



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 – External Trial Stimulator (ETS),
FCC ID: Q4D-SC5170

To Whom It May Concern:

Boston Scientific Neuromodulation Corporation is requesting a grant of equipment authorization (original certification, FCC Rule 15.247) for ETS model numbers SC-5170 and DB-5170 which are components of Boston Scientific Spinal Cord Stimulator (SCS) and Deep Brain Stimulation (DBS) Systems. Models SC-5170 and DB-5170 have identical hardware and the same base firmware. The only difference is the firmware that addresses different therapeutic needs for SCS and DBS applications. The communication related modules are 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