



Food and Drug Administration  
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Silver Spring, MD 20993-0002

August 26, 2016

Stimwave Technologies Incorporated  
Elizabeth Greene  
Vice President of Quality Assurance And Regulatory Affairs  
901 E Las Olas Blvd, Suite 201  
Fort Lauderdale, Florida 33301

Re: K160600

Trade/Device Name: Freedom Spinal Cord Stimulator System  
Regulation Number: 21 CFR 882.5880  
Regulation Name: Implanted Spinal Cord Stimulator For Pain Relief  
Regulatory Class: Class II  
Product Code: GZB  
Dated: July 19, 2016  
Received: July 25, 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,  
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Date: 2016.08.26 13:36:41 -0400'

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):** K160600

**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    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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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**

February 29, 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 (K150517)  
Stimwave Freedom SCS System FRE4-A001, FRT4-A001, WAA-A012 (K141399)

**5. Device Description**

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 (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.
Freedom 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. One (1) Receiver is provided with each 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 Receiver Kit, one straight and one bent, each with diameter of 0.25 mm.
Needle and Cannula Assembly	An assembly that includes 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 into the epidural space.
Guidewire	A stainless steel, rigid, solid core guidewire used to create a hollow pathway in the epidural space for the Stimulator to pass through more easily.
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.

**Wearable Antenna Assembly (WAA Kit)**

WAA	<p>The WAA housing includes the following components:</p> <ol style="list-style-type: none"> <li>i. <u>Transmitting (Tx) Antenna</u> – Antenna used to transmit microwave energy to the implanted Stimulator;</li> <li>ii. <u>Microwave Field Stimulator (MFS)</u> – 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;</li> <li>iii. <u>Button Cover</u> – A silicon 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);</li> <li>iv. <u>Battery Assembly</u> – A battery and wire assembly coupled with the Wireless Charging Coil Assembly for charging and the MFS for power delivery;</li> <li>v. <u>Wireless Charging Coil Assembly</u> – Consists of an inductive charging coil and battery that receives energy from the Wireless Battery Charging Pad. The battery charger components on the</li> </ol>
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**Wearable Antenna Assembly (WAA Kit)**

	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.
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 WAA.
Athletic Pouch Belt	An off-the-shelf assembly constructed of lightweight nylon mesh with an adjustable belt, and a zipper pouch for housing the WAA.

**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.
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 0.25 mm.
Needle and Cannula Assembly	An assembly that includes 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 into the epidural space.
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.

**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.



Stimwave Technologies Incorporated  
 Traditional 510(k) Premarket Submission  
 Freedom Spinal Cord Stimulator (SCS) System

**Table 5A. Comparison of Characteristics**

Comparator	Stimwave Freedom SCS System (K160600)	Stimwave Freedom SCS System (K150517)	Stimwave Freedom SCS System (K141399)
Product Code	GZB	Same as K160600	Same as K160600
Regulation No.	882.5880	Same as K160600	Same as K160600
Regulation Name	Stimulator, Spinal-Cord, Implanted (Pain Relief)	Same as K160600	Same as K160600
Intended Use	Stimulation of spinal cord for chronic, intractable pain of trunk and lower limbs	Same as K160600	Same as K160600
Implant Site	Epidural space, L5 to T5	Same as K160600	Same as K160600
Environmental Use	Hospital, Home	Same as K160600	Same as K160600
Intended Clinician	Orthopedic, Neurosurgeon, Anesthesiologist	Same as K160600	Same as K160600
Intended User	Layperson	Same as K160600	Same as K160600
Electrode Material	Platinum-iridium 90:10	Same as K160600	Same as K160600
Stimulator Body Material	Polyurethane 2363-55D	Same as K160600	Same as K160600
Cable Features	Multi-lumen Tube	Same as K160600	Same as K160600
Stimulator Length	45 centimeters	Same as K160600	Same as K160600
Diameter	1.35 millimeters	Same as K160600	Same as K160600
Electrode Array Length	24.0 millimeters 52.0 millimeters	Same as K160600	24.0 millimeters
No. of Electrodes	4 or 8	Same as K160600	4
Electrode Length	3.0 millimeters	Same as K160600	Same as K160600
Electrode Spacing	4.0 millimeters	Same as K160600	Same as K160600
Electrode Surface Area	12.72 mm <sup>2</sup>	Same as K160600	Same as K160600
Method of Introduction	Percutaneous	Same as K160600	Same as K160600
Tissue Contact	Yes	Same as K160600	Same as K160600
Sterilization	Ethylene Oxide (EO)	Same as K160600	Same as K160600
Labeling	Labeled as Sterile, Single Use, Prescription Device	Same as K160600	Same as K160600
Package	Backer card and two sterile pouches	Same as K160600	Blister Tray/Tyvek Lid
Pulse Frequency	5 to 1500 Hertz	Same as K160600	2 to 1500 Hertz
Pulse Width	50 to 500 microseconds	Same as K160600	Same as K160600
Current/Voltage Regulated	Current	Same as K160600	Same as K160600
Output Voltage (300 Ω)	0 to 4.1 V	Same as K160600	0 to 6.3 V
Output Voltage (500 Ω)	0 to 6.4 V	Same as K160600	0 to 7.2 V
Output Voltage (800 Ω)	0 to 7.5 V	Same as K160600	0 to 8.0 V
Output Current (300 Ω)	0 to 13.5 mA	Same as K160600	0 to 21 mA
Output Current (500 Ω)	0 to 12.8 mA	Same as K160600	0 to 15 mA
Output Current (800 Ω)	0 to 9.4 mA	Same as K160600	0 to 10 mA
Waveform	Charge Balanced (delayed) Biphasic asymmetrical	Same as K160600	Same as K160600
Pulse Shape	Decaying Exponential	Same as K160600	Same as K160600
Average Current Density (300 Ω)	105.0 mA/cm <sup>2</sup>	Same as K160600	111.6 mA/cm <sup>2</sup>
Average Current Density (500 Ω)	95.1 mA/cm <sup>2</sup>	Same as K160600	96.7 mA/cm <sup>2</sup>
Average Current Density (800 Ω)	69.0 mA/cm <sup>2</sup>	Same as K160600	77.0 mA/cm <sup>2</sup>



Stimwave Technologies Incorporated  
 Traditional 510(k) Premarket Submission  
 Freedom Spinal Cord Stimulator (SCS) System

Comparator	Stimwave Freedom SCS System (K160600)	Stimwave Freedom SCS System (K150517)	Stimwave Freedom SCS System (K141399)
Maximum Phase Charge* (300 Ω)	6.8 μC/pulse	Same as K160600	10.5 μC/pulse
Maximum Phase Charge* (500 Ω)	6.4 μC/pulse	Same as K160600	7.2 μC/pulse
Maximum Phase Charge* (800 Ω)	4.7 μC/pulse	Same as K160600	5.0 μC/pulse
Maximum Charge Density* (300 Ω)	53.1 μC/cm <sup>2</sup>	Same as K160600	82.5 μC/cm <sup>2</sup>
Maximum Charge Density* (500 Ω)	50.3 μC/cm <sup>2</sup>	Same as K160600	56.6 μC/cm <sup>2</sup>
Maximum Charge Density* (800 Ω)	36.9 μC/cm <sup>2</sup>	Same as K160600	39.3 μC/cm <sup>2</sup>
Maximum Current Density* (300 Ω)	106.1 mA/cm <sup>2</sup>	Same as K160600	165.1 mA/cm <sup>2</sup>
Maximum Current Density* (500 Ω)	100.6 mA/cm <sup>2</sup>	Same as K160600	113.2 mA/cm <sup>2</sup>
Maximum Current Density* (800 Ω)	73.9 mA/cm <sup>2</sup>	Same as K160600	78.6 mA/cm <sup>2</sup>
Net Charge	0 μC	Same as K160600	Same as K160600
Average Phase Power (300 Ω)	0.053 W/phase	Same as K160600	0.060 W/phase
Average Phase Power (500 Ω)	0.073 W/phase	Same as K160600	0.076 W/phase
Average Phase Power (800 Ω)	0.062 W/phase	Same as K160600	0.060 W/phase
Average Phase Power Density (300 Ω)	0.42 W/cm <sup>2</sup> /phase	Same as K160600	0.48 W/cm <sup>2</sup> /phase
Average Phase Power Density (500 Ω)	0.58 W/cm <sup>2</sup> /phase	Same as K160600	0.59 W/cm <sup>2</sup> /phase
Average Phase Power Density (800 Ω)	0.48 W/cm <sup>2</sup> /phase	Same as K160600	0.60 W/cm <sup>2</sup> /phase
Pulse Delivery Mode	Continuous	Same as K160600	Same as K160600
ON/OFF Times	No Cycling	Same as K160600	Same as K160600
Current Path Options	Bipolar	Same as K160600	Same as K160600
Power Delivery	Embedded receiver and coupled receiver in lumen of Stimulator body	Coupled receiver, built into Stimulator body	Coupled receiver, built into Stimulator body
Transmit Frequency	915 MHz	Same as K160600	Same as K160600
Material	Platinum-iridium 90:10, Polyurethane 2363-55D	Same as K160600	Same as K160600
Sterile	Yes - ethylene oxide	Same as K160600	Same as K160600
Single-Use	Yes	Same as K160600	Same as K160600
Shelf Life	2 year	Same as K160600	1 year
Complies with ISO 10993-1	Yes	Same as K160600	Same as K160600
Safety Testing Passed	Yes	Same as K160600	Same as K160600

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

Table 5B identifies the differences between the cleared Freedom SCS System (K150517) and the modifications identified by this Traditional Premarket Notification.



**Table 5B. Comparison of the similarities and differences between FDA-cleared Stimwave product (Freedom-8A/4A) and products submitted in this Traditional Premarket Notification (Freedom-8A/4A with Receiver).**

Criteria	Freedom-8A/4A	Freedom-8A/4A with Receiver
Product Code	GZB	Same as Freedom-8A/4A
Regulation No.	882.5880	Same as Freedom-8A/4A
Regulation Name	Stimulator, Spinal-Cord, Implanted (Pain Relief)	Same as Freedom-8A/4A
Intended Use	Stimulation of spinal column for chronic, intractable pain of trunk and lower limbs	Same as Freedom-8A/4A
Mode of Action	RF wireless transmission of energy to produce therapeutic stimulation at the Stimulator. The external WAA sends a pulsed RF signal on a carrier frequency of 915 MHz to a passive, implanted Receiver within the Stimulator	Same as Freedom-8A/4A
No. of Electrodes	8 or 4	Same as Freedom-8A/4A
MRI Conditional	No, MR Unsafe	Same as Freedom-8A/4A
Electrode Material	Platinum-Iridium 90:10	Same as Freedom-8A/4A
Stimulator Body Material	Polyurethane 2363-55D	Same as Freedom-8A/4A
Polarity	Programmable (Anode, Cathode, or Off)	Same as Freedom-8A/4A
Packaging	Backer card & 2 Tyvek sterile pouches	Same as Freedom-8A/4A
Sterilization	Ethylene Oxide (EO)	Same as Freedom-8A/4A
Accessories	Guidewire, Stylet(s), Coude Needle, Cannula, Suture Sleeve Cap	Same as Freedom-8A/4A
Pulse Frequency	5 to 1500 Hz	Same as Freedom-8A/4A
Pulse Width	50 to 500 $\mu$ s	Same as Freedom-8A/4A
Output Current (500 $\Omega$ )	0 to 12.8 mA	Same as Freedom-8A/4A
Transmit Frequency	915 MHz	Same as Freedom-8A/4A
Power Delivery	Coupled receiver, built into Stimulator body	Embedded receiver and coupled receiver in lumen of Stimulator body
Wearable Antenna Assembly (WAA)	ABS plastic transmitter contained in a wearable athletic pouch belt	Same as Freedom-8A/4A
iPad Application	WaveCrest™	Same as Freedom-8A/4A
Software Level of Concern	Moderate	Same as Freedom-8A/4A

## 8. Biocompatibility Data

The materials of the Freedom SCS System (Freedom-8A/4A Stimulator) in direct contact with tissue remain unchanged from the Freedom SCS System (K150517 and K141399) 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 and this Traditional Premarket Notification). 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 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 carcinogenic safety. The Receiver is never in direct or indirect contact with tissue. The WAA remains unchanged from K150517 to this Traditional Premarket Notification and 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 (same as 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 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 K160600 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 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 with Receiver was 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

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 K160600 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 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 K160600 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 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 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 complies with design specifications for stylet insertion and withdrawal force. The Stimulator testing presented for K160600 is leveraged from K150517 and is directly applicable for demonstration of device safety and efficacy as the Freedom-8A/4A Stimulator 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 K160600 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 is a passive component that does not impact the outcome of the leveraged tests for safety and effectiveness.

**IEC 60601-1** – The 60601-1 testing presented for K160600 is leveraged from K150517 and is directly applicable for demonstration of device safety and efficacy as the WAA remains the same. 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 IEC 60529 testing presented for K160600 is leveraged from K150517 and is directly applicable for demonstration of device safety and efficacy as the WAA remains the same. 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 of the Freedom SCS System satisfies the outlined Particulate Matter design requirements and the applicable standard, IEC 60529.

**IEC 60601-1-2** – The WAA remains the same from K150517 to K160600. Thus, the testing for electromagnetic compatibility for emissions, magnetic fields, electrostatic discharge, and radiated RF electromagnetic fields is leveraged from K150517, and is directly applicable for demonstration of device safety and efficacy. For testing the Freedom SCS System for electromagnetic compatibility for radiated RF electromagnetic fields, radiated immunity, and wireless coexistence, the System met all acceptance criteria. For both leveraged and new testing, the WAA operated within all test limits and showed no physical damage and was fully operational. Thus, the WAA for the Freedom-8A/4A SCS System satisfies the IEC 60601-1-2 standard. This testing presented for K160600 is both leveraged from K150517 and new for K160600 and is directly applicable for demonstration of device safety and efficacy as the WAA remains the same.

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, both leveraged and new, 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 device (K150517), and the Freedom SCS System (K160600), 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 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.