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

December 16, 2016

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: K162161
Trade/Device Name: Freedom Spinal Cord Stimulation (SCS) System
Regulation Number: 21 CFR 882.5880
Regulation Name: Implanted Spinal Cord Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: GZB
Dated: November 16, 2016
Received: November 18, 2016

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 -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: 2016.12.16 14:42:53 -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): K162161

Device Name: Freedom Spinal Cord Stimulator (SCS) System

Indications For Use:
The Freedom Spinal Cord Stimulator (SCS) System is intended as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain. The Freedom-8A Trial Lead Kit is only used in conjunction with the Freedom-8A Stimulator Receiver Kit, and the Freedom-4A Trial Lead Kit is used for either the Receiver Kit Freedom-4A Stimulator or the Receiver Kit Freedom-8A Stimulator. 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

for

Freedom Spinal Cord Stimulator (SCS) System

1. Submission Sponsor

Stimwave Technologies Incorporated
901 East Las Olas Boulevard
Suite 201
Fort Lauderdale
Florida 33301
USA
Phone: 800.965.5134
Fax: 800.965.5134
Contact: Elizabeth Greene, Vice President of Quality Assurance and Regulatory Affairs

2. Date Prepared

September 7, 2016

3. Device Identification

Trade/Proprietary Name:	Freedom Spinal Cord Stimulator (SCS) System
Common/Usual Name:	Spinal Cord Stimulator
Classification Name:	Stimulator, Spinal-Cord, Implanted (Pain Relief)
Classification Regulation:	882.5880
Product Code:	GZB
Device Class:	Class II
Classification Panel:	Neurology

4. Legally Marketed Predicate Device(s)

Stimwave Freedom SCS System FR8A/FR4A, LBRD-915-2A (K160600)
Stimwave Freedom SCS System FR8A/FR4A, LBRD-915-2A (K150517)
Stimwave Freedom SCS System FRE4-A001, FRT4-A001, WAA-A012 (K141399)

5. Device Description

This submission is based upon the established Stimwave product family offering additional surgical kitting options (Spare Lead Kit and Sterile Revision Kit), updates to the surgical kits (Receiver Kit and Trial Lead Kit) to include new accessory components (Needle, and RF Stylet), a new Wearable Antenna Assembly (WAA) model utilizing a Low Energy (LE) Bluetooth module, a USB battery charger, and upgrades to the WaveCrest Application.

The Stimwave Technologies Incorporated (Stimwave) Freedom Spinal Cord SCS System (System) is used for spinal column stimulation to provide therapeutic relief for chronic, intractable pain of the trunk and/or lower limbs including unilateral or bilateral pain. The therapy utilizes pulsed electrical current to create an energy field that acts on nerves near the spinal column. The System is comprised of an implantable stimulator (Freedom-8A/4A Stimulator), receiver component (Receiver), and an externally worn transmitter (Wearable Antenna Assembly (WAA)) 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 in the patient's epidural space. The Freedom-8A Stimulator has eight (8) electrodes, and the Freedom-4A Stimulator has four (4) electrodes. Identical to K150517 and K160600.
Receiver	A copper and PEEK cable with dual couplers; placed within the center lumen of the Freedom-8A or Freedom-4A 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 K160600, but quantity is increased from one to two.
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 0.30 mm. Similar to K150517 and K160600, but with a larger diameter.
Needle	A 13-gauge stainless steel needle that acts as a conduit for passage of the Stimulator into the epidural space. Similar to K141399, but provided with a larger gauge.
Guidewire	A stainless steel, rigid, solid core guidewire used to create a hollow pathway in the epidural space for the Stimulator to pass through easily. Identical to K141399, K150517, and K160600.
Suture Sleeve Cap	A polyurethane (Pellethane 55D) cap that is placed over the proximal end of the Stimulator. The Suture Sleeve Cap is attached to the Freedom-8A/4A Stimulator and can be sutured to tissue to reduce the possibility of device migration. Identical to K141399, K150517, and K160600.

Wearable Antenna Assembly (WAA Kit)

WAA	The WAA housing includes the following components: A. 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. Similar to K150517 with design updates for USB charging and PCB layout;

Wearable Antenna Assembly (WAA Kit)	
	B. 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). Identical to the component used for K152178 (StimQ PNS System); C. Battery Assembly – A battery and wire assembly for charging and the MFS for power delivery. New component for WAA. Transmitting (Tx) Antenna Assembly – An antenna and coaxial cable assembly that is attached to the WAA that is used to transmit microwave energy to the implanted Stimulator. Similar design and functionality as K152178, with design updates for indication.

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 WAA. New accessory component used to recharge the WAA.

Freedom-8A and Freedom-4A Spare Lead (Spare Lead Kit)	
Freedom-8A Spare Lead, Freedom-4A Spare Lead	A polyurethane (Pellethane 55D) casing with an embedded receiver, flexible circuit board and electrodes (Platinum Iridium 90:10) that is placed in the patient's epidural space. The Freedom-8A Spare Lead has eight (8) electrodes, and the Freedom-4A Spare Lead has four (4) electrodes. Identical in design and functionality to the Freedom-8A and Freedom-4A Stimulator.
RF Stylet	A copper and PEEK cable with dual couplers; placed within the center lumen of the Freedom-8A or Freedom-4A 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 in design and functionality to the Receiver.
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 Spare Lead Kit, one straight and one bent, each with diameter of 0.30 mm. Identical in design and functionality to the stylets in the Receiver Kit.
Needle	A 13-gauge stainless steel needle that acts as a conduit for passage of the Spare Lead into the epidural space. Identical in design and functionality to the needle in the Receiver Kit.
Guidewire	A stainless steel, rigid, solid core guidewire used to create a hollow pathway in the epidural space for the Spare Lead to pass through easily. Identical in design and functionality to the guidewire in the Receiver Kit.

Suture Sleeve Cap	A polyurethane (Pellethane 55D) cap that is placed over the proximal end of the Stimulator. The Suture Sleeve Cap is attached to the Freedom-8A/4A Spare Lead and can be sutured to tissue to reduce the possibility of device migration. Identical in design and functionality to the Suture Sleeve Cap in the Receiver Kit.

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 percutaneously in the patient's epidural space. The Freedom-8A Trial Lead has eight (8) electrodes, and the Freedom-4A Trial Lead has four (4) electrodes. Identical in design and functionality to the Freedom-8A and Freedom-4A Stimulator.
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 in design and functionality to the Receiver.
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 with a diameter of 0.30 mm. Identical in design and functionality to the stylets in the Receiver Kit.
Needle	A 13-gauge stainless steel needle that acts as a conduit for passage of the Trial Lead into the epidural space. Identical in design and functionality to the needle in the Receiver Kit.
Guidewire	A stainless steel, rigid, solid core guidewire used to create a hollow pathway in the epidural space for the Trial Lead to pass through more easily. Identical in design and functionality to the guidewire in the Receiver Kit.

Sterile Revision Kit

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 Sterile Revision Kit, one straight and one bent with a diameter of 0.30 mm. Identical in design and functionality to the stylets in the Receiver Kit.
Needle	A 13-gauge stainless steel needle that acts as a conduit for passage of the Stimulator/Lead into the epidural space. Identical in design and functionality to the needle in the Receiver Kit.
Guidewire	A stainless steel, rigid, solid core guidewire used to create a hollow pathway in the epidural space for the Stimulator/Lead to pass through easily. Identical in design and functionality to the guidewire in the Receiver Kit.

6. Indication for Use Statement

The Freedom Spinal Cord Stimulator (SCS) System is intended as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain. The Freedom-8A Trial Lead Kit is only used in conjunction with the Freedom-8A Stimulator Receiver Kit, and the Freedom-4A Trial Lead Kit is used for either the Receiver Kit Freedom-4A Stimulator or the Receiver Kit Freedom-8A Stimulator. 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 Stimwave Freedom SCS 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.

Table 5A. Comparison of Characteristics

Comparator	Stimwave Freedom SCS System (K162161)	Stimwave Freedom SCS System (K160600)	Stimwave Freedom SCS System (K150517)	Stimwave Freedom SCS System (K141399)
Product Code	GZB	Same as K162161	Same as K162161	Same as K162161
Regulation No.	882.5880	Same as K162161	Same as K162161	Same as K162161
Regulation Name	Stimulator, Spinal-Cord, Implanted (Pain Relief)	Same as K162161	Same as K162161	Same as K162161
Intended Use	Stimulation of spinal cord for chronic, intractable pain of trunk and lower limbs	Same as K162161	Same as K162161	Same as K162161
Mode of Action	RF wireless transmission of energy to produce stimulation at Stimulator electrodes. WAA sends a pulsed RF signal on a carrier frequency of 915MHz to the Stimulator	Same as K162161	Same as K162161	Same as K162161
Implant Site	Epidural space, L5 to T5	Same as K162161	Same as K162161	Same as K162161
Environmental Use	Hospital, Home	Same as K162161	Same as K162161	Same as K162161
Intended Clinician	Orthopedic, Neurosurgeon, Anesthesiologist	Same as K162161	Same as K162161	Same as K162161
Intended User	Layperson	Same as K162161	Same as K162161	Same as K162161
Electrode Material	Platinum-iridium 90:10	Same as K162161	Same as K162161	Same as K162161
Stimulator Body Material	Polyurethane 2363-55D	Same as K162161	Same as K162161	Same as K162161
Cable Features	Multi-lumen Tube	Same as K162161	Same as K162161	Same as K162161
Stimulator Length	45 centimeters	Same as K162161	Same as K162161	Same as K162161
Diameter	1.35 millimeters	Same as K162161	Same as K162161	Same as K162161
Electrode Array Length	24.0 millimeters 52.0 millimeters	Same as K162161	Same as K162161	Same as K162161

Comparator	Stimwave Freedom SCS System (K162161)	Stimwave Freedom SCS System (K160600)	Stimwave Freedom SCS System (K150517)	Stimwave Freedom SCS System (K141399)
No. of Electrodes	4 or 8	Same as K162161	Same as K162161	4
Electrode Length	3.0 millimeters	Same as K162161	Same as K162161	Same as K162161
Electrode Spacing	4.0 millimeters	Same as Freedom	Same as K162161	Same as K162161
Electrode Surface Area	12.72 mm^2	Same as K162161	Same as K162161	Same as K162161
Method of Introduction	Percutaneous and Anchor Incision	Same as K162161	Same as K162161	Same as K162161
Tissue Contact	Yes	Same as K162161	Same as K162161	Same as K162161
Sterilization	Ethylene Oxide (EO)	Same as K162161	Same as K162161	Same as K162161
Labeling	Labeled as Sterile, Single Use, Prescription Device	Same as K162161	Same as K162161	Same as K162161
Package	Backer card and two sterile pouches	Same as K162161	Same as K162161	Blister Tray/Tyvek Lid
Pulse Frequency	5 to 1500 Hertz	Same as K162161	Same as K162161	2 to 1500 Hertz
Pulse Width	50 to 500 microseconds	Same as K162161	Same as K162161	Same as K162161
Current/Voltage Regulated	Current	Same as K162161	Same as K162161	Same as K162161
Output Voltage (300 Ω)	0 to 4.1 V	Same as K162161	Same as K162161	0 to 6.3 V
Output Voltage (500 Ω)	0 to 6.4 V	Same as K162161	Same as K162161	0 to 7.2 V
Output Voltage (800 Ω)	0 to 7.5 V	Same as K162161	Same as K162161	0 to 8.0 V
Output Current (300 Ω)	0 to 13.5 mA	Same as K162161	Same as K162161	0 to 21 mA
Output Current (500 Ω)	0 to 12.8 mA	Same as K162161	Same as K162161	0 to 15 mA
Output Current (800 Ω)	0 to 9.4 mA	Same as K162161	Same as K162161	0 to 10 mA
Waveform	Charge Balanced (delayed) Biphasic asymmetrical	Same as K162161	Same as K162161	Same as K162161
Polarity	Programmable (Anode, Cathode, or Off)	Same as K162161	Same as K162161	Fixed
Pulse Shape	Decaying Exponential	Same as K162161	Same as K162161	Same as K162161
Avg. Current Density (300 Ω)	105.0 mA/cm^2	Same as K162161	Same as K162161	111.6 mA/cm^2
Avg. Current Density (500 Ω)	95.1 mA/cm^2	Same as K162161	Same as K162161	96.7 mA/cm^2
Avg. Current Density (800 Ω)	69.0 mA/cm^2	Same as K162161	Same as K162161	77.0 mA/cm^2
Max. Phase Charge* (300 Ω)	6.8 µC/pulse	Same as K162161	Same as K162161	10.5 µC/pulse
Max. Phase Charge* (500 Ω)	6.4 µC/pulse	Same as K162161	Same as K162161	7.2 µC/pulse
Max. Phase Charge* (800 Ω)	4.7 µC/pulse	Same as K162161	Same as K162161	5.0 µC/pulse
Max. Charge Density* (300 Ω)	53.1 $µC/cm^2$	Same as K162161	Same as K162161	82.5 $µC/cm^2$
Max. Charge Density* (500 Ω)	50.3 $µC/cm^2$	Same as K162161	Same as K162161	56.6 $µC/cm^2$
Max. Charge Density* (800 Ω)	36.9 $µC/cm^2$	Same as K162161	Same as K162161	39.3 $µC/cm^2$

Comparator	Stimwave Freedom SCS System (K162161)	Stimwave Freedom SCS System (K160600)	Stimwave Freedom SCS System (K150517)	Stimwave Freedom SCS System (K141399)
Max. Current Density* (300 Ω)	106.1 mA/cm^2	Same as K162161	Same as K162161	165.1 mA/cm^2
Max. Current Density* (500 Ω)	100.6 mA/cm^2	Same as K162161	Same as K162161	113.2 mA/cm^2
Max. Current Density* (800 Ω)	73.9 mA/cm^2	Same as K162161	Same as K162161	78.6 mA/cm^2
Net Charge	0 µC	Same as K162161	Same as K162161	Same as K162161
Avg. Phase Power (300 Ω)	0.053 W/phase	Same as K162161	Same as K162161	0.060 W/phase
Avg. Phase Power (500 Ω)	0.073 W/phase	Same as K162161	Same as K162161	0.076 W/phase
Avg. Phase Power (800 Ω)	0.062 W/phase	Same as K162161	Same as K162161	0.060 W/phase
Avg. Phase Power Density (300 Ω)	0.42 W/cm^2/phase	Same as K162161	Same as K162161	0.48 W/cm^2/phase
Avg. Phase Power Density (500 Ω)	0.58 W/cm^2/phase	Same as K162161	Same as K162161	0.59 W/cm^2/phase
Avg. Phase Power Density (800 Ω)	0.48 W/cm^2/phase	Same as K162161	Same as K162161	0.60 W/cm^2/phase
Pulse Delivery Mode	Continuous	Same as K162161	Same as K162161	Same as K162161
ON/OFF Times	No Cycling	Same as K162161	Same as K162161	Same as K162161
Current Path Options	Bipolar	Same as K162161	Same as K162161	Same as K162161
Power Delivery	Embedded receiver and coupled receiver in lumen of Stimulator body	Same as K162161	Coupled receiver, built into Stimulator body	Coupled receiver, built into Stimulator body
Transmit Frequency	915 MHz	Same as K162161	Same as K162161	Same as K162161
Material	Platinum-iridium 90:10, Polyurethane 2363-55D	Same as K162161	Same as K162161	Same as K162161
Sterile	Yes - ethylene oxide	Same as K162161	Same as K162161	Same as K162161
Contract Sterilizer	Steris Isomedix Services	Life Science Outsourcing	Life Science Outsourcing	Oscor, Inc.
Single-Use	Yes	Same as K162161	Same as K162161	Same as K162161
Shelf Life	2 year	Same as K162161	Same as K162161	1 year
Complies with ISO 10993-1	Yes	Same as K162161	Same as K162161	Same as K162161
Safety Testing Passed	Yes	Same as K162161	Same as K162161	Same as K162161
MR Conditional	No, MR Unsafe	Same as K162161	Same as K162161	Yes
Accessories	Receiver/RF Stylet, Stylet(s), Guidewire, Needle, Suture Sleeve Cap	Receiver, Stylet(s), Guidewire, Needle, Suture Sleeve Cap	Stylet(s), Guidewire, Needle, Suture Sleeve Cap	Stylet(s), Guidewire, Needle, Suture Sleeve Cap
Charger	USB Charger	Wireless Charger	Wireless Charger	Wireless Charger
Wearable Antenna Assembly	Aluminum transmitter and separate, connected Antenna	ABS plastic transmitter contained in a wearable athletic pouch belt	ABS plastic transmitter contained in a wearable athletic pouch belt	Thermoplastic polyurethane body worn device

Comparator	Stimwave Freedom SCS System (K162161)	Stimwave Freedom SCS System (K160600)	Stimwave Freedom SCS System (K150517)	Stimwave Freedom SCS System (K141399)
Software Level of Concern	Moderate	Same as K162161	Same as K162161	Same as K162161
iPad Application	WaveCrest™ 2.2	WaveCrest™	WaveCrest™	WaveCrest™
Kits	Receiver Kit, Spare Lead Kit, Trial Lead Kit, Sterile Revision Kit, WAA Kit, Charger Kit	Receiver Kit, Trial Lead Kit, WAA Kit	Receiver Kit, Trial Lead Kit, WAA Kit	Receiver Kit, Trial Lead Kit, WAA Kit

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

8. Biocompatibility Data

The materials of the Freedom-8A/4A Stimulator (K162161) in direct contact with tissue remain unchanged from the Freedom SCS System (K141399, K150517, and K160600) and thus, the biocompatibility tests conducted on representative subassemblies of the Freedom SCS System (Freedom-4, K141399) directly apply to the Freedom SCS System (K150517, K160600, and K162161). The materials, construction and intended use of the Freedom SCS System is comparable to the predicate device, and have a long history of safety with respect to biocompatibility. The biological safety of the Freedom-8A/4A Stimulator (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 Freedom-8A/4A Stimulator (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 Freedom SCS System. The Freedom-8A/4A Stimulator materials in direct tissue contact include Pellethane 55D (Stimulator) and Pt-Ir (90:10) (Stimulator only), 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 WAA is intended to be on top of a thin shirt or article of clothing around the midsection of the patient. The User Manual provided to the patient describes that the WAA should always be worn on top of a layer of clothing. The WAA does not come into contact with the patient's skin. The categorization by nature of body contact of the WAA is thus "non-contacting device", and not included in the scope of ISO 10993-1:2009. The Freedom SCS System meets biological safety and compatibility requirements of ISO 10993-1:2009 and Blue Book Memorandum G95-1.

9. Non-Clinical Performance Data

The Freedom SCS System was tested to verify that the performance meets the system design requirements as well as all applicable voluntary standards. The Freedom SCS 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 Freedom-8A/4A 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 Freedom-8A/4A Stimulator 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 K162161 is leveraged from K150517 and is directly applicable for demonstration of device safety and efficacy as the packaging and the Freedom-8A/4A Stimulator 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 Freedom-8A/4A Stimulator and Receiver were verified as functional after exposure to external defibrillation. Thus, the Freedom SCS System complies with testing as specified by AAMI ANSI ISO 14708-3:2008. The Receiver/RF Stylet testing presented for K162161 is leveraged from K160600 and is directly applicable for demonstration of device safety and efficacy as Receiver/RF Stylet remains the same.

Following the thermal shock testing, the Freedom-8A/4A 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 Freedom-8A/4A Stimulator comply with the thermal shock design requirements and the applicable standard. This testing presented for K162161 is leveraged from K150517 and is directly applicable for demonstration of device safety and efficacy as the Freedom-8A/4A Stimulator 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 Freedom-8A/4A Stimulator was produced zero leakage current on all tested paths for all tested samples. Thus, the Freedom-8A/4A Stimulator comply with the leakage design requirements and the applicable standard. This testing presented for K162161 is leveraged from K150517 and is directly applicable for demonstration of device safety and efficacy as the Freedom-8A/4A Stimulator 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 Freedom-8A/4A Stimulator and Receiver/RF Stylet comply with design specifications for stylet insertion and withdrawal force. The Stimulator testing presented for K162161 is leveraged from K150517 and is directly applicable for demonstration of device safety and efficacy as the

Freedom-8A/4A Stimulator remains the same. The Receiver/RF Stylet testing presented for K162161 is leveraged from K160600 and is directly applicable for demonstration of device safety and efficacy as Receiver/RF Stylet remains the same.

For mechanical testing, the Freedom-8A/4A 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 Freedom-8A/4A Stimulator comply with all stimulator mechanical design requirements. This testing presented for K162161 is leveraged from K150517 and is directly applicable for demonstration of device safety and efficacy as the Freedom-8A/4A Stimulator 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.

IEC 60601-1 – The WAA was tested for compliance with IEC 60601-1. For testing the WAA for protection from temperature change, including shipping and storage temperature ranges, the WAA 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 WAA of the Freedom SCS System satisfies the outlined protection from temperature change design requirements and the applicable standard, IEC 60601-1. For atmospheric pressure change testing, the WAA 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 WAA of the Freedom SCS 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 WAA, it was determined through testing that the WAA is robust to withstand expected damage in accordance with general safety standards. The WAA 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 WAA component of the Freedom-8A/4A SCS 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 WAA it was determined through an analysis of the labeling that the WAA 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 WAA it was determined through an analysis of the design that the system satisfies the requirements of the applicable standard, IEC 60601-1.

IEC 60529 – The WAA was tested for compliance with IEC 60529. For testing the ingress of water, the WAA 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 WAA component of the Freedom SCS System satisfies the outlined Ingress of Water design requirements and the applicable standard IEC 60529. For particulate matter testing, the WAA 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 WAA component of the Freedom SCS System satisfies the

outlined Particulate Matter design requirements and the applicable standard, IEC 60529.

IEC 60601-1-2 – The WAA was tested for compliance with IEC 60601-1-2. For testing the WAA 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 WAA operated within all test limits and showed no physical damage and was fully operational. Thus, the WAA for the Freedom SCS System satisfies the IEC 60601-1-2 standard.

The Freedom SCS System complies with the applicable standards for neurostimulators, electrical safety, electromagnetic interference and compatibility, biocompatibility, packaging, and sterilization. The software of the Freedom SCS 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 Freedom SCS 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.

Due to the similarities between the legally marketed predicate devices (K141399, K150517, and K160600), and the Freedom SCS System (K162161), Stimwave Technologies Incorporated has leveraged applicable performance testing in addition to completed a number of tests that demonstrates substantial equivalence to the legally marketed predicate devices. The Freedom SCS System meets all the requirements for overall design, sterilization, biocompatibility, and electrical safety confirms that the output meets the design inputs and specifications. The Freedom SCS 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 Freedom SCS System has the same intended use as the legally marketed predicates devices and is implanted percutaneous into the epidural space ranging from T5 to L5. Performance tested verified that the Freedom SCS

System complies with all applicable voluntary standards such as IEC 60601-1, AAMI ANSI ISO 14708-3, and IEC 60529. The Freedom SCS 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 WAA. 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 Freedom SCS System and the legally marketed predicate devices do not raise any questions regarding its safety and effectiveness as compared to legally marketed predicate devices. Freedom SCS System, as designed and manufactured, is determined to be substantially equivalent to the referenced legally marketed predicate devices.