



Abbott Laboratories

Neuromodulation

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Element Materials Technology  
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#400  
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FCC ID: PX2-GMCHG1

To whom it may concern,

We, Abbott Laboratories (Neuromodulation Division 6901 Preston Road, Plano, TX 75024), are submitting an equipment authorization for an Original certification for the following model which is part of a neurostimulation therapy system. Details of the model name variations, system compatibility and system functionality can be found within the operational description and mandardual (IFU). This system has been approved by the FDA under P010032 S186 and the implantable portion of the system, which is a spinal cord stimulation device that is the world's smallest implantable, rechargeable spinal cord stimulator currently available for the treatment of chronic pain, has been approved under FCC ID PX2-GMIPG1

Charger Model 16000

Rule part 15.247 is applicable since it uses Bluetooth Low Energy technology as described in KDB 558074 Section 8. The product operates at 0dBm or less when factoring in low duty cycle operation. The Charger is an external device that operates near the torso by recharging an implanted IPG.

Rule part 18 is applicable to the charger as well since it produces wireless power energy in the range of 266 kHz-320kHz and follows the characteristics of KDB 680106 Section 5. Power levels are 1.3 Watts or less.

Manasi Khare

Director, Regulatory Affairs