

Medtronic

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Federal Communications Commission
Authorization and Evaluation Division
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To whom it may concern.

Reference: Application for FCC Grant LF5BLEIMPLANT2, Medtronic Implantable Cardiac Resynchronization Therapy Pacemaker models:

- Percepta CRT-P MRI SureScan
- Serena CRT-P MRI SureScan
- Solara CRT-P MRI SureScan
- Percepta Quad CRT-P MRI SureScan
- Serena Quad CRT-P MRI SureScan
- Solara Quad CRT-P MRI SureScan

I, the undersigned, as the authorized signatory for the Medtronic, Inc. hereby apply to seek original grant for Medtronic IPGs Percepta Quad CRT-P MRI SureScan, Percepta CRT-P MRI SureScan, Serena Quad CRT-P MRI SureScan, Serena CRT-P MRI SureScan, Solara Quad CRT-P MRI SureScan and Solara CRT-P MRI SureScan.

The Medtronic Percepta, Serena, Solara CRT-P models are dual chamber implantable pulse generators, which are multi-programmable cardiac devices that monitor and regulate the patient's heart rate by providing single or dual chamber rate-responsive bradycardia pacing. The MRI SureScan feature permits a mode of operation that allows a patient with a SureScan system to be safely scanned by an MRI machine while the device continues to provide appropriate pacing. The users of this device include medical professionals (physicians, nurses, technicians, and their supporting staff) trained in surgery, cardiology, radiology, and magnetic resonance (MR) technology and able to implement the procedures documented in the instructions for use for these devices.

The Medtronic Percepta, Serena, Solara CRT-P models as referenced above, implement Bluetooth Low Energy Telemetry in order to communicate with external devices, including but not limited to patient or clinician monitors, or smart phones or tablets with a Medtronic app installed. In addition, these models also implement an intentional radiator at 175 kHz, which was verified under FCC 15.201(a). All emissions from the 175 kHz transmitter are at least 40 dB below the limits in §15.209. Authorization is sought under FCC rule part 15.247.

In case of any additional questions please feel free to contact me. Many thanks in advance.

Sincerely,

Rick Hursel

RF Regulatory Affairs Specialist
Cardiac Rhythm and Heart Failure

