July 3, 2025

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

Re: K243678
Trade/Device Name: TalisMann 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: November 28, 2024
Received: June 4, 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
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243678

Device Name
TalisMann Neuromodulation System

Indications for Use *(Describe)*
The TalisMann 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 TalisMann Neuromodulation System 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

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Date Prepared: July 2, 2025

II. Name of Device

Device Trade Name:	TalisMann 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:	Bioness Inc.
Predicate #1 Trade Name:	StimRouter Neuromodulation System
Predicate #1 510(k):	K211965
Predicate #2 Manufacturer:	Nalu Medical Inc.
Predicate#2 Trade Name:	Nalu Neurostimulation System for Peripheral Nerve Stimulation
Predicate #2 510(k):	K183579
Predicate #3 Manufacturer:	Advanced Neuromodulation Systems, Inc.
Predicate #3 Trade Name:	Renew System
Predicate #3 510(k):	K000852

IV. Device Description

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

The TalisMann Neuromodulation System works by providing electrical impulses to a target area in the body. These impulses may interrupt or change the pain signals, inducing the feeling of tingling or numbness (paresthesia), and possibly reducing or replacing the feeling of pain.

The TalisMann Neuromodulation System consists of three main parts – the implantable StimRouter Lead (cleared most recently in K211965), the implantable TalisMann Pulse Generator/Receiver that is connected to the implantable Lead, and the external (to the body) components. The Lead is implanted with the stimulation end located at or near the targeted peripheral nerve, whereas the end with the Pulse Generator/Receiver is located near the skin surface. Accessories for the TalisMann include the Clinician Programmer with Software (CPS), the optional Mobile Application (MAPP) installed on a SmartPhone, the StimRouter Electrode (a disposable electrode patch, cleared most recently in K211965), and the TalisMann External Electrical Field Conductor (E-EFC). The TalisMann System incorporates both commercially available and specially designed components. The materials used in the TalisMann Pulse Generator/Receiver and 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 TalisMann 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.

The TalisMann uses the following components unchanged from the StimRouter System (K211965): the StimRouter Lead, the MAPP software, the E-EFC, and the StimRouter (Hydrogel Patch) Electrodes. The new components of the TalisMann System are: the TalisMann Pulse Generator/Receiver, new implant tools, and the updated Clinician Programmer Software (updated to enable TalisMann parameters).

V. Indications for Use

The TalisMann 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 TalisMann Neuromodulation System 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 TalisMann 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 TalisMann System to these previously cleared predicates. Comparison is listed per following aspects:

- Transmitter and Receiver
- Leads
- Externally Worn Devices
- Clinician Programmer
- Patient Remote Control

Table 1: Substantial Equivalence - Transmitter and Receiver modules

Transmitter and Receiver	Subject Device	Primary Predicate Device	Secondary Predicate Device	Tertiary Predicate Device	Equivalency discussion
510(k) Number	K243678	K211965	K183579	K000852	
Device Name	TalisMann Neuromodulation System	Bioness StimRouter Neuromodulation System	Nalu Neurostimulation System for Peripheral Nerve Stimulation	Renew Neurostimulation System	
Regulation and Product Codes	21 CFR 882.5870 GZF	21 CFR 882.5870 GZF	21 CFR 882.5870 GZF	21 CFR 882.5870 GZF	
Indication for Use	The TalisMann 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 TalisMann Neuromodulation System 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.	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.	Not publicly available	
Implant site	Subcutaneous, stimulating electrode(s) of the lead are at peripheral nerves, excluding craniofacial region.	Not publicly available	Peripheral nerves, excluding craniofacial region	Not publicly available	Similar. The subject device and predicates target the peripheral nerves.
Mode of action	Wireless electrical coupling, delivering high frequency electrical energy to the receiver lead to produce stimulation at stimulating electrodes.	Not publicly available	Radio Frequency (RF) coupling delivering energy to produce stimulation at stimulating electrodes.	Not publicly available	Similar. The subject device and predicates deliver wireless energy to the implanted receiver.

Transmitter and Receiver	Subject Device	Primary Predicate Device	Secondary Predicate Device	Tertiary Predicate Device	Equivalency discussion
Receiver materials in contact with human body	Titanium electrode, PEEK (polyether ether ketone), silicone	Pt-Ir electrode, silicone insulator sheath	Silicone and Pellethane 2363- 55D	Not publicly available	Differences in the receiver materials do not impact safety or effectiveness. Non-clinical bench testing was conducted to support cytotoxicity, sensitization, irritation, acute systemic toxicity, material mediated pyrogenicity, chemical characterization, toxicological risk assessment and implant endpoints.
Electrical components	Embedded receiver, rigid miniature circuit board in a hermetically sealed Titanium can	Not publicly available	Embedded receiver, flexible circuit board, sealed	Not publicly available	Similar. The subject device and Nalu predicate use an embedded receiver and circuitry that pick up externally applied stimulation which the circuitry transforms into electrical stimulation that is provided to the distally located stimulation electrodes.
Biocompatibility Testing	Yes	Yes	Yes	Not publicly available	All devices are confirmed through testing to be biocompatible.
Power source (receiver)	No internal power source. Powered by external transmitter.	Not publicly available	No internal power source. Powered external transmitter.	Not publicly available	Equivalent
Power source (transmitter) battery type	One Lithium Polymer, rechargeable	One Lithium Polymer, rechargeable	Rechargeable Lithium Ion Battery	Not publicly available	Similar: All devices use battery power source. Differences in battery materials/chemistry do not affect safety and effectiveness of intended use.
Location of transmitter	External	External	External	Not publicly available	same

Transmitter and Receiver	Subject Device	Primary Predicate Device	Secondary Predicate Device	Tertiary Predicate Device	Equivalency discussion
Transdermal energy delivery	Wireless, Electrical coupling, 35 or 50 kHz	Not publicly available	Wireless, RF, 40.68 MHz	Not publicly available	Differences do not affect safety and effectiveness of intended use
Current / Voltage regulated	Current	Current	Current	Not publicly available	The difference in voltage regulated vs. current regulated does not bring up any issues of safety and effectiveness.
Amplitude of implant current (max)	26 mA*	Not publicly available	10.2 mA	Not publicly available	Subject device within range of predicates.
RMS value of implant current (max)	2.15 mA*	Not publicly available	Not publicly available	Not publicly available	The differences do not affect safety and effectiveness of intended use
Repetition frequency	Burst repetition frequency 1 - 200 Hz	Pulse repetition frequency 1 - 200 Hz	Pulse repetition frequency 2 - 1,500 Hz	Not publicly available	Similar: TalisMann repetition frequency range is the same as StimRouter predicate, and is within the range of the Nalu predicate device
Duration	Burst duration 100 - 500 µsec	Not publicly available	Pulse duration (positive phase) 12 – 1,000 µsec	Not publicly available	Similar: TalisMann pulse width is within the range of predicate devices
Maximum charge	Charge per burst 5.6 µC*	Not publicly available	Charge per pulse (positive phase) 10.2 µC	Not publicly available	Subject device within range of predicates.
Maximum charge density	Charge during burst 29.6 µC/cm^2 *	Charge during pulse 15.9 µC/cm^2*	Charge during pulse 83.3 µC/cm^2	Not publicly available	Subject device within range of predicates.
Maximum current density	137.6 mA/cm^2 *	Not publicly available	83.3 mA/cm^2	Not publicly available	Subject device within range of predicates.
Net charge	0 µC	Not publicly available	0 µC	Not publicly available	The same

Transmitter and Receiver	Subject Device	Primary Predicate Device	Secondary Predicate Device	Tertiary Predicate Device	Equivalency discussion
Max average power	Power during burst 0.08 W *	Not publicly available	Power during pulse 0.031 W (300Ω load) 0.052 W (500Ω load) 0.083 W (800Ω load)	Not publicly available	Subject device within range of predicates.
Max average power density	Power during burst 0.42W/cm^2 *	Not publicly available	Power during pulse 0.25 W/cm^2 (300Ω load) 0.51 W/cm^2 (500Ω load) 0.55 W/cm^2 (800Ω load)	Not publicly available	Subject device within range of predicates.
Waveform	Charge balanced (delayed) biphasic asymmetrical	Charge balanced, symmetrical or asymmetrical	Charge balanced (delayed) biphasic asymmetrical	Not publicly available	Differences do not affect safety and effectiveness of intended use
Pulse shape	Positive phase: rectangular, Negative: Decaying exponential	Not publicly available	Decaying exponential	Not publicly available	Differences do not affect safety and effectiveness of intended use
Stimulation modality	Monopolar	Not publicly available	Bipolar	Not publicly available	Similar. Differences do not affect safety and effectiveness of intended use

* For 20% max pick-up ratio, 300 Ω load. The principle of delivery of transcutaneous energy to the implant of TalisMann is identical to that StimRouter. A porcine model was used for both the StimRouter and TalisMann for determination of pick-up ratio. A similar implantation of the StimRouter Lead and the TalisMann Lead was performed.

Table 2: Substantial Equivalence Table - Leads

Leads	Subject Device	Primary Predicate Device	Secondary Predicate Device	Tertiary Predicate Device	Equivalency discussion
510(k) Number	K243678	K211965	K183579	K000852	
Device Name	TalisMann Neuromodulation System	Bioness StimRouter Neuromodulation System	Nalu Neurostimulation System for Peripheral Nerve Stimulation	Renew Neurostimulation System	
Number of stimulating electrodes	3	3	8	Not publicly available	The TalisMann Neuromodulation System uses the previously cleared StimRouter Lead. Differences with other predicate devices do not affect safety and effectiveness of the intended use.
Electrode shape	Cylindrical	Cylindrical	Circular	Not publicly available	The same
Electrode surface area	6.3 mm^2 (Total area for 3 electrodes is 18.9mm^2)	Not publicly available	12.25 mm^2	Not publicly available	The TalisMann Neuromodulation System uses the previously cleared StimRouter Lead. Differences with other predicate devices do not affect safety and effectiveness of the intended use.
Electrode array length	5 mm	Not publicly available	52 mm	Not publicly available	The TalisMann Neuromodulation System uses the previously cleared StimRouter Lead. Differences with other predicate devices do not affect safety and effectiveness of the intended use.
Individual electrode length	1 mm	Not publicly available	3 mm	Not publicly available	The TalisMann Neuromodulation System uses the previously cleared StimRouter Lead. Differences with other predicate devices do not affect safety and effectiveness of the intended use.
Electrode spacing	1 mm	Not publicly available	4 mm	Not publicly available	The TalisMann Neuromodulation System uses the previously cleared StimRouter Lead. Differences with other predicate devices do not affect safety and effectiveness of the intended use.
Electrode material	Platinum – Iridium (90:10)	Platinum – Iridium (90:10)	Platinum – Iridium (90:10)	Not publicly available	The same
Insulation body material	Silicone	Silicone	Pellethane 2363-55D	Not publicly available	The TalisMann Neuromodulation System uses the previously cleared StimRouter Lead. Differences with other predicate devices do not affect safety and effectiveness of the intended use.

Leads	Subject Device	Primary Predicate Device	Secondary Predicate Device	Tertiary Predicate Device	Equivalency discussion
Cable features	Multi-strand, non-insulated, helical	Not publicly available	Multilumen tube	Not publicly available	The TalisMann Neuromodulation System uses the previously cleared StimRouter Lead. Differences with other predicate devices do not affect safety and effectiveness of the intended use.
Anchor	Silicone anchor	Not publicly available	Molded silicone anchor with Ti locking mechanism	Not publicly available	The TalisMann Neuromodulation System uses the previously cleared StimRouter Lead. Differences with other predicate devices do not affect safety and effectiveness of the intended use.
Lead length	15 cm	15 cm	40cm, 60cm	Not publicly available	The TalisMann Neuromodulation System uses the previously cleared StimRouter Lead. Differences with other predicate devices do not affect safety and effectiveness of the intended use.
Lead body diameter	1.2 mm	1.2 mm	1.30 mm	Not publicly available	The TalisMann Neuromodulation System uses the previously cleared StimRouter Lead.
Sterilization method	Ethylene Oxide	Not publicly available	Ethylene Oxide	Not publicly available	The same

Table 3: Substantial Equivalence Table – Externally Worn Devices

Externally worn devices	Subject Device	Primary Predicate Device	Secondary Predicate Device	Tertiary Predicate Device	Equivalency discussion
510(k) Number	K243678	K211965	K183579	K000852	
Device Name	TalisMann Neuromodulation System	Bioness StimRouter Neuromodulation System	Nalu Neurostimulation System for Peripheral Nerve Stimulation	Renew Neurostimulation System	
Name	TalisMann External Electrical Field Conductor (E-EFC)	StimRouter External Electrical Field Conductor (E-EFC)	Therapy Disc and Trial Therapy Disc	Not publicly available	N/A
Electronics	A printed circuit board (PCB) that generates high frequency electrical current with embedded waveform parameter settings and buttons for setting amplitude and changing parameter settings as needed by the user.	A printed circuit board (PCB) that generates high frequency electrical current with embedded waveform parameter settings and buttons for setting amplitude and changing parameter settings as needed by the user.	A printed circuit board (PCB) that generates RF power with embedded waveform parameters settings and buttons for changing parameter settings as needed by the user.	Not publicly available	TalisMann E-EFC uses the same PCB and firmware as StimRouter E-EFC. Differences do not affect safety and effectiveness of intended use.
User interface	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 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.	Not publicly available	The same
Delivery of energy	TalisMann E-EFC delivers 35 kHz or 50 kHz electrical pulses via hydrogel patch attached to the skin over the implanted receiver.	Not publicly available.	Integrated antenna supporting 40.68 MHz power and data transfer.	Not publicly available	TalisMann E-EFC is TalisMann uses the same hydrogel patch as predicate StimRouter device. Difference with other predicate devices does not affect safety and effectiveness of intended use.
Area of skin electrodes	14 cm^2	Not publicly available	N/A (not used for Nalu System)	Not publicly available	Difference with other predicate devices does not affect safety and effectiveness of intended use.
Max transcutaneous current (RMS)	16.8 mA (RMS)	Not publicly available	N/A	N/A	Subject device within range of predicates.
Max current density (at gel patch electrode)	1.2 mA/cm^2 (RMS)	Not publicly available	N/A	Not publicly available	Subject device within range of predicates.

Externally worn devices	Subject Device	Primary Predicate Device	Secondary Predicate Device	Tertiary Predicate Device	Equivalency discussion
Wearing	TalisMann 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.	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.	Therapy Disc is positioned over IPG via two options: - Adhesive clip (hydrocolloid adhesive) - Elastic Belt / Cuff	Not publicly available	Difference does not affect safety and effectiveness of intended use.
Size / Weight	TalisMann E-EFC: 5.7 x 3.7 x 1.2cm 28g Patch: 10.6 x 3.4 x 0.26cm 6g	StimRouter E-EFC: 5.7 x 3.7 x 1.2cm 28g	Disc: ~1.5cm thick, 7.5cm diameter Weight: ~80g	Not publicly available	Difference does not affect safety and effectiveness of intended use.
Externally contacting materials	E-EFC: Housing - Tritan™ Copolyester MX731 Button overlay: Polycarbonate polyform Snap connector: CDA 260 Brass 200 Series S.S Patch: Hydrogel, Non- woven fabric (Ml)	E-EFC: Housing - Tritan™ Copolyester MX731 Button overlay: Polycarbonate polyform Snap connector: CDA 260 Brass 200 Series S.S	PC ABS housing. Textile material of belt / cuff may be worn over clothing. Hydrocolloid adhesive applied to skin.	Not publicly available	Difference does not affect safety and effectiveness of intended use.
Battery charging	Medical grade USB charger with a USB-A to USB-C cable that plugs into TalisMann E- EFC.	E-EFC uses USB-C charging port	Electrically isolated cradle charger	Not publicly available	The differences do not affect safety and effectiveness of intended use

Table 4: Substantial Equivalence Table – Clinician Programmer

Clinician Programmer	Subject Device	Primary Predicate Device	Secondary Predicate Device	Tertiary Predicate Device	Equivalency discussion
510(k) Number	K243678	K211965	K183579	K000852	
Device Name	TalisMann Neuromodulation System	Bioness StimRouter Neuromodulation System	Nalu Neurostimulation System for Peripheral Nerve Stimulation	Renew Neurostimulation System	

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 a Windows tablet.	Software installed on an Android tablet.	Not publicly available	similar
Purpose	Allows healthcare provider to set desired therapy levels and device settings on TalisMann E-EFC.	Allows healthcare provider to set desired therapy levels and device settings on StimRouter E-EFC.	Allows healthcare provider to set desired therapy levels and device settings across Therapy Disc and Patient Remote Control.	Not publicly available	similar
Communication	Bluetooth Low Energy (BLE) to E- EFC.	Bluetooth Low Energy (BLE) to E- EFC.	Bluetooth to Therapy Disc and Patient Remote Control.	Not publicly available	similar

Table 5: Substantial Equivalence Table – Patient Remote Control

Patient Remote Control	Subject Device	Primary Predicate Device	Secondary Predicate Device	Tertiary Predicate Device	Equivalency discussion
510(k) Number	K243678	K211965	K183579	K000852	
Device Name	TalisMann Neuromodulation System	Bioness StimRouter Neuromodulation System	Nalu Neurostimulation System for Peripheral Nerve Stimulation	Renew Neurostimulation System	
Name	Patient Mobile App (MAPP)	Patient Mobile App (MAPP)	Patient Remote Control	Not publicly available	N/A
Remote Control Required?	Optional	Optional	Optional	Not publicly available	differences do not affect safety and effectiveness of intended use.
Configuration	Software app installed on a mobile device (Android / iOS) providing wireless selection among preconfigured options and status readout for paired TalisMann E-EFC.	Not publicly available	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	TalisMann MAPP and StimRouter MAPP uses the same Smartphone software. The differences with Nalu and ANS predicates do not affect safety and effectiveness of intended use.
Communication	Bluetooth Low Energy (BLE)	Bluetooth Low Energy (BLE)	Bluetooth	Not publicly available	Differences do not affect safety and effectiveness of intended use.

Performance Testing

The TalisMann Neuromodulation 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 E-EFC, 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 TalisMann implant
    - Tests of the external modules (E-EFC)
    - TalisMann System Testing
- Animal testing (Acute and Long-term studies in porcine animal model)
- Sterilization and Shelf Life (TalisMann Pulse Generator /Receiver and Implant Kit)
- Biocompatibility (for Receiver, Implant Tools and E-EFC)

VII. Conclusion

In conclusion, the TalisMann Neuromodulation System can be deemed to be as safe and effective as the predicate devices for the proposed indications for use and no new or differing questions of safety or effectiveness are raised. Therefore, it can be determined that the TalisMann Neuromodulation System is substantially equivalent to the predicate devices.