



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

NOV 10 2010

Marilee Schaeffer  
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4100 Hamline Avenue North  
St. Paul, MN 55112

Re: P910073/S077

Endotak Reliance 4-Site Lead Models 0262, 0263, 0265, 0266  
Endotak Reliance 4-Site Lead Models 0272, 0273, 0275, 0276  
Endotak Reliance 4-Site Lead Models 0282, 0283, 0285, 0286  
Endotak Reliance 4-Site Lead Models 0292, 0293, 0295, 0296  
4-Site Terminal Tool Model 7001  
Lead Cap Kit Model 7007  
4-Site Lead Pulling Tip Model 7006  
P830060/S062  
Lead Tunneler Model 6888

Filed: February 24, 2009

Amended: August 28, 2009; February 2, 2010; September 9, 2010

Procode: NVY

Dear Ms. Shaeffer:

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 Endotak Reliance 4-Site Leads and Accessories. 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.

Expiration dating for Endotak Reliance 4-Site leads has been established and approved at 2 years. Expiration dating for separately packaged 4-Site lead accessories has been established and approved at 4 years.

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 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 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 overall, and by model number.

In addition to the Annual Report requirements, you have agreed to provide the following data in post-approval study (PAS) reports.

1. Post-approval study of Chronic Lead Performance of the Reliance Endotak 4-Site Lead and Header system. This study will be 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 primary hypothesis of this study will evaluate if the five year Endotak Reliance 4-Site defibrillation lead-related chronic complication-free proportion is greater than 92.5%. In addition to the chronic lead/header-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. The sample size will be 1,810, accounting for estimated attrition resulting in 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.

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. Two copies, identified as "PMA Post-Approval Study Report" and bearing the applicable PMA reference number, should be submitted to the address below. Any future request to add PAS study data to device labeling should be submitted separately in a PMA supplement. Please refer to the guidance document on how to handle post-approval studies imposed by approval orders, located at the following website:

[www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm#2](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm#2)).

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.

Within 30 days of your receipt of this letter, you must submit a PMA supplement that includes the final complete protocol and case report forms for your post-approval study. The supplement should certify that these documents are identical to those submitted by email on October 26, 2010 during the interactive review of P910073/S077, or clearly identify any differences. Your PMA supplement should be clearly labeled as a "Post-Approval Study Protocol" and submitted in triplicate to the address below. Please reference the PMA number above to facilitate processing. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order"

[www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm#2](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm#2)).

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 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.

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:

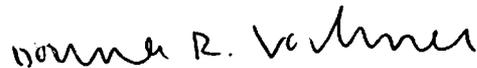
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm>; clinical and statistical data:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm136377.htm> )

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
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If you have questions concerning this approval order, please contact Mark Fellman at (301) 796-6357 or by email at [mark.fellman@fda.hhs.gov](mailto:mark.fellman@fda.hhs.gov).

Sincerely yours,



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