DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

SEP 28 2012

Mr. Alan F. Marcovecchio
Director, Regulatory Affairs, Quality Assurance and Reliability
Cameron Health, Inc.
906 Calle Amanecer, Suite 300
San Clemente, CA 92673

Re: P110042
Subcutaneous Implantable Defibrillator (S-ICD®) System
Filed: December 23, 2011 and January 25, 2012
Amended: March 9, May 7, 21 and 31 and June 4, 6 and 11, 2012
Procode: LWS, NVY

Dear Mr. Marcovecchio:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Subcutaneous Implantable Defibrillator (S-ICD®) System. This device is indicated to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device.

FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of

devices.

Expiration dating for this device has been established and approved at 13 months after the date of battery attach or 12 months after sterile tray seal whichever is sooner. For the Q-Trak® Electrode, expiration dating has been established at 2 years from the date of sterilization; for the Q-Guide™ Electrode Insertion Tool, expiration dating has been established at 690 days from the date of pouch seal; and for sterile accessory, Suture Sleeve, expiration dating has been established at 3 years from the date of sterilization.

Continued approval of this PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report" (please use this title even if the specified interval is more frequent than one year) and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

You have agreed to provide the following data as part of the annual report: The results of ongoing reliability testing on the lead, batteries, capacitors and device circuitry.

In addition, because your device is a pacemaker, implantable cardioverter-defibrillator (ICD), or system lead, FDA has determined that the following additional information is necessary to provide continued reasonable assurance of the safety and effectiveness of the device. In the Annual Report, provide the following information known by or reported to the applicant:

1. The number of pulse generators and leads domestically implanted and the number of reported explants and deaths.

2. A breakdown of the reported deaths into pulse generators/leads related and non-pulse generators/leads related.

3. A breakdown of the reported explants into the number reported that were:

    a. For pulse generators: at end of battery life, the number that had complications not resolvable by programming, and, as applicable, the numbers that experienced other safety and effectiveness complications as ascertained by the user, applicant, or otherwise, or

b. For leads: associated with mechanical failure, associated with clinical complications, and as applicable, the numbers that experienced other safety and effectiveness complications as ascertained by the user, applicant, or otherwise.

4. The number of pulse generators and leads returned to the applicant for cause from domestic sources, with a breakdown into:

   a. For pulse generators: the number currently in analysis, the number operating properly, and the number at normal battery depletion and failed (with the failure mechanisms described).

   b. For leads: the number currently in analysis, the number operating properly, the number failed (with failure mechanisms described); broken down into groupings for full leads and partial leads.

5. A cumulative survival table for the pulse generators and leads.

In addition to the Annual Report requirements, you must provide the following data in post-approval study reports (PAS). Two (2) copies, identified as "PMA Post-Approval Study Report" and bearing the applicable PMA reference number, should be submitted to the address below.

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

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA.

In addition to the conditions outlined above, you must conduct a post-approval study (PAS) as described below:

S-ICD Post-approval Registry: The study must be conducted as per protocol Version 3.0, dated June 21, 2012 which was submitted via email. This study will consist of the continued follow-up of patients who participated in the S-ICD® Clinical Investigation (IDE G090013) and prospective enrollment of patients newly implanted with the S-ICD® System and who may also be concurrently enrolled in the ACC NCDR® ICD Registry™. Approximately 1,616 patients from approximately 50 investigational centers (up to 150) in the US will be followed annually according to standard of care through 60 months post implant with at least 1,025 evaluable at 60 months.

The primary safety endpoint of the study is the Type I Complication Free Rate at 60 months, which will be compared to a performance criterion of 85%. The primary effectiveness endpoint is the Overall Shock Effectiveness in Converting Spontaneous Discrete Episodes of VT/VF through 60 months, which will be compared to a performance criterion of 94%.

The secondary safety endpoint of the study is the Electrode-Related Complication Free Rate at 60 months, which will be compared to a performance criterion of 92.5%. The secondary effectiveness endpoint is First Shock Effectiveness in Converting Induced (Acute) and Spontaneous Discrete Episodes of VT/VF through 60 months, which will be compared to a performance criterion of 84.0%.

Other procedure and system related adverse events will be collected and analyzed in the study:

- Freedom from complications requiring surgical revisions of the pulse generator or electrode, including pocket revisions, surgical repositioning or removal of the device in response to product performance issues (the 95.0% one-sided lower confidence interval should exceed 75.0%.)
- Individual rates of each clinical event category contributing to the primary safety endpoint will be examined including two-sided 95% exact confidence intervals
- All cause mortality
- Premature battery depletion and other device malfunctions
- Mechanical lead electrode failures
- Electrical performance data recorded by the device(e.g., electrode impedance status, total number of treated and untreated episodes since implant and since the last follow-up session, total number of shocks delivered since implant and since the last follow-up session, stored ECGs for all treated and untreated episodes, changes to programmed parameters)
- Explants and causes (e.g., infection, need for pacing therapy, inappropriate shocks)
- TV-ICD implantation following S-ICD explant
- Surgical revisions in response to suboptimal placement or system movement
- Chronic pain/discomfort requiring surgical intervention
- Implant test analysis (induced episode VT/VF conversion , VT/VF detection sensitivity and time to therapy)
- Removal of S-ICD system in response to implant testing
- Syncope associated with VT/VF episodes
- Spontaneous episodes of VT/VF
  - Incidence
  - Shock effectiveness (treated episodes only)
  - Time to therapy (treated episodes only)
- Inappropriate shock incidence
  - SVT with high ventricular rate
  - Discrimination errors for AF/SVT in the conditional shock zone
  - Oversensing

FDA would like to remind you that you are required to submit separate a PAS Progress Report every six months during the first two years and annually thereafter. The reports should clearly be identified as Post-Approval Study Report. Two copies, identified as "PMA Post-Approval Study Report" and bearing the applicable PMA reference number, should be submitted to the address below. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm

Before making any change affecting the safety or effectiveness of the device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm).

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading. CDRH will notify the public

of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. Final printed labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing. One of those three copies may be an electronic copy (eCopy), in an electronic format that FDA can process, review and archive (general information: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm; clinical and statistical data: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm136377.htm)

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

If you have any questions concerning this approval order, please contact Doris Terry at (301) 796-6365.

Sincerely yours,

Christy Foreman

Christy Foreman
Director
Office of Device Evaluation
Center for Devices and
Radiological Health