DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
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WARNING LETTER

NWE-07-09W

VIA CERTIFIED MAIL

DATE: February 18, 2009

Mrs. Gail Byrne
President
Brymill Corporation
7940 Silverton Avenue,
Suite 215,
San Diego, CA 92126.

Dear Mrs. Byrne:

During an inspection of your firm located in Ellington, Connecticut, on November 3 through November 7, 2008, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures liquid nitrogen cryosurgical devices; the CRY-AC Tracker®, the CRY-AC® and the CRY-AC3®. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

The inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351 (h)), in that the methods used in, or the facilities or controls used for, the manufacture, packing, storage or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations, (CFR), Part 820. These violations include, but are not limited to, the following:

1. Failure of the design verification to confirm that the design output meets the design input requirements, as required by 21 CFR 820.30 (f).

   For example, review of the [redacted] (b) (4) [redacted] protocol found no raw data used to support the verification of the software used in the BryMill Tracker device.

2. Failure to evaluate and investigate complaints involving the possible failure of a device to meet any of its specifications as required per 21 CFR 820.198 (c).

For example, review of service reports indicating requests for service are not reviewed for possible complaints that the units failed to operate in their intended uses. Review of Repair Track Sheet for a unit identified as (b) (4) under ' (b) (4) (b) (4) " lists as the reason for return "None Specified". There is no documentation the employee attempted to determine the nature of the complaint or performed an investigation into the possible reason for the return of the device for service.

3. Failure to maintain purchasing data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received products and services, as required per 21 CFR 820.50(b).

   For example, your firm purchases the (b) (4) " or digital reader used in the production of the BryMill Device purchased from (b) (4) There is no documentation that facility was evaluated as a supplier/Vendor for the (b) (4) used in the production of the BryMill Tracker Device. Your firm received (b) (4) from that vendor under (b) (4) . The invoice was ink stamped "accepted" by your firm in May of 2007 with no Certificate of Conformance or incoming acceptance testing documented identifying the units were manufactured according to your specifications and documentation they met incoming production specifications.

4. Failure of the device history record to demonstrate that the device is manufactured in accordance with the device master record, as required per 21 CFR 820.184.

   For example, review of the Device History Records (DHR) for the BryMill Tracker cryosurgical devices identified as (b) (4) lacks documentation the units were tested after assembly to assure they accurately achieve a temperature set by the assembler during assembly.

5. Failure to adequately train your employees as required by 21 CFR 820.25(b).

   For example, review of your training records found no documentation that employees involved in receiving and evaluating complaints on the cryosurgical devices sold by your firm had received training. Review of service reports indicating requests for service are not reviewed for possible complaints that the units failed to operate in their intended uses.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an

explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to: Maren Forsyth, Food & Drug Administration, One Montvale Avenue, Fourth Floor, Stoneham, Massachusetts 02180. If you have any questions about the content of this letter please contact: Ms. Forsyth at 781 596-7769.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely yours,

John R. Marzilli
District Director
New England District