ADVANCED BIONICS

August 19, 2004

Federal Communications Commission
445 12th Street, SW
Washington, DC 20554

RE: PRECISION™ Spinal Cord Stimulation System
Request for Authorization - Remote Control

To Whom It May Concern:

Advanced Bionics is requesting a grant of equipment authorization for a Remote Control, model number SC-5210, a component of the PRECISION™ Spinal Cord Stimulation (SCS) System. The PRECISION SCS System is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain, and works by using electrical stimulation of a nerve to generate paresthesia.

The PRECISION SCS system is divided into the Implantable Pulse Generator (IPG), External Trial Stimulator (ETS), Clinician Programmer, Remote Control (RC), and Charger. The IPG is a small, implanted device that generates an electrical impulse that is delivered to a nerve by implanted leads. The ETS has the same functionality as the IPG, but is an external device used during an assessment period during which the doctor determines the suitability of spinal cord stimulation for treating a particular patient. The Clinician Programmer is a commercially available laptop with proprietary software used to program the IPG and record relevant data. The Remote Control is a handheld device used to adjust the stimulation parameters of the IPG or ETS via a telemetry link over a distance of approximately 3 feet.

The IPG, ETS, and Remote Control were authorized previously. In order to improve manufacturability, modifications have been made to these components that require new authorizations under 47 CFR 2.932(a). No changes are being made to the Charger, currently authorized under FCC Identifier Q4DSC-5300.

Changes to IPG and ETS:
The telemetry and microcontroller circuits used in the IPG (submitted separately as FCC ID Q4D-PSC1110W) and ETS (submitted separately as FCC ID Q4D- PSC5110W) have been modified. A custom ASIC was replaced by an off-the-shelf microcontroller, and corresponding interface changes were made to the digital and analog IC, which resulted in reduced power consumption. The telemetry circuit was simplified. The ceramic

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substrate was replaced with a printed circuit board. Refinements were made in the battery charging circuitry for greater power efficiency, and additional feedback to the microprocessor was added to more finely control the end of charging. No changes were made to the stimulation output section of the IPG electronics.

Remote Control Changes

The electronics in the Remote Control were updated in order to support the telemetry protocol of the IPG. To reduce costs, the housing and electronics/firmware were changed to utilize components currently used in another product line.

Please note that some of the documentation included may reflect earlier names considered for this product, including the SCS2, SCS-II, and similar variants.

Sincerely,

Kaoru Lee Adair, Vice President
Regulatory Affairs and Clinical Research

Technical Information:

1. **Manufacturer name and address:**
   Advanced Bionics Corporation
   12740 San Fernando Road
   Sylmar, CA 91342

2. **FCC Identifier:** Q4D-PSC5210W

3. **FRN Number:** 0008832529

4. **Equipment Specifications:**

Frequency range in MHz	Rated RF power output in watts	Frequency tolerance %, Hz, ppm	Emission designator	Microprocessor model number
0.125	N/A	50 ppm	125KF1D	N/A

5. **A sample FCC ID label containing the FCC identifier and the following compliance statement: This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: 1. This device may not cause harmful interference, and, 2. This device must accept any interference received including interference that may cause undesired operation.**
Because of space constraints, the FCC ID number is on the label, and the rest of the compliance statement is found in the manuals. A draft version of the label is included as "SCS 2 RC label". The final version may be formatted differently, but no changes will be made to the content.

6. **A sketch or photo showing the location of the label on the EUT.**
The picture "SCS 2 RC Bottom View" shows the location of the label on the EUT.

7. **A copy of the User Manual.**
The content of the following manuals is included in PDF format. The cover artwork has not been finalized. Please note that all manuals and labels are draft copies. The final version may vary from what is shown.
MP9055182 Rev A Physician Implant Manual
MP9055183 Rev A Physician Lead Manual
MP9055184 Rev A Patient System Handbook
MP9055185 Rev A Patient Trial Handbook

8. **A full operating description of the EUT.**

The RC is a portable, hand-held unit used by the patient to change stimulation parameters. The patient can use the RC to turn stimulation on/off, change the area being stimulated, switch between different therapy programs, and increase/decrease stimulation amplitude, and other parameters as set by the physician.

Microprocessor

The microprocessor is the system controller. It runs off a 4 MHz crystal and contains an internal phase lock loop used to create a 16 MHz clock. The microprocessor core normally runs off the 4 MHz clock, but can be switched to run off the 16 MHz clock. The 16 MHz Phase Locked Loop (PLL) output is supplied to the direct digital frequency synthesizer. The microprocessor also uses a real time clock module which runs off a 32 kHz crystal.

Telemetry System

The telemetry system is a short range, magnetically coupled system. It is a 2 level Frequency Shift Keying (FSK) transceiver operating at 125 kHz. The data rate is 4115 bits per second and uses ± 4 kHz of deviation. The transmitted bandwidth is 12 kHz. This magnetically coupled system does not transmit RF power per se. The transmitter generates 100 mA of current in a parallel resonant circuit tuned to 125 kHz which generates a magnetic field strength of 98 μA/m at 3 meters. The device does not intentionally generate an E field. The receiver mixes the incoming 125 kHz signal with a 330 kHz local oscillator to create a 455 kHz IF frequency. Filtering and FM demodulation are done at 455 kHz.

Direct Digital Synthesizer

The local oscillator used by the telemetry system is the output from a Direct Digital Synthesizer (DDS). It runs off the 16 MHz clock created by the microprocessor's PLL and its output frequency is controlled by a 32 bit programming word. While transmitting, the DDS is programmed to output either 242 kHz or 258 kHz which is controlled by a frequency select control pin. The output is divided by 2 to give 121 kHz or 129 kHz. The frequency select pin is driven by the data coming from the microprocessor's Universal Asynchronous Receiver/Transmitter (UART). While receiving, the DDS is programmed for 660 kHz which is divided by 2 to give the 330 kHz used by the mixer. Frequency stability for the system is determined by the 4 MHz crystal and is ±50 PPM.

Antenna

Since far field signals are not intentionally generated, the "antenna" is a magnetic pick-up coil, not an antenna in the traditional sense. It is a 42 turn air wound coil, rectangular in shape, approximately 4.5 cm x 8.6 cm in size. The coil is parallel tuned to resonate at 125 kHz.

Power Supply Module

The Remote Control runs off 3 AAA batteries. All of the circuitry runs off a regulated 3.3 Volts, except for the IRDA module and the transmitter amplifier which are supplied directly from the battery.

IRDA Module

The main communication link to Clinicians Programmer and test systems.

Display Module

Custom made dot matrix graphics LCD.

Key Pad

A push button, membrane switch for commands and menu selections

9. A block diagram showing the frequency of all oscillators in the device. The signal path and frequency shall be indicated at each block. The tuning range(s) and intermediate frequency(ies) shall be indicated at each block.
A block diagram of the Remote Control is included as "SCSII RC Block Diagram.doc".

10. Photographs
The following JPEG files are included:

SCS 2 RC Bottom View
SCS 2 RC Digital Board Bottom View
SCS 2 RC PCB Digital Board Top View
SCS 2 RC RF Board Bottom View
SCS 2 RC RF Board Top View
SCS 2 RC Top View

11. Schematic diagram and a description of all circuitry and devices.
The following documents are included in PDF format:

9015282, Schematic Digital Remote Control
9015283, Schematic Diagram Telemetry Card