ADVANCED BIONICS

August 19, 2004

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

RE: PRECISION™ Spinal Cord Stimulation System
Request for Authorization – Implantable Pulse Generator

To Whom It May Concern:

Advanced Bionics is requesting a grant of equipment authorization for a IPG, model number SC-1110, 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 IPG 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 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, iwhich resulted in reduced power consumption. The telemetry circuit was simplified. The ceramic substrate was replaced with a printed circuit board.

12740 San Fernando Road, Sylmar, CA 91342
(V) 800.678.2575 • (F) 661.362.1500 • (TTY) 800.678.3575 • AdvancedBionics.com

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 (submitted separately as FCC ID Q4D-PSC5210W) 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 reflectsearlier 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-PSC1110W

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 IPG 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.
Because the device is intended as a long-term medical implant, the FCC ID label is not located on the device. Instead, the FCC ID is located on the sterile packaging label, and the complete statement is found in the accompanying manuals..

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 IPG is a fully-implantable medical device that generates an electrical pulse that is delivered to a nerve via an implanted electrode. The Remote Control is used to adjust the stimulation parameters in the IPG via a telemetry signal.

Microprocessor Module

The microprocessor is the system controller. It sets the Digital IC parameters which in turn controls the Analog IC which generates the stimulation pulses applied to the patient. The microprocessor normally runs off the 1 MHz clock supplied by the Digital IC, but uses the 4 MHz clock while performing telemetry functions. Since this device is implanted in the patient, it has no user interface such as a key pad. Control of the device is achieved through the telemetry system.

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 25 mA of current in a series resonant circuit tuned to 125 kHz which generates a magnetic field strength of 3.5 μA/m at 3 meters. The device does not intentionally generate an E field. There is no local oscillator in this system. The microprocessor's timer circuit divides down the 4 MHz clock to generate the 121 kHz and 129 kHz signal used to transmit data. The receiver amplifies the incoming signal to logic levels which is sampled by the microprocessors Universal Asynchronous Receiver/Transmitter (UART). FM demodulation is done by software.

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 300 turn ferrite wound coil, cylindrical in shape, approximately 0.7 cm long and 0.5 cm in diameter. The coil is series tuned to resonate at 125 kHz.

Analog IC

The integrated circuit provides power regulation, stimulus output, impedance measurement and monitoring.

Digital IC

The sequencer interface between the Analog IC and the microprocessor. Controls and changes stimulus levels and sequences when prompted by the processor.

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 IPG is included as "SCSII IPG Block Diagram.doc".

10. Photographs

The following JPEG files are included:

SCS 2 IPG Bottom View
SCS 2 IPG PCB Bottom View
SCS 2 IPG PCB Top View
SCS 2 IPG Top View

11. Schematic diagram and a description of all circuitry and devices.

The following document is included in PDF format:

9015264, Schematic Diagram, SCS2 IPG