DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 11, 2016

StimQ LLC
Elizabeth Greene
Director of Quality Assurance and Regulatory Affairs
901 East Las Olas Boulevard
Suite 201
Fort Lauderdale, Florida 33301

Re: K152178
Trade/Device Name: StimQ Peripheral Nerve Stimulator (PNS) System
Regulation Number: 21 CFR 882.5870
Regulation Name: Stimulator, Peripheral Nerve, Implanted (Pain Relief)
Regulatory Class: Class II
Product Code: GZF
Dated: March 8, 2016
Received: March 9, 2016

Dear Ms. 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 yours,

William J. Heetderks -A

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -A
Date: 2016.03.11 15:31:15 -05'00'

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

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

July 31, 2015

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:	2
Classification Panel:	Neurology

4. Legally Marketed Predicate Device(s)

Stimwave Freedom SCS System FR8A-A1, FR8A-B1, FR4A-A1, FR4A-B1, LBRD-915-2A (K150517)
Stimwave Freedom SCS System FRE4-A001, FRT4-A001, WAA-A012 (K141399)
Medtronic Mattrix 3271/3272 Neuromodulation System (K934065)
Medtronic Xtrel, Model Number 3425 Receiver (K883780)
ANS Renew Neurostimulation System Transmitter, Model 2508, Receiver Model 3408, Antennae Models 1220 and 1230, Lead Models 3143, 3146, 3153, 3156, 3183 and 3186, Extension Models 3382, 3383, 3341, 3342 and 3343 (K000852)

5. Device Description

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/4A Stimulator) 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.

Freedom-8A and Freedom-4A Stimulator (Receiver Kit)

Freedom-8A Stimulator, Freedom-4A 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, and the Freedom-4A Stimulator has four (4) electrodes.
Stylet(s)	A stainless steel wire with a polypropylene handle that is inserted into the open central lumen of the stimulator to provide rigidity during implantation. Two (2) stylets are provided in the Receiver Kit, one straight and one bent, each with diameter of 0.25 mm.
Needle and Cannula	A 16-gauge stainless steel needle that is packaged inserted in the fluorinated ethylene propylene (FEP) Cannula that acts as a conduit for passage of the Stimulator next to the peripheral nerve.
Guidewire	A stainless steel, rigid, solid core guidewire used to create a hollow pathway in tissue for the Stimulator to pass through easily. The manufacturer of the guidewire is Guidewire Technologies.

StimQ Wearable Antenna Gear (SWAG) Transmitter Kit

Transmitter	The SWAG Transmitter housing includes the following components: i. Transmitting (Tx) Antenna – Flexible Dipole Antenna used to transmit microwave energy to the implanted Stimulator; ii. Microwave Field Stimulator (MFS) – A printed circuit board (PCB) that generates 915 MHz RF power with embedded waveform parameter settings and switches for changing parameter settings as needed by the user; iii. Switch Membrane – A 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); iv. Battery Assembly – A battery and wire assembly coupled with the Wireless Charging Coil Assembly for charging and the MFS for power delivery; v. Wireless Charging Coil Assembly – Consists of an inductive charging coil and battery that receives energy from the Wireless Battery Charging Pad. The battery charger components on the MFS are used to transfer charge into the 3.7V lithium ion battery by facilitating power transfer and warns the system when battery power is low.

StimQ Wearable Antenna Gear (SWAG) Transmitter Kit	
Wireless Battery Charging Pad	An off-the-shelf Qi-compliant charging pad (RP-WCN7, RP-WCN12, or RP-WCN13) that uses inductive charging technology to recharge the encased lithium ion battery of the SWAG Transmitter.

StimQ Wearable Antenna Gear (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 Velcro Hook for attaching the SWAG Transmitter.
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 Velcro Hook for attaching the SWAG Transmitter.
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 with the Velcro Hook for attaching the SWAG Transmitter.
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 Velcro Hook for attaching the SWAG Transmitter.
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 Velcro Hook for attaching the SWAG Transmitter.

Freedom-8A and Freedom-4A Trial Lead (Trial Lead Kit)	
Freedom-8A Trial Lead, 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.
Stylet(s)	A stainless steel wire with a polypropylene handle that is inserted into the open central lumen of the stimulator to provide rigidity during implantation. Two (2) stylets are provided in the Trial Lead Kit, one straight and one bent each with a diameter of 0.25 mm.
Needle and Cannula	A 16-gauge stainless steel needle that is packaged inserted in the fluorinated ethylene propylene (FEP) Cannula that acts as a conduit for passage of the Stimulator next to the peripheral nerve.
Guidewire	A stainless steel, rigid, solid core guidewire used to create a hollow pathway in tissue for the Stimulator to pass through easily. The manufacturer of the guidewire is Guidewire Technologies.

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 device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence. Stimwave physically measured Medtronic and ANS predicate devices to obtain the values listed in Table 5A.

Table 5A. Comparison of Characteristics

Comparator	StimQ PNS System	Stimwave Freedom SCS System (K150517)	Stimwave Freedom SCS System (K141399)	Medtronic Mattrix 3271/3272 (K934065)	Medtronic Xtrel, Model Number 3425 (K883780)	ANS Renew (K000852)
Product Code	GZF	GZB	GZB	GZB and GZF	GZB	GZB and GZF
Regulation No.	882.5870	882.5880	882.5880	882.5880 & 882.5870	882.5880	882.5880 & 882.5870
Regulation Name	Stimulator, Peripheral Nerve, Implanted (Pain Relief)	Stimulator, Spinal-Cord, Implanted (Pain Relief)	Stimulator, Spinal-Cord, Implanted (Pain Relief)	Stimulator, Spinal-Cord, Implanted (Pain Relief) Stimulator, Peripheral Nerve, Implanted (Pain Relief)	Stimulator, Spinal-Cord, Implanted (Pain Relief)	Stimulator, Spinal-Cord, Implanted (Pain Relief) Stimulator, Peripheral Nerve, Implanted (Pain Relief)
Intended Use	Stimulation of peripheral nerves for chronic, intractable pain of peripheral nerve origin	Stimulation of spinal cord for chronic, intractable pain of trunk and lower limbs	Stimulation of spinal cord for chronic, intractable pain of trunk and lower limbs	Stimulation of spinal cord for chronic, intractable pain of trunk and lower limbs; and peripheral nerve origin	Stimulation of spinal cord for chronic, intractable pain of trunk and lower limbs	Stimulation of spinal cord for chronic, intractable pain of trunk and lower limbs; and peripheral nerve origin
Implant Site	Peripheral nerves, excluding craniofacial region	Epidural space, L5 to T5	Epidural space, L5 to T5	Epidural space, L5 to T5; Peripheral nerves, excluding craniofacial region	Epidural space, L5 to T5	Epidural space, L5 to T5; Peripheral nerves, excluding craniofacial region

Comparator	StimQ PNS System	Stimwave Freedom SCS System (K150517)	Stimwave Freedom SCS System (K141399)	Medtronic Mattrix 3271/3272 (K934065)	Medtronic Xtrel, Model Number 3425 (K883780)	ANS Renew (K000852)
Environmental Use	Hospital, Home	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ
Intended Clinician	Orthopedic, Neurosurgeon, Anesthesiologist	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ
Intended User	Layperson	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ
Electrode Material	Platinum-iridium 90:10	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ
Stimulator Body Material	Polyurethane 2363-55D	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ
Cable Features	Multi-lumen Tube	Multi-lumen Tube	Multi-lumen Tube	Coiled Wires	Coiled Wires	Braided Wire
Stimulator Length	45 cm	45 cm	45 cm	30 to 110 cm	30 to 110 cm	30 and 60 cm
Diameter	1.35 mm	1.35 mm	1.35 mm	1.3 mm	1.3 mm	1.37 mm
Electrode Array Length	24 mm 52 mm	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ
No. of Electrodes	4 or 8	4 or 8	4	4	4	4 or 8
Electrode Length	3.0 mm	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ
Electrode Spacing	4.0 mm	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ
Electrode Surface Area	12.72 mm^2	12.72 mm^2	12.72 mm^2	12.25 mm^2	12.25 mm^2	"Approx. 13 mm^2"
Method of Introduction	Percutaneous	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ
Tissue Contact	Yes	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ
Sterilization	Ethylene Oxide (EO)	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ
Labeling	Labeled as Sterile, Single Use, Prescription Device	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ
Package	Backer card and two sterile pouches	Blister Tray/Tyvek Lid	Blister Tray/Tyvek Lid	Blister Tray/Tyvek Lid	Blister Tray/Tyvek Lid	Blister Tray/Tyvek Lid
Pulse Frequency	5 to 1500 Hertz	2 to 1500 Hertz	2 to 1500 Hertz	5 to 240 Hertz	5 to 1400 Hertz	10 to 1500 Hertz
Pulse Width	50 to 500 microseconds	50 to 500 microseconds	50 to 500 microseconds	50 to 500 microseconds	50 to 1000 microseconds	50 to 500 microseconds
Current/Voltage Regulated	Current	Current	Current	Voltage	Voltage	Current
Output Voltage (300 Ω)	0 to 4.1 V	0 to 4.1 V	0 to 6.3 V	0 to 7 V	0 to 5.4 V	0 to 5.7 V
Output Voltage (500 Ω)	0 to 6.4 V	0 to 6.4 V	0 to 7.2 V	0 to 10.8 V	0 to 7.1 V	0 to 7.6 V
Output Voltage (800 Ω)	0 to 7.5 V	0 to 7.5 V	0 to 8.0 V	0 to 11.6 V	0 to 8.4 V	0 to 9.6 V
Output Current (300 Ω)	0 to 13.5 mA	0 to 13.5 mA	0 to 21 mA	0 to 23.3 mA	0 to 18.0 mA	0 to 19.0 mA

Comparator	StimQ PNS System	Stimwave Freedom SCS System (K150517)	Stimwave Freedom SCS System (K141399)	Medtronic Mattrix 3271/3272 (K934065)	Medtronic Xtrel, Model Number 3425 (K883780)	ANS Renew (K000852)
Output Current (500 Ω)	0 to 12.8 mA	0 to 12.8 mA	0 to 15 mA	0 to 21.6 mA	0 to 14.2 mA	0 to 15.2 mA
Output Current (800 Ω)	0 to 9.4 mA	0 to 9.4 mA	0 to 10 mA	0 to 14.5 mA	0 to 10.5 mA	0 to 12.0 mA
Waveform	Charge Balanced (delayed) Biphasic asymmetrical	Charge Balanced (delayed) Biphasic asymmetrical	Charge Balanced (delayed) Biphasic asymmetrical	Charge Balanced Biphasic asymmetrical	Charge Balanced Biphasic asymmetrical	Charge Balanced (delayed) Biphasic asymmetrical
Pulse Shape	Decaying Exponential	Decaying Exponential	Decaying Exponential	Decaying Exponential	Decaying Exponential	Decaying Exponential
Average Current Density (300 Ω)	105.0 mA/cm^2	105.0 mA/cm^2	111.6 mA/cm^2	175.0 mA/cm^2	125.8 mA/cm^2	117.7 mA/cm^2
Average Current Density (500 Ω)	95.1 mA/cm^2	95.1 mA/cm^2	96.7 mA/cm^2	151.7 mA/cm^2	101.7 mA/cm^2	103.1 mA/cm^2
Average Current Density (800 Ω)	69.0 mA/cm^2	69.0 mA/cm^2	77.0 mA/cm^2	106.7 mA/cm^2	75.8 mA/cm^2	86.2 mA/cm^2
Maximum Phase Charge* (300 Ω)	6.8 µC/pulse	6.8 µC/pulse	10.5 µC/pulse	11.7 µC/pulse	18.0 µC/pulse	9.5 µC/pulse
Maximum Phase Charge* (500 Ω)	6.4 µC/pulse	6.4 µC/pulse	7.2 µC/pulse	10.8 µC/pulse	14.2 µC/pulse	7.6 µC/pulse
Maximum Phase Charge* (800 Ω)	4.7 µC/pulse	4.7 µC/pulse	5.0 µC/pulse	7.3 µC/pulse	10.5 µC/pulse	6.0 µC/pulse
Maximum Charge Density* (300 Ω)	53.1 $\mu C/cm^2$	53.1 $\mu C/cm^2$	82.5 $\mu C/cm^2$	97.2 $\mu C/cm^2$	150.0 $\mu C/cm^2$	73.1 $\mu C/cm^2$
Maximum Charge Density* (500 Ω)	50.3 $\mu C/cm^2$	50.3 $\mu C/cm^2$	56.6 $\mu C/cm^2$	90.0 $\mu C/cm^2$	118.3 $\mu C/cm^2$	58.5 $\mu C/cm^2$
Maximum Charge Density* (800 Ω)	36.9 $\mu C/cm^2$	36.9 $\mu C/cm^2$	39.3 $\mu C/cm^2$	60.4 $\mu C/cm^2$	87.5 $\mu C/cm^2$	46.2 $\mu C/cm^2$
Maximum Current Density* (300 Ω)	106.1 mA/cm^2	106.1 mA/cm^2	165.1 mA/cm^2	194.4 mA/cm^2	150.0 mA/cm^2	146.2 mA/cm^2
Maximum Current Density* (500 Ω)	100.6 mA/cm^2	100.6 mA/cm^2	113.2 mA/cm^2	180.0 mA/cm^2	118.3 mA/cm^2	116.9 mA/cm^2
Maximum Current Density* (800 Ω)	73.9 mA/cm^2	73.9 mA/cm^2	78.6 mA/cm^2	120.8 mA/cm^2	87.5 mA/cm^2	92.3 mA/cm^2
Net Charge	0 µC	0 µC	0 µC	0 µC	0 µC	0 µC
Average Phase Power (300 Ω)	0.053 W/phase	0.053 W/phase	0.060 W/phase	0.132 W/phase	0.068 W/phase	0.070 W/phase
Average Phase Power (500 Ω)	0.073 W/phase	0.073 W/phase	0.076 W/phase	0.166 W/phase	0.074 W/phase	0.090 W/phase
Average Phase Power (800 Ω)	0.062 W/phase	0.062 W/phase	0.060 W/phase	0.131 W/phase	0.066 W/phase	0.100 W/phase
Average Phase Power Density (300 Ω)	0.42 W/cm^2/phase	0.42 W/cm^2/phase	0.48 W/cm^2/phase	1.10 W/cm^2/phase	0.57 W/cm^2/phase	0.54 W/cm^2/phase
Average Phase Power Density (500 Ω)	0.58 W/cm^2/phase	0.58 W/cm^2/phase	0.59 W/cm^2/phase	1.38 W/cm^2/phase	0.62 W/cm^2/phase	0.69 W/cm^2/phase
Average Phase Power Density (800 Ω)	0.48 W/cm^2/phase	0.48 W/cm^2/phase	0.60 W/cm^2/phase	1.09 W/cm^2/phase	0.55 W/cm^2/phase	0.77 W/cm^2/phase

Comparator	StimQ PNS System	Stimwave Freedom SCS System (K150517)	Stimwave Freedom SCS System (K141399)	Medtronic Mattrix 3271/3272 (K934065)	Medtronic Xtrel, Model Number 3425 (K883780)	ANS Renew (K000852)
Pulse Delivery Mode	Continuous	Continuous	Continuous	Continuous	Continuous	Continuous
ON/OFF Times	No Cycling	No Cycling	No Cycling	ON/OFF Cycling Option	ON/OFF Cycling Option	No Cycling
Current Path Options	Bipolar	Bipolar	Bipolar	Bipolar	Bipolar	Bipolar
Power Delivery	Coupled receiver built into Stimulator body	Same as StimQ	Same as StimQ	Coupled receiver, hardwired connector	Coupled receiver, hardwired connector	Coupled receiver, hardwired connector
Transmit Frequency	915 MHz	915 MHz	915 MHz	2 MHz	1.60 MHz	2 MHz
Material	Platinum-iridium 90:10, Polyurethane 2363-55D	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ
Sterile	Yes - ethylene oxide	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ	Same as StimQ
Single-Use	Yes	Yes	Yes	Yes	Yes	Yes
Shelf Life	2 year	2 year	1 year	1 year	1 year	2 years
Complies with ISO 10993-1	Yes	Yes	Yes	Yes	Yes	Yes
Safety Testing Passed	Yes	Yes	Yes	Yes	Yes	Yes

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

8. Biocompatibility Data

The StimQ PNS System uses the same stimulator as the Stimwave Freedom SCS System. Thus, the materials of the StimQ PNS System remain unchanged from the Freedom SCS System (K150517 and K141399). 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 StimQ 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 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 Freedom-8A/4A 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 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 (similar in form to the Freedom SCS System, K141399 and K150517) meets biological safety and compatibility requirements of ISO 10993-1:2009 and Blue Book Memorandum G95-1.

9. Non-Clinical Performance Data

The StimQ PNS System was 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 StimQ Stimulator was 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 StimQ Stimulator was functional following post testing functionality inspection and passed atmospheric pressure change testing as specified by AAMI ANSI ISO 14708-3:2008.

For testing external defibrillation exposure, the StimQ Stimulator was verified as functional after exposure to external defibrillation. Thus, the StimQ Stimulator complies with testing as specified by AAMI ANSI ISO 14708-3:2008.

Following the thermal shock testing, the StimQ Stimulator was 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 StimQ Stimulator complies with the thermal shock design requirements and the applicable standard.

For leakage current testing, the StimQ Stimulator produced zero leakage current on all tested paths for all tested samples. Thus, the StimQ Stimulator complies with the leakage design requirements and the applicable standard.

For testing the insertion and withdrawal of the stimulator within the stylet, the StimQ Stimulator was found to require less than 2.5N 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 StimQ Stimulator complies with design specifications for stylet insertion and withdrawal force.

For mechanical testing, the StimQ Stimulator 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 StimQ Stimulator complies with all stimulator mechanical design requirements.

IEC 60601-1 – For testing the external unit for protection from temperature change, including shipping and storage temperature ranges, the external unit 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 external unit 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 external unit 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 external unit of the StimQ PNS System satisfies the outlined atmospheric pressure change design requirements and the applicable standard, IEC 60601-1. For the push, drop, and impact testing of the external unit, it was determined through testing that the external unit is robust to withstand expected damage in accordance with general safety standards. The external unit 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, and impact, design requirements and the applicable standard, IEC 60601-1. For the identification, marking and documents of the external unit it was determined through an analysis of the labeling that the external unit 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 external unit it was determined through an analysis of the design that the system satisfies the requirements of the applicable standard, IEC 60601-1.

IEC 60529 – For testing the ingress of water, the external unit 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 external unit 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.

IEC 60601-1-2 – For testing the external unit for electromagnetic compatibility, the unit met all acceptance criteria for emissions, low-frequency magnetic fields, immunity, radiated RF electromagnetic fields, electrical fast transients and bursts, and magnetic fields. For testing the external unit for electrostatic discharge, the unit met all acceptance criteria for exposure to contact discharge testing from discharge levels per IEC 60101-1-2. During air discharge testing, observations were noted for exposure to discharge levels of ±8 kV and ±15 kV. The noted observations are acceptable, the device remains safe; the StimQ PNS System is in compliance with IEC 60601-1-2 §5.2.2.1(e). The external unit operated within all test limits and showed no physical damage and was fully operational. Thus, the external unit for the StimQ PNS System satisfies the IEC 60601-1-2 standard.

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.

Following performance testing, it has been determined that the StimQ PNS System is substantially equivalent to legally marketed predicate devices for the therapy for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain.

StimQ LLC completed a number of tests for the StimQ PNS System 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 device. 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 devices 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 stimulator body durability testing, programmable parameters, as well as power and performance of the external unit. 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.