



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

DEC 23 2010

Mr. Jon Brumbaugh  
Vice President, Regulatory Affairs and Compliance  
Biotronik, Inc  
6024 Jean Road  
Lake Oswego, OR 97035

Re: P070008/S015  
Corox OTW-L BP Left Ventricular Lead  
Filed: March 9, 2010  
Amended: August 25, 2010 and December 14, 2010  
Procode: OJX

Dear Mr. Brumbaugh:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your premarket approval application (PMA) supplement, which requested approval for the Corox OTW-L BP model left ventricular lead which incorporates a different distal tip geometry compared to the market-approved Corox OTW BP leads. Based upon the information submitted, the PMA supplement is approved. You may begin commercial distribution of the device as modified by your PMA supplement in accordance with the conditions 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.

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.

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 leads domestically implanted and the number of reported explants and deaths.
2. A breakdown of the reported deaths into leads related and non-leads related.
3. A breakdown of the reported explants into the number reported that were:
  - a. For pacemakers and 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 leads returned to the applicant for cause from domestic sources, with a breakdown into:
  - a. For pacemakers and 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 leads.

You have also agreed to conduct the Post-approval study of BIOTRONIK's Corox BP LV pacing leads as used in conjunction with any BIOTRONIK CRT pulse generator CRT-P or CRT-D. This study is intended to be rolled into the requirements for the Corox OTW BP and Corox OTW-S BP LV pacing leads (P070008) approved on May 12, 2008. The existing study requirement for P070008 is a prospective study designed to characterize chronic lead performance following

device implant, as well as a robust process to retrospectively collect implant data for each study subject with a post-approval study patient follow-up duration of at least 5 years. The first primary endpoint will evaluate if the serious adverse event-free rate for the Corox BP LV leads at 5-years post-enrollment is greater than 92.5%. In addition to the chronic lead related 5-year complication-free rate, individual adverse events contributing to the endpoint will also be examined. The individual adverse event rates and 95% upper confidence bounds should be provided. Both endpoints should be evaluated separately for each Corox BP lead model. You have also agreed to increase the overall sample size to 2,500. This would allow for estimation of a 2-sided 95% upper confidence bound of no more than 1.0% for individual adverse event rates, assuming an expected rate of 0.4%, using the exact binomial method. In order to incorporate the Corox BP LV pacing leads into the existing post-approval study, you have agreed to amend the P070008 requirement to include a minimum of 600 evaluable subjects for the Corox OTW-L BP lead which assumes an equal 1/3 distribution of each lead model (Corox OTW BP LV lead, Corox OTW-S BP LV lead, and Corox OTW-L BP LV lead).

FDA would like to remind you that you are required to submit PAS Progress Reports every six months. The PAS Progress Reports should be submitted separately from the Annual Reports. Please refer to the guidance document on how to handle post-approval studies imposed by approval orders, located at the following website:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm>

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.

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](http://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

Page 4 – Mr. Jon Brumbaugh

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](http://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](http://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.

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.

If you have questions concerning this approval order, please contact Erin Cutts at 301-796-6307.

Sincerely yours,

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