

To: Federal Communications Commission

Office of Engineering and Technology

7435 Oakland Mills Road Columbia, MD 21046

From: CVRx Inc

9201 West Broadway

Suite 650

Minneapolis MN 55445

Date: October 14, 2013

Subject: Application for certification of a Medical Implant Transceiver

FCC ID: SVHBAROSTIMIPG1

Dear Sir or Madam:

CVRx Inc., located at 9201 West Broadway Suite 650, Minneapolis, MN 55445 submits this application to operate an implantable medical device in the Medical Implant Communications Service (MICS), operating in the 402–405 MHz frequency band, under Part 95 of the FCC Rules and Regulations.

This original grant request is for device approval under FCCID: SVHBAROSTIMIPG1

The CVRx Neo Legacy Model 2100 implantable pulse generator (IPG), is an implantable medical device intended for the treatment of hypertension.

This device uses an integrated antenna, and contains an RF transceiver that transmits and receives in the MICS band. The radio equipment in the IPG communicates wirelessly between the IPG and the Model 9010 Programmer System. The submission of the application for the Model 9010 Programmer is pending the approval of the IPG submission.

The submitted technical reports for the IPG demonstrate compliance to the applicable technical requirements contained in CFR Title 47 Part 95 Subpart I, and Part 15.109.

This application also contains a section of the CVRx Neo Legacy System Reference Guide which captures the required labeling statements and the FCC ID number associated with the transmitter and the information required by Section 2.925 of the FCC Rules. The FCC ID number is also placed on the shipping container for the transmitter, instead of being placed



directly on the transmitter. Each IPG has a unique, permanently assigned RF identification number.

This application also contains a request for long term confidential treatment of portions of the submitted application material.

I further certify that no party (as defined in 1.2002 of CFR 47, 1995) to this application, including myself, is subject to denial of federal benefits, that includes FCC benefits, pursuant to Section 5301 of the Anti-Drug Abuse Act of 1988, 21 U.S.C.,853A.

Equipment: CVRx IPG Model 2100

FCC Grantee Code: SVH FCCID: SVHBAROSTIMIPG1

Further details and supporting documents are attached.

Should you have any questions regarding this letter, please feel free to contact me.

Sincerely,

Dated: October 14, 2013

Russell Anderson Technical Fellow CVRx, Inc.

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