



May 25, 2012

Federal Communications Commission
Authorization and Evaluation Division
7435 Oakland Mills Road
Columbia, Maryland 21046

Neuromodulation

25155 Rye Canyon Loop
Valencia, CA 91355

661.949.4000 Tel
661.949.4843 Fax

www.bostonscientific.com

RE: Precision Spectra Spinal Cord Stimulator System
Request for Authorization – Implantable Pulse Generator (IPG),
FCC ID: Q4D-SC1132

To Whom It May Concern:

Boston Scientific Neuromodulation Corporation is requesting a grant of equipment authorization (original certification, FCC Rule 15C) for an IPG, model number SC-1132, a component of the Precision Spectra Spinal Cord Stimulator (SCS) System. The Precision Spectra 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.

The Precision Spectra SCS System is divided into the Implantable Pulse Generator (IPG), External Trial Stimulator (ETS), Clinician Programmer, Remote Control (RC), the Programming Wand and the Charger. The IPG is an implanted device that generates an electrical impulse that is delivered to the nerve by implanted leads. The ETS has the same functionality as the IPG, but is an external device used during an assessment period in which the physician 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/ETS and record relevant data. The Programming Wand is used to provide a data link between the Clinician Programmer and the ETS/IPG. The telemetry range between the Wand and ETS/IPG is 18 inches. The RC is a handheld device used to adjust the stimulation parameters of the IPG or ETS via a telemetry link over a distance of approximately 36 inches.

Sincerely,

Kaoru Lee Adair

Vice President, Clinical and Regulatory Affairs