DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 26, 2015

CVRx, Inc.
Dean Bruhn-Ding, RAC
Vice President of Regulatory Affairs & Quality Assurance
9201 West Broadway Avenue, Suite 650
Minneapolis, MN 55445

Re: Q150760
Barostim *neo* System
Received: May 27, 2015

Dear Mr. Bruhn-Ding:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received the above submission dated May 26, 2015, including your request for Expedited Access Pathway (EAP) designation. The Barostim neo system is indicated for subjects with heart failure, defined as New York Heart Association (NYHA) functional Class III and left ventricular ejection fraction (LVEF) ≤ 35%, despite being treated with the appropriate heart failure guideline directed therapy and excluding subjects eligible for or with a Cardiac Resynchronization Therapy (CRT) device(s). We are pleased to inform you that your device and future premarket submission meets the criteria and has been granted EAP designation and priority review processing. Please refer to the guidance entitled, "Expedited Access for Premarket Approval and *De Novo* Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions " available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM393978.pdf for additional information.

EAP designation can be granted for the following reasons:

- The device is intended to treat or diagnose a life-threatening or irreversibly debilitating disease or condition,

- The device meets at least one of the criteria for addressing an unmet need:
  - No approved alternative treatment or means of diagnosis exists,
  - The device represents a breakthrough technology that provides a clinically meaningful advantage over existing legally marketed technology,
  - The device offers significant, clinically meaningful advantages over existing legally marketed alternatives, or
  - The availability of the device is in the best interest of patients (e.g., addresses an unmet medical need), and

- A draft Data Development Plan has been provided.

EAP designation was granted because your device is intended to treat or diagnose a life-threatening or irreversibly debilitating disease or condition. In addition, your device has met at least one criterion for addressing an unmet need: no appropriate alternative; and the availability of the device is in the best interest of patients. You also provided a draft Data Development Plan.

Even though we have determined that your device does qualify for the EAP designation, we recommend you use the Pre-Submission review process, as described in the Pre-Submission guidance, to request feedback from FDA on your draft Data Development Plan.
This new submission should include two copies (one hardcopy and a valid ecopy), the FDA reference number for this Pre-Submission, and should be submitted to the following address:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

You are reminded that it is imperative that the information used to support a premarket submission meets the requirements of valid scientific evidence (21 CFR 860.7). You are further advised that the granting of EAP designation and priority review does not guarantee that the application will ultimately be approved. Note that CDRH will reassess your qualification for priority review status upon receipt of your marketing application.

If you have any questions, please Eric Richardson at 240-402-3758 or Eric.Richardson@fda.hhs.gov.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health