

Medtronic

January 31, 2019

Federal Communications Commission
Authorization and Evaluation Division
7435 Oakland Mills Road
Columbia, Maryland 21046

Medtronic, Inc.

710 Medtronic Parkway
Minneapolis, MN-55432, USA

www.medtronic.com
Kim.brannen@medtronic.com
Tel: 763-526-3945

To whom it may concern.

Reference: Application for FCC Grant LF5MICSIMPLANT4, Medtronic Cardiac Defibrillator (ICD) model EV ICD

I, the undersigned, as the authorized signatory for Medtronic, Inc. hereby apply to seek original grant for Medtronic ICD model EV ICD.

The Medtronic EV ICD device is an extravascular implantable cardioverter defibrillator that provides fast ventricular tachyarrhythmia/fibrillation detection and defibrillation therapy. The device is built off the Evera MRI platform, with a device volume consistent with transvenous ICDs. The EV ICD device will have a DF4 connector and will support both 1.5T and 3T Conditional MRI.

The EV ICD device will be programmable and will have the capability of transmitting via telemetry the programmed values, measured and collected data, event markers, and real-time waveforms. The EV ICD system will utilize a commercially available Medtronic programmer for both the implant and in-office follow-up. The device automatically detects and records the occurrence of atrial fibrillation (AF) for diagnostic purposes. The devices also provide diagnostic and monitoring information that assists with system evaluation and patient care.

The Medtronic EV ICD model as referenced above will include a two-way longer-range UHF (MICS Band) telemetry system which is used to communicate with ancillary equipment. 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 95I.

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

Sincerely,



Kim Brannen

Regulatory Affairs Specialist
Cardiac Rhythm and Heart Failure

