DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

August 4, 2017

Stimwave Technologies Incorporated
% Elizabeth Greene
Vice President of Quality Assurance and Regulatory Affairs
901 East Las Olas Boulevard , Suite 201
Fort Lauderdale, Florida 33301

Re: K171366
Trade/Device Name: StimQ Peripheral Nerve Stimulator System
Regulation Number: 21 CFR 882.5870
Regulation Name: Implanted Peripheral Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: GZF
Dated: July 14, 2017
Received: July 19, 2017

Dear Elizabeth Greene:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

William J. Heetderks -S
2017.08.04 13:20:28 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Name: StimQ Peripheral Nerve Stimulator (PNS) System

Indications For Use:
The StimQ Peripheral Nerve Stimulator (PNS) 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 StimQ PNS System is not intended to treat pain in the craniofacial region. The StimQ Trial Lead Kit is only used in conjunction with the StimQ Stimulator Receiver Kit. The trial devices are solely used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device.

Prescription Use__X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary
for
StimQ Peripheral Nerve Stimulator (PNS) System

1. Submission Sponsor

Stimwave Technologies Incorporated, DBA StimQ LLC
901 East Las Olas Boulevard
Suite 201
Fort Lauderdale
Florida 33301
USA
Phone: 786.475.7228
Fax: 786.475.7228
Contact: Elizabeth Greene, Vice President of Quality Assurance and Regulatory Affairs

2. Date Prepared

May 5, 2017

3. Device Identification

Trade/Proprietary Name:	StimQ Peripheral Nerve Stimulator (PNS) System
Common/Usual Name:	Peripheral Nerve Stimulator
Classification Name:	Stimulator, Peripheral Nerve, Implanted (Pain Relief)
Classification Regulation:	882.5870
Product Code:	GZF
Device Class:	Class II
Classification Panel:	Neurology

4. Legally Marketed Predicate Device(s)

StimQ PNS System FR8A/FR4A, PDBT-915-1A (K152178)
Stimwave Freedom SCS System FR8A/FR4A, PDBT-915-2A (K170141)

5. Device Description

This submission builds upon the existing StimQ product family by incorporating identical products from other regulatory submissions (cleared) for use in peripheral pain indications:

A. Freedom Spinal Cord Stimulator (SCS) System, K170141:
   i. Wearable Antenna Assembly (WAA) known in this submission as the StimQ Wearable Antenna Gear (SWAG);
   ii. WaveCrest software;
   iii. Use of the Receivers/RF Stylets;

iv. Battery Charger;
v. Contract sterilizer;
vi. Kitting options.

B. StimQ PNS System, K152178:
i. Freedom-4A and Freedom-8A Stimulators;
ii. SWAG Accessory Kits.

The StimQ Stimulator presented in this submission is identical to the Freedom-4A Stimulator (K150517, K152178, K160600, K162161 and K170141) with a minor design modification to add tines to the body of the stimulator for migration mitigation.

This submission also includes performance testing to support MR Conditional Labeling for the Freedom-4A Stimulator with Receiver as well as the StimQ Stimulator with Receiver.

The SWAG Transmitting (Tx) Antenna utilizes a lightweight, flexible dipole antenna identical in functionality to the Tx Antenna of K170141, but designed to be mindful of peripheral indications (arms, ankles, etc.).

The StimQ LLC (StimQ) StimQ Peripheral Nerve Stimulator System (System) is used for peripheral neural stimulation to provide therapeutic relief for chronic, intractable pain of peripheral nerve origin. The therapy utilizes pulsed electrical current to create an electrical energy field that acts on peripheral nerves in the limbs and torso to alter the transmission of pain signals to the brain. The System is comprised of an implantable stimulator (Freedom-8A, Freedom-4A or StimQ), receiver component (Receiver/RF Stylet), and an externally worn transmitter (StimQ Wearable Antenna Gear (SWAG)) to power the device. The System is implanted only following a successful trial period with the Freedom-8A/4A Trial Lead.

Receiver Kit

Freedom-8A, Freedom-4A, StimQ Stimulator	A polyurethane (Pellethane 55D) casing with an embedded receiver, flexible circuit board and electrodes (Platinum Iridium 90:10) that is placed next to peripheral nerves in the extremities and torso. The Freedom-8A Stimulator has eight (8) electrodes, while the Freedom-4A and StimQ Stimulators each have four (4) electrodes. Freedom-8A and Freedom-4A Stimulators are identical to K152178 and K170141. The StimQ Stimulator is identical to Freedom-4A in terms of function, with the addition of polyurethane (Pellethane 55D) tines proximal to the electrodes.
Receiver	A copper and PEEK cable with dual couplers; placed within the center lumen of the Stimulator with the distal end combination of Receiver and Stimulator being placed under the skin. Two (2) Receivers are provided with each kit. Identical to K170141.

Receiver Kit

Stylet	A stainless steel wire with a polypropylene handle that is inserted into the open central lumen of the stimulator to provide rigidity during implantation. One (1) bent stylet is provided in the Receiver Kit. Identical to K170141.
Guidewire	A stainless steel, rigid, solid core guidewire used to create a hollow pathway for the Stimulator to pass through easily. Identical to K152178 and K170141.
Introducer Assembly	A 15-gauge stainless steel dilator and yellow Hytrel introducer assembly that is used to create a pathway for the stimulator to be placed next to peripheral nerves for the Stimulator to pass through easily. Functionally identical to the Needle and Cannula Assembly of K152178.

SWAG Transmitter Kit

SWAG The WAA housing includes the following components:

A. Microwave Field Stimulator (MFS) – A printed circuit board (PCB) that generates RF power with embedded waveform parameter settings and switches for changing parameter settings as needed by the user. Identical to K170141;
B. Switch Membrane – An elastomeric silicon rubber pad that corresponds to switches on the MFS that allows the user to turn the device on/off or increase or decrease power amplitude as well as interpret device power status (On, Off, Charging, Transmitting, and Bluetooth® Connection). Identical to K152178 and K170141;
C. Battery Assembly – A battery and wire assembly for charging and the MFS for power delivery. Identical to K170141.

Transmitting (Tx) Antenna Assembly – An antenna and coaxial cable assembly that is attached to the SWAG that is used to transmit microwave energy to the implanted Stimulator. Similar in form and function to the Tx Antenna of K170141, but a smaller form factor. Similar in form and function to the Tx Antenna of K170141, but a smaller form factor

SWAG Accessory Kit (each packaged separately)

Upper Arm	A wearable unit, sourced "off-the-shelf," designed to fit an upper extremity, adjustable from small to extra large sizes constructed of lightweight elastic neoprene fabric that is compatible with the SWAG Transmitter. Identical to K152178.
Lower Arm	A wearable unit, sourced "off-the-shelf," designed to fit an upper extremity, adjustable from small to extra large sizes constructed of lightweight elastic neoprene fabric that is compatible with the SWAG Transmitter. Identical to K152178.

SWAG Accessory Kit (each packaged separately)	
Torso	A wearable unit, sourced "off-the-shelf," designed to fit around the torso, adjustable from small to extra large sizes constructed of lightweight elastic neoprene fabric that is compatible the SWAG Transmitter. Identical to K152178.
Upper Leg	A wearable unit, sourced "off-the-shelf," designed to fit a lower extremity, adjustable from small to extra large sizes constructed of lightweight elastic neoprene fabric that is compatible with the SWAG Transmitter. Identical to K152178.
Lower Leg	A wearable unit, sourced "off-the-shelf," designed to fit a lower extremity, adjustable from small to extra large sizes constructed of lightweight elastic neoprene fabric that is compatible with the SWAG Transmitter. Identical to K152178.

Charger Kit	
Battery Charger	An off-the-shelf battery charger that uses a power adapter and USB to micro-USB cable to recharge the encased lithium ion battery of the SWAG Transmitter. Identical to K170141.

Spare Lead Kit	
Freedom-8A, Freedom-4A, StimQ Spare Lead	A polyurethane (Pellethane 55D) casing with an embedded receiver, flexible circuit board and electrodes (Platinum Iridium 90:10) that is placed next to peripheral nerves in the extremities and torso. The Freedom-8A Spare Lead has eight (8) electrodes, while the Freedom-4A and StimQ Spare Leads each have four (4) electrodes. Freedom-8A and Freedom-4A Spare Leads are identical to K170141. The StimQ Stimulator is identical to Freedom-4A in terms of function, with the addition of polyurethane (Pellethane 55D) tines proximal to the electrodes.
RF Stylet	A copper and PEEK cable with dual couplers; placed within the center lumen of the Spare Lead with the distal end combination of RF Stylet and Spare Lead being placed under the skin. Two (2) RF Stylets are provided with each kit. Identical to K170141.
Stylet	A stainless steel wire with a polypropylene handle that is inserted into the open central lumen of the stimulator to provide rigidity during implantation. One (1) bent stylet is provided in the Receiver Kit. Identical to K170141.
Guidewire	A stainless steel, rigid, solid core guidewire used to create a hollow pathway for the Spare Lead to pass through easily. Identical to K152178 and K170141.
Introducer Assembly	A 15-gauge stainless steel dilator and yellow Hytrel introducer assembly that is used to create a pathway for the stimulator to be placed next to peripheral nerves for the Stimulator to pass through easily. Functionally identical to the Needle and Cannula Assembly of K152178.

Trial Lead Kit

Freedom-8A, Freedom-4A Trial Lead	A polyurethane (Pellethane 55D) casing with an embedded receiver, flexible circuit board and electrodes (Platinum Iridium 90:10) that is placed next to peripheral nerves in the extremities and torso. The Freedom-8A Trial Lead has eight (8) electrodes, and the Freedom-4A Trial Lead has four (4) electrodes. Identical to K152178 and K170141.
RF Stylet	A copper and PEEK cable with dual couplers; placed within the center lumen of the Freedom-8A or Freedom-4A Trial Lead with the distal end combination of RF Stylet and Trial Lead being placed under the skin. Two (2) RF Stylets are provided with each kit. Identical to K170141.
Stylet	A stainless steel wire with a polypropylene handle that is inserted into the open central lumen of the stimulator to provide rigidity during implantation. One (1) bent stylet is provided in the Receiver Kit. Identical to K170141.
Guidewire	A stainless steel, rigid, solid core guidewire used to create a hollow pathway for the Stimulator to pass through easily. Identical to K152178 and K170141.
Introducer Assembly	A 15-gauge stainless steel dilator and yellow Hytrel introducer assembly that is used to create a pathway for the stimulator to be placed next to peripheral nerves for the Stimulator to pass through easily. Functionally identical to the Needle and Cannula Assembly of K152178.

Sterile Revision Kit

Stylet	A stainless steel wire with a polypropylene handle that is inserted into the open central lumen of the stimulator to provide rigidity during implantation. One (1) bent stylet is provided in the Receiver Kit. Identical to K170141.
Guidewire	A stainless steel, rigid, solid core guidewire used to create a hollow pathway for the Stimulator to pass through easily. Identical to K152178 and K170141.
Introducer Assembly	A 15-gauge stainless steel dilator and yellow Hytrel introducer assembly that is used to create a pathway for the stimulator to be placed next to peripheral nerves for the Stimulator to pass through easily. Functionally identical to the Needle and Cannula Assembly of K152178.

6. Indication for Use Statement

The StimQ Peripheral Nerve Stimulator (PNS) 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 StimQ PNS System is not intended to treat pain in the craniofacial region. The StimQ Trial Lead Kit is only used in conjunction with the StimQ Stimulator Receiver Kit. The trial devices are solely used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device.

7. Substantial Equivalence Discussion

The following table compares the StimQ PNS System to the predicate devices with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A. Comparison of Characteristics

Comparator	StimQ PNS System (This Submission)	StimQ PNS System (K152178)	Freedom SCS System (K170141)
Product Code	GZF	Same as StimQ	GZB
Regulation No.	882.5870	Same as StimQ	882.5880
Regulation Name	Stimulator, Peripheral Nerve, Implanted (Pain Relief)	Same as StimQ	Stimulator, Spinal-Cord, Implanted (Pain Relief)
Intended Use	Stimulation of peripheral nerves for chronic, intractable pain of peripheral nerve origin	Same as StimQ	Stimulation of spinal cord for chronic, intractable pain of trunk and lower limbs
Implant Site	Peripheral nerves, excluding craniofacial region	Epidural space, L5 to T5	Epidural space, L5 to T5
Mode of Action	RF wireless transmission of energy to produce stimulation at Stimulator electrodes. SWAG sends a pulsed RF signal on a carrier frequency of 915MHz to the Stimulator	Same as StimQ	Same as StimQ
Environmental Use	Hospital, Home	Same as StimQ	Same as StimQ
Intended Clinician	Orthopedic, Neurosurgeon, Anesthesiologist	Same as StimQ	Same as StimQ
Intended User	Layperson	Same as StimQ	Same as StimQ
Electrode Material	Platinum-iridium 90:10	Same as StimQ	Same as StimQ
Stimulator Body Material	Polyurethane 2363-55D	Same as StimQ	Same as StimQ
Cable Features	Multi-lumen Tube	Same as StimQ	Same as StimQ
Stimulator Length	45 centimeters	Same as StimQ	Same as StimQ
Diameter	1.35 millimeters	Same as StimQ	Same as StimQ
Electrode Array Length	24 millimeters 52 millimeters	Same as StimQ	Same as StimQ

Comparator	StimQ PNS System (This Submission)	StimQ PNS System (K152178)	Freedom SCS System (K170141)
No. of Electrodes	4 or 8	Same as StimQ	Same as StimQ
Electrode Length	3.0 millimeters	Same as StimQ	Same as StimQ
Electrode Spacing	4.0 millimeters	Same as StimQ	Same as StimQ
Electrode Surface Area	12.72 mm^2	Same as StimQ	Same as StimQ
Method of Introduction	Percutaneous	Same as StimQ	Percutaneous and Anchor Incision
Tissue Contact	Yes	Same as StimQ	Same as StimQ
Sterilization	Ethylene Oxide (EO)	Same as StimQ	Same as StimQ
Labeling	Labeled as Sterile, Single Use, Prescription Device	Same as StimQ	Same as StimQ
Package	Backer card and two sterile pouches	Blister Tray/Tyvek Lid	Same as StimQ
Pulse Frequency	5 to 1500 Hertz	Same as StimQ	Same as StimQ
Pulse Width	50 to 500 microseconds	Same as StimQ	Same as StimQ
Current/Voltage Regulated	Current	Same as StimQ	Same as StimQ
Output Voltage (300 Ω)	0 to 4.1 V	Same as StimQ	Same as StimQ
Output Voltage (500 Ω)	0 to 6.4 V	Same as StimQ	Same as StimQ
Output Voltage (800 Ω)	0 to 7.5 V	Same as StimQ	Same as StimQ
Output Current (300 Ω)	0 to 13.5 mA	Same as StimQ	Same as StimQ
Output Current (500 Ω)	0 to 12.8 mA	Same as StimQ	Same as StimQ
Output Current (800 Ω)	0 to 9.4 mA	Same as StimQ	Same as StimQ
Waveform	Charge Balanced (delayed) Biphasic asymmetrical	Same as StimQ	Same as StimQ
Polarity	Programmable (Anode, Cathode, or Off)	Same as StimQ	Same as StimQ
Pulse Shape	Decaying Exponential	Same as StimQ	Same as StimQ
Avg. Current Density (300 Ω)	105.0 mA/cm^2	Same as StimQ	Same as StimQ
Avg. Current Density (500 Ω)	95.1 mA/cm^2	Same as StimQ	Same as StimQ
Avg. Current Density (800 Ω)	69.0 mA/cm^2	Same as StimQ	Same as StimQ
Max. Phase Charge* (300 Ω)	6.8 µC/pulse	Same as StimQ	Same as StimQ
Max. Phase Charge* (500 Ω)	6.4 µC/pulse	Same as StimQ	Same as StimQ
Max. Phase Charge* (800 Ω)	4.7 µC/pulse	Same as StimQ	Same as StimQ
Max. Charge Density* (300 Ω)	53.1 $µC/cm^2$	Same as StimQ	Same as StimQ
Max. Charge Density* (500 Ω)	50.3 $µC/cm^2$	Same as StimQ	Same as StimQ
Max. Charge Density* (800 Ω)	36.9 $µC/cm^2$	Same as StimQ	Same as StimQ
Max. Current Density* (300 Ω)	106.1 mA/cm^2	Same as StimQ	Same as StimQ
Max. Current Density* (500 Ω)	100.6 mA/cm^2	Same as StimQ	Same as StimQ
Max. Current Density* (800 Ω)	73.9 mA/cm^2	Same as StimQ	Same as StimQ
Net Charge	0 µC	Same as StimQ	Same as StimQ
Avg. Phase Power (300 Ω)	0.053 W/phase	Same as StimQ	Same as StimQ
Avg. Phase Power (500 Ω)	0.073 W/phase	Same as StimQ	Same as StimQ
Avg. Phase Power (800 Ω)	0.062 W/phase	Same as StimQ	Same as StimQ
Avg. Phase Power Density (300 Ω)	0.42 W/cm^2/phase	Same as StimQ	Same as StimQ
Avg. Phase Power Density (500 Ω)	0.58 W/cm^2/phase	Same as StimQ	Same as StimQ
Avg. Phase Power Density (800 Ω)	0.48 W/cm^2/phase	Same as StimQ	Same as StimQ
Pulse Delivery Mode	Continuous	Same as StimQ	Same as StimQ
ON/OFF Times	No Cycling	Same as StimQ	Same as StimQ
Current Path Options	Bipolar	Same as StimQ	Same as StimQ

Comparator	StimQ PNS System (This Submission)	StimQ PNS System (K152178)	Freedom SCS System (K170141)
Power Delivery	Embedded receiver and coupled receiver in lumen of Stimulator body	Coupled receiver built into Stimulator body	Same as StimQ
Transmit Frequency	915 MHz	Same as StimQ	Same as StimQ
Material	Platinum-iridium 90:10, Polyurethane 2363-55D	Same as StimQ	Same as StimQ
Sterile	Yes - ethylene oxide	Same as StimQ	Same as StimQ
Contract Sterilizer	Steris Isomedix Services	Life Science Outsourcing	Same as StimQ
Single-Use	Yes	Same as StimQ	Same as StimQ
Shelf Life	2 year	Same as StimQ	Same as StimQ
Complies with ISO 10993-1	Yes	Same as StimQ	Same as StimQ
Safety Testing Passed	Yes	Same as StimQ	Same as StimQ
MR Conditional	Yes, FR4A/STQ4 MR Conditional	No, MR Unsafe	Yes
Accessories	Receiver/RF Stylet, Stylet, Introducer Assembly, Guidewire	Receiver/RF Stylet, Stylet(s), Guidewire, Needle and Cannula	Receiver/RF Stylet, Stylet(s), Guidewire, Needle, Suture Sleeve Cap
Charger	USB Charger	Wireless Charger	Same as StimQ
Wearable Antenna Assembly	Aluminum transmitter and separate, connected Antenna	Fabric-encased plastic transmitter	Same as StimQ
Software Level of Concern	Moderate	Same as StimQ	Same as StimQ
iPad Application	WaveCrest™	Same as StimQ	Same as StimQ
Kits	Receiver Kit, Spare Lead Kit, Trial Lead Kit, Sterile Revision Kit, SWAG Kits, Charger Kit	Receiver Kit, Trial Lead Kit, WAA Kit,	Same as StimQ

(*) asterisk denotes that formulas were used for the calculations.

8. Biocompatibility Data

Materials of this submission are identical to K141399, K152178, K162161, and K170141. The materials of the Freedom-8A/4A and StimQ Stimulator in direct contact with tissue remain unchanged from the Freedom SCS System (K170141 and K141399) and thus, the biocompatibility tests conducted on representative subassemblies of the Freedom SCS System (Freedom-4, K141399) directly apply to the StimQ PNS System The materials, construction and intended use of the StimQ PNS System is comparable to the predicate device, and have a long history of safety with respect to biocompatibility. The biological safety of the Stimulators (same as the Freedom-4 Stimulator) was evaluated in accordance to ISO 10993-1:2009 and guidance document Blue Book Memorandum G95-1 *Use of International Standard ISO-10993, and Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing*. Under these, for the stated indications for use, the device was classified as a (C), implant device in contact

with tissue/bone. The results for the biocompatible testing of the Stimulators (same as the Freedom-4 Stimulator) for cytotoxicity, sensitization, irritation or intracutaneous reactivity, acute systemic toxicity, genotoxicity, implantation (4, 8, and 13 weeks), and subchronic toxicity demonstrated no negative impacts from the materials that are used in the StimQ PNS System. The Stimulator materials in direct tissue contact include Pellethane 55D and Pt-Ir (90:10), both having an extensive record (previously cleared and approved) of chronic and carcinogenetic safety. The Receiver/RF Stylet is never in direct or indirect contact with tissue. The SWAG is intended to be on top of an article of clothing. The User Manual provided to the patient describes that the SWAG should always be worn on top of a layer of clothing. The SWAG does not come into contact with the patient's skin. The categorization by nature of body contact of the SWAG is thus "non-contacting device," and not included in the scope of ISO 10993-1:2009. The StimQ PNS System meets biological safety and compatibility requirements of ISO 10993-1:2009 and Blue Book Memorandum G95-1.

9. Non-Clinical Performance Data

No modifications were made to the components of K170141 (Freedom-8A/4A Stimulators, SWAG, WaveCrest, Battery Charger, Sterilization, Kitting Options) in support of the device safety and performance of this submission. The StimQ PNS System testing is leveraged from prior cleared premarket notifications where components were tested to verify that the performance meets the system design requirements as well as all applicable voluntary standards. The StimQ PNS System complies with all design requirements and applicable voluntary standards.

AAMI ANSI ISO 14708-3:2008 – For protection from temperature change including shipping and storage temperature ranges, the Stimulators were functional, receiving a safe rating following post visual inspection and passed the change of temperature testing performed as specified by AAMI ANSI ISO 14708-3:2008. For atmospheric pressure change, the Stimulators were functional following post testing functionality inspection and passed atmospheric pressure change testing as specified by AAMI ANSI ISO 14708-3:2008. This testing presented for this submission is leveraged from K170141 and K141399, and is directly applicable for demonstration of device safety and efficacy as the packaging and the Stimulators remains the same. The Receiver/RF Stylet is a passive component that does not impact the outcome of the leveraged tests for safety and effectiveness.

For testing external defibrillation exposure, the Stimulator and Receiver were verified as functional after exposure to external defibrillation. Thus, the StimQ PNS System complies with testing as specified by AAMI ANSI ISO 14708-3:2008. The Receiver/RF Stylet testing presented for this submission is leveraged from K170141, and is directly applicable for demonstration of device safety and efficacy as Receiver/RF Stylet remains the same.

Following the thermal shock testing, the Stimulators were found to have "no irreversible damage" and fully functional as specified by the manufacturer, and to have no physical anomalies present at the time of inspection. Thus, the Stimulators comply with the thermal shock design requirements and the applicable standard. This testing presented for this submission is leveraged from K170141, and is directly applicable for demonstration of device safety and efficacy as the Stimulators remains the same. The Receiver/RF Stylet is a passive component that does not impact the outcome of the leveraged tests for safety and effectiveness.

For leakage current testing, the Stimulators produced zero leakage current on all tested paths for all tested samples. Thus, the Stimulators comply with the leakage design requirements and the applicable standard. This testing presented for this submission is leveraged from K170141 and K141399, and is directly applicable for demonstration of device safety and efficacy as the Stimulators remains the same. The Receiver/RF Stylet is a passive component that does not impact the outcome of the leveraged tests for safety and effectiveness.

For testing the insertion and withdrawal of the stylet within the Stimulator, the stylet was found to require less than 2.5N of insertion or withdrawal force for all tested stylets in all tested stimulator samples. For testing the insertion and withdrawal of the Receiver within the Stimulator, the Receiver/RF Stylet was found to require less than 2.2N of insertion or withdrawal force for all tested stylets in all tested stimulator samples. Visual inspection confirmed no damage was present in any stimulator samples. Thus, the Stimulator and Receiver/RF Stylet comply with design specifications for stylet insertion and withdrawal force. The Stimulator testing presented for this submission is leveraged from K170141 and K141399, and is directly applicable for demonstration of device safety and efficacy as the Stimulators remains the same. The Receiver/RF Stylet testing presented for this submission is leveraged from K170141, and is directly applicable for demonstration of device safety and efficacy, as Receiver/RF Stylet remains the same.

For mechanical testing, the Stimulators passed all criteria of the test, showing no visible damage to the stimulator body or functional damage to the components. Mechanical testing included tensile testing, flex testing and torsion testing. Thus, the Stimulators comply with all stimulator mechanical design requirements. This testing presented for this submission is leveraged from K170141 and K141399, and is directly applicable for demonstration of device safety and efficacy as the Stimulators remains the same. The Receiver/RF Stylet is a passive component that does not impact the outcome of the leveraged tests for safety and effectiveness.

For magnetic resonance imaging (MRI) radio frequency (RF) induced heating as related to specific absorbance rate (SAR), the Freedom-4A and StimQ Stimulator produced a maximum temperature increase lower than the allowable limit for the 1.5T MRI procedure and thus passed the 1.5T testing. The Freedom-4A and StimQ Stimulator produced a maximum temperature increase lower than the allowable limit for the 1.5T MRI procedure and thus passed both.

ASTM F2182-11a – In accordance with F2182-11a – American Society for Testing and Materials (ASTM) International Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging, the Freedom-4A Stimulator showed that its presence would not cause injury to the patient with the implant during an MRI procedure. The Freedom-4A (StimQ) Stimulator with Receiver is a passive implant that is not powered while the external unit is not transmitting to it.

IEC 60601-1 – The SWAG was tested for compliance with IEC 60601-1. For testing the SWAG for protection from temperature change, including shipping and storage temperature ranges, the SWAG met the passing criteria of both of the visual and functional inspections following the testing. It showed no physical damage and was fully operational. Thus, the SWAG of the StimQ PNS System satisfies the outlined protection from temperature change design requirements and the applicable standard, IEC 60601-1. For atmospheric pressure change testing, the SWAG met the passing criteria of both of the visual and functional inspections following the testing. It showed no physical damage and was fully operational. Thus, the SWAG of the StimQ PNS System satisfies the outlined atmospheric pressure change design requirements and the applicable standard, IEC 60601-1. For the push, drop, impact and mold stress relief testing of the SWAG, it was determined through testing that the SWAG is robust to withstand expected damage in accordance with general safety standards. The SWAG met the passing criteria of both of the visual and functional inspections following the testing. It showed no physical damage and was fully operational. Thus, the SWAG component of the StimQ PNS System satisfies the outlined push, drop, impact, and mold stress relief design requirements and the applicable standard, IEC 60601-1. For the identification, marking and documents of the SWAG it was determined through an analysis of the labeling that the SWAG complies with the requirements of the standard. All requirements and markings are clearly identified and viewable either from the external case of the product or from within the accompanying documents. For the means of protection, creepage distances, and air clearances of the SWAG it was determined through an analysis of the design that the system satisfies the requirements of the applicable standard, IEC 60601-1. This testing presented for this submission is leveraged from K170141 and is directly applicable for demonstration of device safety and efficacy as the SWAG, identical to the WAA of K170141, remains the same.

IEC 60529 – The SWAG was tested for compliance with IEC 60529. For testing the ingress of water, the SWAG met the passing criteria of both of the visual and functional inspections following the testing. It showed no physical damage and was fully operational. Thus, the SWAG component of the StimQ PNS System satisfies the outlined Ingress of Water design requirements and the applicable standard IEC 60529. For particulate matter testing, the SWAG met the passing criteria of both of the visual and functional inspections following the testing. It showed no physical damage and was fully operational. Thus, the SWAG component of the StimQ PNS System satisfies the outlined Particulate Matter design requirements and the applicable standard, IEC 60529. This

testing presented for this submission is leveraged from K170141 and is directly applicable for demonstration of device safety and efficacy as the SWAG, identical to the WAA of K170141, remains the same.

IEC 60601-1-2 – The SWAG was tested for compliance with IEC 60601-1-2. For testing the SWAG for electromagnetic compatibility, the unit met all acceptance criteria for emissions, low-frequency magnetic fields, immunity, electrostatic discharge, radiated RF electromagnetic fields, electrical fast transients and bursts, and magnetic fields. The SWAG operated within all test limits and showed no physical damage and was fully operational. Thus, the SWAG for the StimQ PNS System satisfies the IEC 60601-1-2 standard. This testing presented for this submission is leveraged from K170141 and is directly applicable for demonstration of device safety and efficacy as the SWAG, identical to the WAA of K170141, remains the same.

The StimQ PNS System complies with the applicable standards for neurostimulators, electrical safety, electromagnetic interference and compatibility, biocompatibility, packaging, and sterilization. The software of the StimQ PNS System passed all verification tests outlined and the design requirements for Software Verification have been met. The device passed all the testing in accordance with national and international standards. This testing presented for this submission is leveraged from K170141 and is directly applicable for demonstration of device safety and efficacy as the StimQ PNS System remains the same.

Following performance testing, it has been determined that the StimQ PNS System is substantially equivalent to legally marketed predicate devices for the therapeutic relief for chronic, intractable pain of peripheral nerve origin.

Due to the similarities between the legally marketed predicate devices (K170141 and K152178), and the StimQ PNS System (this submission), StimQ has leveraged applicable performance testing in addition to completed a number of tests that demonstrates substantial equivalence to the legally marketed predicate devices. The StimQ PNS System meets all the requirements for overall design, sterilization, biocompatibility, and electrical safety confirms that the output meets the design inputs and specifications. The StimQ PNS System passed all testing stated above as shown by the acceptable results obtained.

10. Clinical Performance Data

There was no clinical testing required to support the medical device, as the indications for use are equivalent to the legally marketed predicate devices. These types of devices, including the legally marketed predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to legally marketed predicate devices when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. The StimQ PNS System has the same intended use as the legally marketed predicates device and is implanted percutaneous next to the peripheral nerves of the torso and extremities. Performance tested verified that the StimQ PNS System complies with all applicable voluntary standards such as IEC 60601-1, AAMI ANSI ISO 14708-3, and IEC 60529. The StimQ PNS System also meets the design requirements where no applicable standard could be used. This included Receiver/RF Stylet performance testing, stimulator body durability testing, programmable parameters, as well as power and performance of the SWAG. There were no recognized performance standards for this device. There was no clinical testing performed on this device since performance testing demonstrated similar performance as the legally marketed predicate devices, and materials for the implanted stimulator are the same as the legally marketed predicate devices.

It has been shown in this 510(k) submission that the difference between the StimQ PNS System and the legally marketed predicate devices do not raise any questions regarding its safety and effectiveness as compared to legally marketed predicate devices. StimQ PNS System, as designed and manufactured, is determined to be substantially equivalent to the referenced legally marketed predicate devices.