Boston Scientific

Neuromodulation

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April 2, 2020

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

RE: Request for Authorization – Implantable Pulse Generator (IPG),
FCC ID: Q4D-SC1232

To Whom It May Concern:

Boston Scientific Neuromodulation Corporation is requesting a grant of equipment authorization (original certification, FCC Rule 15.247) for IPG model numbers SC-1232, SC-1216, DB-1232 and DB-1216 which are components of Boston Scientific Spinal Cord Stimulator (SCS) and Deep Brain Stimulation (DBS) Systems. All the listed IPG models have the same Bluetooth Low Energy (BLE) design which includes same antenna, same device PCBA, and same BLE firmware. The only difference in hardware is the epoxy header where different numbers of electrode contact ports are embedded. All IPGs have the same base firmware except for configuration properties programmed in the stimulators during manufacturing depending on the therapeutic needs for SCS vs DBS and the stimulator specific features like number of contacts supported. These differences in firmware properties do not impact telemetry performance. The firmware supporting BLE functionality is the same.

The SCS and DBS Systems include the Implantable Pulse Generator (IPG). External Trial Stimulator (ETS), Clinician Programmer and Remote Control (RC) all of which use Bluetooth Low Energy (BLE) for communication. 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 SCS or DBS 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 RC is a handheld device used to adjust the stimulation parameters of the IPG or ETS via a telemetry link.

Sincerely,

Kaoru Lee Adair
Vice President, Clinical and Regulatory Affairs