for Remote Control.	Allows healthcare provider to set desired therapy levels and device settings across Trial Therapy Disc and Patient Remote Control.	Allows healthcare provider to set desired therapy levels and device settings across StimRouter E-EFC and optional Mobile App for Remote Control.	Not publicly available.	The differences do not affect safety and effectiveness of intended use.
Communication	Bluetooth Low Energy (BLE) to External Stimulator.	Bluetooth Low Energy (BLE) to Trial Therapy Disc and Patient Remote Control.	Bluetooth Low Energy (BLE) to E-EFC.	Not publicly available.	The differences do not affect safety and effectiveness of intended use.

Substantial Equivalence Table – Patient Remote Control

	Subject Device	Primary Predicate Device	Secondary Predicate Device	Tertiary Predicate Device	Equivalency discussion
Name	Patient Mobile App (MAPP)	Patient Remote Control	Patient Mobile App (MAPP)	None	The differences do not affect safety and effectiveness of intended use.
Remote Control Required?	Optional	Optional	Optional	None	The differences do not affect safety and effectiveness of intended use.
Configuration	Software app installed on a mobile device (iOS or Android) providing wireless selection among preconfigured options and status readout for paired External Stimulator.	Software app installed on a mobile device (Android / iOS) providing wireless selection among preconfigured options and status readout for paired Therapy Disk.	Not publicly available.	None	The differences do not affect safety and effectiveness of intended use.
Communication	Bluetooth Low Energy (BLE)	Bluetooth Low Energy (BLE)	Bluetooth Low Energy (BLE)	None	The differences do not affect safety and effectiveness of intended use.

VII. Performance Testing

The StimTrial System was qualified through the following labeling, software, electrical, usability, bench, functional and animal testing. Additionally, sterility, shelf life and biocompatibility testing were performed.

- Labeling Validation
- Software verification and validation (for External Stimulator, MAPP and CPS software devices)
- EMC, Wireless Co-Existence and Electrical Safety
- Usability testing (for Implanting Physician, Treating Clinician and Patient)
- Bench testing
    - Tests of the StimTrial Lead
    - Tests of the External Stimulator
    - StimTrial System Testing
- Animal testing (Acute and Long-term studies in porcine animal model)
- Sterilization and Shelf Life (StimTrial Surgical Kit)
- Biocompatibility (for StimTrial Lead, Insertion Tools and External Stimulator)

VIII. Conclusion.

Bioventus concludes that the StimTrial System is substantially equivalent to the Nalu Neurostimulation System for Peripheral Nerve Stimulation predicate device and does not raise any new issues or concerns of safety or effectiveness.