

23 April, 2019

Federal Communications Commission
Office of Engineering and Technology
7435 Oakland Mills Road
Columbia, Maryland 21046

Dear Sir or Madam:

We, Cardiac Pacemakers, Inc. (a wholly owned subsidiary of Boston Scientific Corporation), located at 4100 Hamline Avenue North, Arden Hills, MN 55112-5798, are submitting this application for Class II Permissive Change, concerning the 402 – 405 MHz radio function incorporated in the following ACCOLADE™/ PROPONENT™/ ESSENTIO™/ VISIONIST™/ VALITUDE™ Implantable Pacemakers and Cardiac Resynchronization Therapy Pacemakers (CRT-P) models, currently authorized under FCC ID: ESCCRMU22814.

ACCOLADE™ : L300, L301, L321, L310, L311, L331
PROponent™ : L200, L201, L221, L210, L211, L231
ESSENTIO™ : L100, L101, L121, L110, L111, L131
VISIONIST™ : U225, U226, U228
VALITUDE™ : U125, U128

This request is for Class II Permissive Change under FCC ID: ESCCRMU22814.

Modifications to the originally certificated equipment evidenced in documentation reported to the Commission are fully described in the accompanying updated exhibits. This Class II Permissive Change request is the result of hardware changes to the incorporated 402 – 405 MHz transmitter radio module, which include changes to the SAW filter and crystal. The RF design retains the identical transceiver described in the Operational Description on file under the existing authorization. The accompanying test report (BSTN0835) demonstrates conformance to CFR Title 47 Part 95 regulations, concerning the 402 – 405 MHz radio function. The report title specifies “Ingenio 2”, which is a term used for internal documentation purposes addressing all device families and models listed in this letter. The models referenced in the test Configurations are chosen to represent the performance of all models listed in this letter, which incorporate the identical 402 – 405 MHz telemetry radio design.

No changes have been made to the integrated low power inductively coupled telemetry coil, operating at 57 KHz. The inductive telemetry radio relies on inductive coupling and is subject to manufacturer verification under FCC 15.201(a). All emissions are at least 40 dB below the FCC 15.209 limits. All devices listed incorporate the identical 57 kHz inductive telemetry radio design.

Sincerely,



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