Form 442 Question 7: Experimentation Description

Axonics Sacral Neuromodulation (SNM) System

Axonics Modulation Technologies, Inc. (Axonics) seeks this experimental license to conduct experimental operations and testing in connection with clinical trials of its Sacral Neuromodulation (SNM) System (Device). The system will operate in conformance with Part 95I, Part 2, Part 15, and Part 18 of the Commission's rules. The expected duration of the trials is thirty-six (36) months and will involve between 99 and 120 patients. The Device is designed for treating patients suffering from symptoms of Over Active Bladder (OAB), including urinary urgency incontinence and significant symptoms of urgency-frequency in patients who have failed or could not tolerate more conservative treatments.

The Device is comprised of the following components which will be in operation at every clinical test site: (1) Neurostimulator for implant (IPG) or external (EPG) use; (2) Patient Remote Control (PR); (3) Charging Device (CD); and (4) Clinician Programmer (CP). The IPG, PR, CD and CP have been tested for Part 95I compliance (MedRadio) and the CD has also been tested for Part 18 compliance (ISM) in the 125 kHz band; all of these components have been shown to meet the applicable FCC emissions limits. The EPG has been developed but has not yet been formally tested for Part 95I compliance; however, the EPG uses the same RF circuitry as the IPG and will perform the same functionality. The PR, CD, and CP devices use the Listen-Before-Talk (LBT) technique to communicate with the IPG/EPG and therefore comply with the frequency monitoring requirement for the MedRadio band. No other frequencies are used by any of these devices for any telecommunication functions.

The IPG (Neurostimulator) is a rechargeable implanted device that provides electrical pulses to stimulate the S3 sacral nerve. It is used in conjunction with a tined lead which is a stimulation cable with four (4) electrode contacts to provide stimulation. The IPG is implanted in the upper buttocks area and has less than 1.0 mW (EIRP) output power.

The PR (Patient Remote) is a battery-operated hand held device that uses radiofrequency (RF) signals to communicate with the neurostimulator. The PR allows the patient to adjust IPG stimulation levels, check the status of the IPG battery charge level, observe the IPG stimulation level, and to turn the IPG stimulation on or off. The PR is used within 20 cm of the head or torso and has less than 22.0 mW (EIRP) output power.

The CD (Charging Device) is a portable, body worn device powered by a rechargeable battery. The CD is used for transcutaneous charging of the neurostimulator through RF induction, and can either be adhered to the patient's skin (in the lower back area) or it can be held in place using a belt. The CD uses 125 kHz for non-communications and inductive charging only. The CD is used within 20 cm of the head or torso and has less than 22.0 mW (EIRP) output power, from communication antenna, while inductive charging has less than 4 W output power.

The CP (Clinician Programmer) is a handheld device used by a clinician to wirelessly program the neurostimulator. The CP also has the capability to record stimulation-induced

electromyograms (EMGs) to facilitate lead placement and programming. The CP is used within 20 cm of the head or torso and less than 22.0 mW (EIRP) output power.

The EPG (Neurostimulator) is a battery operated, body worn device (temporary use device, used for less than 30 days) that generates stimulation pulses which are transferred to the region of therapy by a PNE Lead via a Basic Trial Cable or by a Quadripolar tined lead via a Percutaneous Extension cable. The EPG is expected to have the same functionality as the IPG.

Experimental activities will be of limited duration on selected days during which the trials will be conducted (i.e. once a day for less than 30 seconds (IPG, EPG, and PR), every two weeks for 30 minutes (CD), once at surgical procedure for 30 minutes (CP)) at selected locations in the United States. All the components will be in operation at every site. When the Device is not in use, the device will be turned off.

To the extent that a waiver of one or more Commission rules is needed to market and operate the Device beyond the permitted uses under the experimental license requested pursuant to this application, Axonics will seek such a waiver.