



March 29, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 04 - 20

Raymond W. Cohen
Chairman of the Board and Chief Executive Officer
Cardiac Science, Inc.
16931 Millikan Avenue
Irvine, California 92606

Dear Mr. Cohen:

During an inspection of your establishment located at 5474 Feltl Road, Minneapolis, MN, on January 13-28, 2004, our investigators determined that your company manufactures Automatic External Defibrillators (AEDs), which are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System regulation for medical devices, as specified in Title 21, Code of Federal Regulations, Part 820 (21 CFR 820), as follows:

1. Corrective and preventive action (CAPA) activities have not been documented, including investigations of causes of nonconformities, as required by 21 CFR 820.100(b). Specifically:
 - a. CAPA #0225, which addresses "Cap Timer Overflow" failures, does not document that AEDs will not always shock to the specified energy.
 - b. CAPA #0225 does not document that therapy can be delayed due to long charge times.
 - c. No written testing protocol was used in the "Cap Timer Overflow" returned product failure investigation charge testing.
 - d. The energy level settings of the returned AEDs (as received) were not documented.

Raymond W. Cohen
March 29, 2004

2. Procedures for implementing corrective and preventive actions were not implemented as required by 21 CFR 820.100(a). Specifically, CAPA Procedure 100-0025, Rev 4, requires that any CAPA investigation greater than  calendar days past its target due date will be reviewed, and if an extension is granted, a revised target date shall be indicated and an explanation of the extension documented in the CAPA system. Numerous CAPAs are overdue (e.g., CAPA #0225, 0229, 0234), and there is no documented explanation for time extensions.
3. The procedures addressing verification or validation of corrective and preventive actions were not implemented as required by 21 CFR 820.100(a)(4). Specifically, CAPA Procedure 100-0025, Rev 4, requires documentation of verification and validation, but this was not completed for CAPA #0225.
4. Quality system procedures were not implemented as required by 21 CFR 820.20(e). Specifically, Recall Procedure 800136-001, Rev 4, requires that potential risks and hazards be determined. Not all of the risks and hazards associated with the "Cap Timer Overflow" problem were included in CAPA #0225. For example, delays in shock therapy caused by capacitors failing to charge before timeout and failure to deliver specified shock energies were not included.
5. Statistical techniques are not used for control purposes where statistical techniques are applicable as required by 21 CFR 820.250(a). Specifically, there is no documented statistical support for the  requirement in the Final Test/Inspection 101-0079, Rev E, for finished AEDs.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration (FDA). You also must promptly initiate permanent corrective and preventive action on your Quality System.

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, no pre-market submissions for Class III devices to which the Quality System/Current Good Manufacturing Practice deficiencies are reasonably related will be cleared or approved until the violations have been

Page 3

Raymond W. Cohen
March 29, 2004

corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying system problems necessary to ensure that similar violations will not recur. 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 Compliance Officer Timothy G. Philips at the address indicated on the letterhead. If you have any questions concerning this matter, please contact Mr. Philips at (612) 758-7133.

Sincerely,



W. Charles Becoat
Director
Minneapolis District

xc: Kenneth F. Olson
Chief Technical Officer
Cardiac Science, Inc.
5474 Feltl Road
Minneapolis, MN 55343

TGP/ccl
