U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Caridian BCT Inc. 3/18/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Denver District Office
Bldg, 20-Denver Federal Center
P.O. Box 25087
6110 Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX: 303-236-3551

March 18, 2011

WARNING LETTER

VIA UPS

Mr. David B. Perez
President and CEO
Caridian BCT Inc.
14143 Denver West Parkway, Suite 200
Lakewood, CO 84401-3275

Ref # DEN-11-09-WL

Dear Mr. Perez:

During an inspection of your firm located at 10811 W. Collins Avenue, Lakewood, Colorado, on October 19 - November 11, 2010, investigators from the United States Food and Drug Administration (FDA) determined that your firm manufactures Class II automated blood cell separators and associated disposable collection sets. Under section 201(h) o 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.

This 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, their 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. You can find these regulations or the FDA website at www.fda.gov [1]

Significant deviations include, but are not limited to, the following:

1. You have failed to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, that ensures that all complaints are: evaluated to determine whether the complaint represents an event which is required to be reported to FDA under 21 CFR 803, Medical Device Reporting (MDR), (21 CFR 820.198(a); and evaluated to determine whether an investigation is necessary, (21 CFR 820.198(b)

Specifically:

• Because of a software default, **(b)(4)** disposable product complaints reviewed by our investigator were not investigated by you to make appropriate MDR reportability determinations. No attempt was made to have the subject devices returned for failure analysis;

• **(b)(4)** complaints identified by you as "high priority complaints," did not contain sufficient information to make an MDR reportability determination. The subject complaints did not document if medical intervention was required, or the type of medical intervention provided;

• Your complaint evaluation system failed to identify **(b)(4)** disposable product complaints reviewed by ou investigator as MDR events, even though medical intervention was reported by the complainant.

• Your complaint evaluation system also failed to identify **(b)(4)** other disposable product complaints as MDR events, even though the available information suggested that your devices malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

2. You have failed to validate with a high degree of assurance, a process where the results cannot be fully verifiec by subsequent inspection and test, (21 CFR 820.75(a)).

Specifically:

• You have not validated the preparation of the **(b)(4)** bonding solution which is used to bond the **(b)(4)** subassembly, a component of the Trima ACCEL disposable set;

• You have not validated the preparation of the **(b)(4)** which is used to bond the **(b)(4)** subassembly and **(b)(4)** subassembly, components of the Spectra disposable sets.

3. You have failed to document in-process and final acceptance activities, (21 CFR 820.80(e)).

Specifically:

• You did not document the final leak test performed on Trima disposable sets;

• You did not document the in-process occlusion Lest performed on Trima disposable sets.

• You did not document the verification of the **(b)(4)** setup at the start of each shift, and after maintenance. The **(b)(4)** is used in the packaging process of the Trima disposable sets.

4. You have failed to establish and maintain procedures for implementing corrective and preventive action which include requirements for analyzing complaints, (21 CFR 820.100(a)).

Specifically, you have not established a procedure for reviewing, evaluating and investigating software defect complaints which are entered into your firm's **(b)(4)**

5. Failure to establish and maintain procedures to adequately control environmental conditions which could reasonably be expected to have an adverse effect on product quality, (21 CFR 820.70(c).

Specifically:

• On **(b)(4)** occasions following power outages, you failed to follow your Cleanroom Projects procedure, **(b)(4)** in that you failed to address the impact of **(b)(4)**:

• You have failed to follow your Pest Control procedure, **(b)(4)** which states that the purpose of the procedure is to ensure products are manufactured in an environment free of contamination from pests. During the period January 10 - September 27, 2010, you ignored **(b)(4)** separate pest control inspection reports from your contract pest control company which stated that the weather stripping on exterior doors needed to be replaced. During the inspection it was observed that weather stripping under the door had no been repaired and dead insects were noted in building **(b)(4)**and in building **(b)(4)** where raw materials are stored.

6. Failure to establish procedures for identifying training needs, ensure that all personnel are trained to adequately perform their assigned responsibilities, and document the training, (21 CFR 820.25(b)).

Specifically, you did not have documentation that **(b)(4)** contract cleaning employees observed cleaning the "Cleanroom" had been trained in procedure Cleanroom/Controlled Environmental Access, **(b)(4)**

We acknowledge receipt of your November 12, 2010 response to our Form FDA 483 and your update responses dated December 21, 2010, January 19, 2011 and March 7, 2011. You appear to be addressing our concerns; however, your corrective actions will be fully evaluated and verified during our next inspection of your firm.

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 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 any additional steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violation(s), or similar violation(s), 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.

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, issued at the closeout of the inspectio 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.

Your response should be sent to: Food and Drug Administration, Denver District, P.O. Box 25087, Denver, CO 80225-0087, Attention: William H. Sherer, Compliance Officer. If you have any questions, please contact Mr. Sherer at (303) 236-3051.

Sincerely,
/S/
Gerald D. Bromley
Acting District Director

Links on this page:

1. http://www.fda.gov