September 19, 2018

Stimwave Technologies Incorporated
Elizabeth Greene
Vice President of Quality Assurance and Regulatory Affairs
1310 Park Central Boulevard South
Pompano Beach, Florida 33064

Re: K180981
Trade/Device Name: Freedom Spinal Cord Stimulator (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: August 16, 2018
Received: August 20, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Pamela D. Scott -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K180981

Device Name
Freedom Spinal Cord Stimulator (SCS) System

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

For Freedom Spinal Cord Stimulator (SCS) System

1. Submission Sponsor

Stimwave Technologies Incorporated
1310 Park Central Boulevard
Pompano Beach
Florida 33064
USA
Phone: 800.965.5134
Fax: 800.965.5134
Contact: Elizabeth Greene, Chief Compliance Officer

2. Date Prepared

March 31, 2018

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, PDBT-915-2A (K170141)

5. Device Description

This submission is identical to K170141, but includes the following updates:

Section	Change Description
Section 11	A. Inclusion of single pack accessories (sterile and non-sterile); B. Updated Application Specific Integrated Circuit (ASIC) for Freedom-8A/4A Stimulators (see Section 18 for design verification); C. Wearable Antenna Assembly (WAA) manufacturing at Stimwave Technologies Inc.; D. Contract manufacturing and packaging for Freedom-8A/4A Stimulators at Oscor, Inc.

Section	Change Description
Section 13	A. Revision of applicable Instructions for Use to replace the Suture Sleeve Cap with the SandShark Injectable Anchor (SIA) System (K172644).
Section 14	A. Increased sterilization capacity from 2 cases to one-half pallet.
Section 16	A. Release of WaveCrest 2.4 version; B. Inclusion of new patient programmer, WaveCrest Mobile (wcMobile); C. Updated firmware version for WaveCrest 2.4 and wcMobile.
Section 18	A. Inclusion of testing summaries in support of the modifications described in this submission.

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. Matches device specifications of K170141.
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 K170141.
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. Identical to K170141.
Needle	A 13-gauge stainless steel needle that acts as a conduit for passage of the Stimulator into the epidural space. Identical to K170141.
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 K170141.

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 RF power with embedded waveform parameter settings and switches for changing parameter settings as needed by the user. Identical to K170141; B. Switch Membrane – An elastomeric silicon rubber pad that corresponds to switches on the MFS that allows the user to turn the device on/off or increase or decrease power amplitude as well as interpret device power status (On, Off, Charging, Transmitting, and Bluetooth® Connection). Identical to K170141; C. Battery Assembly – A battery and wire assembly for charging and the MFS for power delivery. Identical to K170141. Transmitting (Tx) Antenna Assembly – An antenna and coaxial cable assembly that is attached to the WAA that is used to transmit microwave energy to the implanted Stimulator. Identical to K170141.

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. Identical to K170141.

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. Matches device specifications of K170141.
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 to K170141.
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 to K170141.
Needle	A 13-gauge stainless steel needle that acts as a conduit for passage of the Spare Lead into the epidural space. Identical to K170141.
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 to K170141.

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. Matches device specifications of K170141..
RF Stylet	A copper and PEEK cable with dual couplers; placed within the center lumen of the Freedom-8A or Freedom-4A Trial Lead with the distal end combination of RF Stylet and Trial Lead being placed under the skin. Two (2) RF Stylets are provided with each kit. Identical to K170141.
Stylet(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 to K170141.
Needle	A 13-gauge stainless steel needle that acts as a conduit for passage of the Trial Lead into the epidural space. Identical to K170141.
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 to K170141.

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 to K170141.
Needle	A 13-gauge stainless steel needle that acts as a conduit for passage of the Stimulator/Lead into the epidural space. Identical to K170141.
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 to K170141.

Sterile Single Pack Accessories

RF Stylet	A copper and PEEK cable with dual couplers; placed within the center lumen of the Freedom-8A or Freedom-4A Stimulator, Spare Lead, or Trial Lead with the distal end combination of RF Stylet and Stimulator, Spare Lead, or Trial Lead being placed under the skin. One (1) RF Stylet is provided in the single pack. Identical to K170141.
Needle (4.5")	A 13-gauge stainless steel needle that acts as a conduit for passage of the Stimulator/Lead into the epidural space. Identical to K170141.
Needle (6")	A 13-gauge stainless steel needle that acts as a conduit for passage of the Stimulator/Lead into the epidural space. Similar to K170141 no change in materials or supplier.
Guidewires	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. Three (3) guidewires are provided, each with different diameters (1.05mm (MD0570), 1.30mm (MD0575), and 1.60mm (MD0580)), but all the same length (45cm). Similar to K170141, no change in materials or supplier.
Introducer	A stainless steel stylet and polymer sheath that dilates the path over the guidewire for advancing the Stimulator/ Lead into place. Identical to K171366.

Non-Sterile Single Pack Accessories

Small SeaSilk Antenna (12" Cable Length)	An antenna (conductive ink printed onto laminate) bonded to the outside of a fabric shirt and coaxial cable assembly. Attaches to the WAA and used to transmit microwave energy to the implanted Stimulator/Lead.
Small SeaSilk Antenna (27" Cable Length)	An antenna (conductive ink printed onto laminate) bonded to the outside of a fabric shirt and coaxial cable assembly. Attaches to the WAA and used to transmit microwave energy to the implanted Stimulator/Lead.
Large SeaSilk Antenna (30" Cable Length)	An antenna (conductive ink printed onto laminate) bonded to the outside of a fabric shirt and coaxial cable assembly. Attaches to the WAA and used to transmit microwave energy to the implanted Stimulator/Lead. Identical performance to the Tx Antenna Assembly of K170141 and this submission.
Large SeaSilk Antenna (28" Cable Length)	An antenna (conductive ink printed onto laminate) bonded to the outside of a fabric shirt and coaxial cable assembly. Attaches to the WAA and used to transmit microwave energy to the implanted Stimulator/Lead. Identical performance to the Tx Antenna Assembly of K170141 and this submission.
Small Antenna (12" Cable Length)	A flexible dipole antenna and coaxial cable assembly that is attached to the WAA that is used to transmit microwave energy to the implanted Stimulator.
Small Antenna (27" Cable Length)	A flexible dipole antenna and coaxial cable assembly that is attached to the WAA that is used to transmit microwave energy to the implanted Stimulator.
Large Antenna (30" Cable Length)	A flexible dipole array antenna and coaxial cable assembly that is attached to the WAA that is used to transmit microwave energy to the implanted Stimulator. Identical to K170141.

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 (Predicate – K170141)	Stimwave Freedom SCS System (Subject device)
Product Code	GZB	Same as K170141
Regulation No.	882.5880	Same as K170141
Regulation Name	Stimulator, Spinal-Cord, Implanted (Pain Relief)	Same as K170141
Intended Use	Stimulation of spinal cord for chronic, intractable pain of trunk and lower limbs	Same as K170141
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 K170141
Implant Site	Epidural space, L5 to T5	Same as K170141
Environmental Use	Hospital, Home	Same as K170141
Intended Clinician	Orthopedic, Neurosurgeon, Anesthesiologist	Same as K170141
Intended User	Layperson	Same as K170141
Electrode Material	Platinum-iridium 90:10	Same as K170141
Stimulator Body Material	Polyurethane 2363-55D	Same as K170141
Cable Features	Multi-lumen Tube	Same as K170141
Stimulator Length	45 centimeters	Same as K170141
Diameter	1.35 millimeters	Same as K170141
Electrode Array Length	24.0 millimeters 52.0 millimeters	Same as K170141
No. of Electrodes	4 or 8	Same as K170141
Electrode Length	3.0 millimeters	Same as K170141
Electrode Spacing	4.0 millimeters	Same as K170141
Electrode Surface Area	12.72 mm^2	Same as K170141
Method of Introduction	Percutaneous and Anchor Incision	Same as K170141
Tissue Contact	Yes	Same as K170141
Sterilization	Ethylene Oxide (EO)	Same as K170141
Labeling	Labeled as Sterile, Single Use, Prescription Device	Same as K170141
Package	Backer card and two sterile pouches	Same as K170141
Pulse Frequency	5 to 1500 Hertz	Same as K170141
Pulse Width	50 to 500 microseconds	Same as K170141
Current/Voltage Regulated	Current	Same as K170141
Output Voltage (300 Ω)	0 to 4.1 V	Same as K170141
Output Voltage (500 Ω)	0 to 6.4 V	Same as K170141
Output Voltage (800 Ω)	0 to 7.5 V	Same as K170141
Output Current (300 Ω)	0 to 13.5 mA	Same as K170141
Output Current (500 Ω)	0 to 12.8 mA	Same as K170141
Output Current (800 Ω)	0 to 9.4 mA	Same as K170141
Waveform	Charge Balanced (delayed) Biphasic asymmetrical	Same as K170141
Polarity	Programmable (Anode, Cathode, or Off)	Same as K170141
Pulse Shape	Decaying Exponential	Same as K170141
Avg. Current Density (300 Ω)	105.0 mA/cm^2	Same as K170141
Avg. Current Density (500 Ω)	95.1 mA/cm^2	Same as K170141
Avg. Current Density (800 Ω)	69.0 mA/cm^2	Same as K170141
Max. Phase Charge* (300 Ω)	6.8 µC/pulse	Same as K170141
Max. Phase Charge* (500 Ω)	6.4 µC/pulse	Same as K170141

Comparator	Stimwave Freedom SCS System (Predicate – K170141)	Stimwave Freedom SCS System (Subject device)
Max. Phase Charge* (800 Ω)	4.7 µC/pulse	Same as K170141
Max. Charge Density* (300 Ω)	53.1 µC/cm^2	Same as K170141
Max. Charge Density* (500 Ω)	50.3 µC/cm^2	Same as K170141
Max. Charge Density* (800 Ω)	36.9 µC/cm^2	Same as K170141
Max. Current Density* (300 Ω)	106.1 mA/cm^2	Same as K170141
Max. Current Density* (500 Ω)	100.6 mA/cm^2	Same as K170141
Max. Current Density* (800 Ω)	73.9 mA/cm^2	Same as K170141
Net Charge	0 µC	Same as K170141
Avg. Phase Power (300 Ω)	0.053 W/phase	Same as K170141
Avg. Phase Power (500 Ω)	0.073 W/phase	Same as K170141
Avg. Phase Power (800 Ω)	0.062 W/phase	Same as K170141
Avg. Phase Power Density (300 Ω)	0.42 W/cm^2/phase	Same as K170141
Avg. Phase Power Density (500 Ω)	0.58 W/cm^2/phase	Same as K170141
Avg. Phase Power Density (800 Ω)	0.48 W/cm^2/phase	Same as K170141
Pulse Delivery Mode	Continuous	Same as K170141
ON/OFF Times	No Cycling	Same as K170141
Current Path Options	Bipolar	Same as K170141
Power Delivery	Embedded receiver and coupled receiver in lumen of Stimulator	Same as K170141
Transmit Frequency	915 MHz	Same as K170141
Material	Platinum-iridium 90:10, Polyurethane 2363-55D	Same as K170141
Sterile	Yes - ethylene oxide	Same as K170141
Contract Sterilizer	Steris Isomedix Services	Same as K170141
Single-Use	Yes	Same as K170141
Shelf Life	2 year	Same as K170141
Complies with ISO 10993-1	Yes	Same as K170141
Safety Testing Passed	Yes	Same as K170141
MR Conditional	Yes	Yes
Accessories	Receiver/RF Stylet, Stylet(s), Guide-wire, Needle, Suture Sleeve Cap	RF Stylet, Stylet(s), Guidewire, Needle
Single Pack Accessories	No	Sterile: RF Stylet, Needle(s), Guidewires, Introducer Non-Sterile: SeaSilk Antenna(s), Antenna Assembly
Charger	USB Charger	Same as K170141
Wearable Antenna Assembly	Aluminum transmitter & separate, connected Antenna	Same as K170141
Software Level of Concern	Moderate	Same as K170141
iPad Application	WaveCrest™	Same as K170141
Patient Programmer Application	No	WaveCrest Mobile
Kits	Receiver Kit, Spare Lead Kit, Trial Lead Kit, Sterile Revision Kit, WAA Kit, Charger Kit	Same as K170141, but includes Single Pack Accessories

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

8. Biocompatibility Data

Materials of this submission are identical to K170141. The materials of the Freedom-8A/4A Stimulator in direct contact with tissue remain unchanged from the Freedom SCS System (K170141) and thus, the biocompatibility tests conducted on representative subassemblies of the Freedom SCS System (Freedom-4, K141399) directly apply to the

Freedom SCS System (K170141, and this submission). 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 following modifications to the Freedom SCS System of K170141 were made in support of this submission:

A. Stimulator/Lead:
    i. The ASIC component of the Freedom-8A/4A devices has been upgraded to a new design, but there are no changes to system performance or specification.
B. Software/Firmware:
    i. Release of version 2.4 of the WaveCrest programming application;
    ii. Addition of patient programmer, wcMobile, for basic program selections;
    iii. New WAA Firmware version for enabling ASIC upgrade communication.
C. WAA Accessories:
    i. Addition of various Antenna options (style and length) for patient usability.
D. Kitted Components:
    i. Addition of single pack accessories for use by clinicians (sterile) and patients (non-sterile) as needed;
    ii. Removal of the Suture Sleeve Cap from Receiver and Spare Lead Kits in favor of the SandShark Injectable Anchor (SIA) System (K172644).

E. Sterilization:
    i. Increased sterilization capacity from 2 cases to one-half pallet.
F. Manufacturing:
    i. WAA manufacturing at Stimwave Technologies Inc.;
    ii. Contract manufacturing and packaging for Freedom-8A/4A Stimulators at Oscor, Inc.

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 this submission is leveraged from K170141, and is directly applicable for demonstration of device safety and efficacy as the packaging and the Freedom-8A/4A Stimulator remains unchanged by electrical component upgrades. The testing for the Freedom-8A/4A Stimulator with the upgraded ASIC demonstrates no change to device performance and specification, and thus, demonstrates continued safety and efficacy compared to the predicate. The Receiver/RF Stylet is a passive component that does not impact the outcome of the leveraged tests for safety and effectiveness. The Receiver/RF Stylet testing presented for this submission is leveraged from K170141, and is directly applicable for demonstration of device safety and efficacy as Receiver/RF Stylet remains the same.

For 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 testing for the Freedom-8A/4A Stimulator with the upgraded ASIC demonstrates no change to device performance and specification, and thus, demonstrates continued safety and efficacy compared to the predicate. The Receiver/RF Stylet testing presented for this submission is leveraged from K170141, and is directly applicable for demonstration of device safety and efficacy as Receiver/RF Stylet remains the same.

Following the thermal shock testing, the 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 complies with the thermal shock design requirements and the applicable standard. This testing presented for this submission is leveraged from K170141, and is directly applicable for demonstration of device safety and efficacy as the Freedom-8A/4A Stimulator remains unchanged by electrical component upgrades. The testing for the Freedom-8A/4A Stimulator with the upgraded ASIC demonstrates no change to device performance and specification, and thus, demonstrates continued safety and efficacy

compared to the predicate. 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 complies with the leakage design requirements and the applicable standard. This testing presented for this submission is leveraged from K170141, and is directly applicable for demonstration of device safety and efficacy as the Freedom-8A/4A Stimulator remains unchanged by electrical component upgrades. The testing for the Freedom-8A/4A Stimulator with the upgraded ASIC demonstrates no change to device performance and specification, and thus, demonstrates continued safety and efficacy compared to the predicate. The Receiver/RF Stylet is a passive component that does not impact the outcome of the leveraged tests for safety and effectiveness. The Receiver/RF Stylet testing presented for this submission is leveraged from K170141, and is directly applicable for demonstration of device safety and efficacy as Receiver/RF Stylet remains the same.

For 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 this submission is leveraged from K170141, and is directly applicable for demonstration of device safety and efficacy as the Freedom-8A/4A Stimulator remains unchanged by electrical component upgrades. The testing for the Freedom-8A/4A Stimulator with the upgraded ASIC demonstrates no change to device performance and specification, and thus, demonstrates continued safety and efficacy compared to the predicate. The Receiver/RF Stylet testing presented for this submission is leveraged from K170141, and is directly applicable for demonstration of device safety and efficacy as Receiver/RF Stylet remains the same.

For mechanical testing, the 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 complies with all stimulator mechanical design requirements. This testing presented for this submission is leveraged from K170141, and is directly applicable for demonstration of device safety and efficacy as the Freedom-8A/4A Stimulator remains unchanged by electrical component upgrades. The testing for the Freedom-8A/4A Stimulator with the upgraded ASIC demonstrates no change to device performance and specification, and thus, demonstrates continued safety and efficacy compared to the predicate. The Receiver/RF Stylet is a passive component that does not impact the outcome of the leveraged tests for safety and effectiveness. The Receiver/RF Stylet testing presented for this submission is leveraged from K170141, and is directly applicable for demonstration of device safety and efficacy as Receiver/RF

Stylet remains the same.

For magnetic resonance imaging (MRI) radio frequency (RF) induced heating as related to specific absorbance rate (SAR), the Freedom-8A Stimulator produced a maximum temperature increase lower than the allowable limit for the 1.5T and 3T MRI procedure and thus passed the 1.5T and 3T testing. The Freedom-8A Stimulator produced a maximum temperature increase lower than the allowable limit for the 1.5T and 3T MRI procedure and thus passed both. The Stimulator testing presented for this submission is leveraged from K170141, and is directly applicable for demonstration of device safety and efficacy as the Freedom-8A/4A Stimulator remains unchanged by electrical component upgrades. The testing for the Freedom-8A/4A Stimulator with the upgraded ASIC demonstrates no change to device performance and specification, and thus, demonstrates continued safety and efficacy compared to the predicate.

ASTM F2182-11a – In accordance with F2182-11a – American Society for Testing and Materials (ASTM) International Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging, the Freedom-8A/4A Stimulator showed that its presence would not cause injury to the patient with the implant during an MRI procedure. The Freedom-8A Stimulator is a passive implant that is not powered while the external unit is not transmitting to it. The Stimulator testing presented for this submission is leveraged from K170141, and is directly applicable for demonstration of device safety and efficacy as the Freedom-8A/4A Stimulator remains unchanged by electrical component upgrades. The testing for the Freedom-8A/4A Stimulator with the upgraded ASIC demonstrates no change to device performance and specification, and thus, demonstrates continued safety and efficacy compared to the predicate.

ASTM F2119-07 – In accordance with F2119-07 – American Society for Testing and Materials (ASTM) International Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants, the Freedom-8A Stimulator showed that it does not produce image artifacts in 1.5T or 3T MRI procedures. The Stimulator testing presented for this submission is leveraged from K170141, and is directly applicable for demonstration of device safety and efficacy as the Freedom-8A/4A Stimulator remains unchanged by electrical component upgrades. The testing for the Freedom-8A/4A Stimulator with the upgraded ASIC demonstrates no change to device performance and specification, and thus, demonstrates continued safety and efficacy compared to the predicate.

ASTM F2052-06 – In accordance with F2052-06 – The American Society for Testing and Materials (ASTM) International Designation Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment, the Freedom-8A Stimulator showed that it does not harm the patient due to its displacement by forces induced by 1.5T or 3T MRI exposure. The Freedom-8A Stimulator passes the ASTM acceptance criteria for deflection angle in a 1.5T and 3T MRI system. The Freedom-8A Stimulator will not present an additional risk or hazard to a patient when used in their tested MR environment. The Stimulator testing

presented for this submission is leveraged from K170141, and is directly applicable for demonstration of device safety and efficacy as the Freedom-8A/4A Stimulator remains unchanged by electrical component upgrades. The testing for the Freedom-8A/4A Stimulator with the upgraded ASIC demonstrates no change to device performance and specification, and thus, demonstrates continued safety and efficacy compared to the predicate.

ASTM F2213-06 – In accordance with F2213-06 – American Society for Testing and Materials (ASTM) International Standard Test Method for Measurement of Magnetically Induced Torque on Passive Implants in the Magnetic Resonance Environment, the Freedom-8A/4A Stimulator must show that it does not harm the patient due to its torque by forces induced by MRI exposure. The Freedom-8A Stimulator will not present an additional risk or hazard to a patient in the 1.5T MRI or 3T environments or less with regard to torque.

The stimulation waveforms following post-exposure showed no component damage had occurred after MR exposure. During testing, no component damage was observed in any waveform. Based on these test results, the Freedom-8A Stimulator will be fully functional following standard 1.5T or 3T MR procedures and its performance or functionality is not affected by such exposures.

The Stimulator testing presented for this submission is leveraged from K170141, and is directly applicable for demonstration of device safety and efficacy as the Freedom-8A/4A Stimulator remains unchanged by electrical component upgrades. The testing for the Freedom-8A/4A Stimulator with the upgraded ASIC demonstrates no change to device performance and specification, and thus, demonstrates continued safety and efficacy compared to the predicate.

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. This testing presented for this submission is leveraged from K170141 and is directly applicable for demonstration of device safety and efficacy as the WAA remains the same. Performance testing for the additional Tx Antennas included in this submission demonstrates no change to device performance and specification, and thus, demonstrates continued safety and efficacy compared to the predicate.

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. This testing presented for this submission is leveraged from K170141 and is directly applicable for demonstration of device safety and efficacy as the WAA remains the same. Performance testing for the additional Tx Antennas included in this submission demonstrates no change to device performance and specification, and thus, demonstrates continued safety and efficacy compared to the predicate.

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. This testing presented for this submission is leveraged from K170141 and is directly applicable for demonstration of device safety and efficacy as the WAA remains the same. Performance testing for the additional Tx Antennas included in this submission demonstrates no change to device performance and specification, and thus, demonstrates continued safety and efficacy compared to the predicate.

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 device (K170141), and the Freedom SCS System (this submission), 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 device 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 device, and materials for the implanted stimulator are the same as the legally marketed predicate device.

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 device.