Axonics Sacral Neuromodulation (SNM) System
Summary of Modifications

Axonics Modulation Technologies, Inc. (Axonics) submits this experimental license modification to update the equipment information associated with the license for Experimental Radio Station Authority with call sign WI2XYC.

Axonics has developed an updated model of its PR (Patient Remote) device, model number 2301, that allows communication with the neurostimulators, IPG (Implantable Pulse Generator) and EPG (External Pulse Generator), on both core band (402 MHz – 405 MHz) and wing bands (401-402 MHz and 405-406 MHz), respectively, and seeks to add the updated device to the list of transmitting equipment part of the experimental license. The PR (2301) has been "confidence" tested for Part 95I compliance (MedRadio) and shown to meet the applicable FCC emissions limits. The PR (2301) is a battery-operated hand held device that uses radiofrequency (RF) signals to communicate with the IPG (402 MHz – 405 MHz) and EPG (401-402 MHz and 405-406 MHz). The PR (2301) allows the patient to adjust IPG or EPG stimulation levels, check the status of the battery level, observe the IPG/EPG stimulation level, and to turn the IPG/EPG stimulation on or off. The PR (2301) is used within 20 cm of the head or torso and has less than 22.0 mW (EIRP) output power. The PR model number 1301 only used the 402-405 MHz spectrum to communicate with neurostimulator.

The EPG (External Pulse Generator), model number 1601, is being modified to add the MedRadio wing bands (401-402 MHz and 405-406 MHz) to its operation. The EPG has now also been "confidence" tested for Part 95I compliance (MedRadio) and shown to meet the applicable FCC emissions limits. The EPG 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.

For all of the transmitting equipment being updated and listed in the experimental license, Axonics seeks to modify the number of units, to accommodate more patients in the clinical trials of the Sacral Neuromodulation (SNM) System. The initial number of clinical trial patients was 120 and now the number of patients is 175.