



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

*Purged 11/24/97
HFI-35
689*

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(617)279-1675 FAX: (617)279-1742

November 21, 1997

WARNING LETTER

RETURN RECEIPT REQUESTED
VIA CERTIFIED MAIL

NWE-05-98W

Richard A. Packer, President
Zoll Medical Corporation
32 Second Avenue
Burlington, Massachusetts 01803

Dear Mr. Packer:

During an inspection of your establishment located in Burlington, Massachusetts on September 15-19, 23, 29, 30 and October 2, and 7, 1997, our Investigators and Analyst determined that your establishment manufactures various products, such as the Zoll PD 1200, Zoll PD 1400 and Zoll PD 1600 defibrillators. The Zoll PD 1200, Zoll PD 1400 and Zoll PD 1600 defibrillators 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 (QSR) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820, as follows:

1. Failure to review, evaluate, and investigate complaints involving the possible failure of a device to meet any of its performance specifications. Your Complaint Handling Procedure, Document No. [REDACTED], instructs not all device failures have to be investigated. For example:
 - Step [REDACTED] states a product complaint is any written or oral expression of dissatisfaction from a customer, distributor, service person or other qualified user regarding the identity, quality, durability, reliability, safety, effectiveness, or performance of a Zoll Medical product. Therefore, any customer call that does not express dissatisfaction with a Zoll Medical product is not considered a complaint and therefore is not investigated.

- Step [REDACTED] categorizes claims in order to expedite the review process. This step fails to categorize claims received for devices that are more than one (1) year old. Step [REDACTED] determines if the complaint is to be investigated by the category it is given in Step [REDACTED]. Since devices that are more than one (1) year old have no category, they are not investigated. Examples of claims received for devices that are more than one year and were not investigated are Customer Call Report, claim #s 527482, 527427, 527031, 527982 and 527577. The explanations on the Customer Call Reports of why they were not investigated were because they were greater than one (1) year old.
 - Step [REDACTED] categorizes the failure of a device that occurs within the first year of product use for products in commercial distribution for more than one year, except for abuse as Complaint Type E. Step [REDACTED], instructs that, Type E complaints are trended by reported complaint and confirmed failure, but are not necessarily investigated. Complaints which are trended do not require a formal investigation because data is being collected and is reviewed on a monthly basis. Therefore, these steps instruct that failure of devices that have been in commercial distribution for more than one year do not have to be investigated.
2. Failure to thoroughly evaluate and investigate complaints. For example, according to Customer Call Report, Claim # 527357, a PD 1400 defibrillator malfunctioned during use on a seventy-eight (78) year old patient in a "code" situation. The complaint investigation revealed that the digital board was a fault and the digital circuit board and main control board of the device were replaced. The device was then returned to the customer on August 6, 1997, after repair. On August 11, 1997, the customer contacted Zoll Medical and indicated that the problem with the device continued to exist.
 3. Failure to process complaints in a uniform and timely manner in that all completed Customer Call Reports are not forwarded to the Complaint Coordinator on a daily basis for complaint determination and processing. For example: memos from QA, dated June 5, 1997, June 25, 1997, August 22, 1997, and September 19, 1997, requested Customer Call Reports received on April 11, 1997 (55 days old), April 11, 1997 (75 days old), June 3, 1997 (80 days old), and July 28, 1997 (52 days old), respectively.
 4. Failure to validate software used in tracking and trending service and complaints. For example, the [REDACTED] and [REDACTED] software packages that are used in tracking and trending service complaints have not been validated.
 5. Failure of your Material Control Procedure [REDACTED] to ensure that only those devices approved for release are distributed. For example, tested and untested printed circuit boards were observed to be stored next to each other in the stockroom. Your records show that two (2) untested power supply boards were shipped out to a customer.

6. Failure of your Purchasing Controls to ensure that all purchased or otherwise received product and services conform to specified requirements. For example, Material Review Report # 5992 has a lot quantity of ninety (90). Fifty (50) of the ninety had to be reworked because they did not meet your specifications.

Additionally, the above stated inspection revealed that your devices are misbranded within the meaning of Section 502(t)(2) of the Act, in that your establishment failed to submit information to the Food and Drug Administration (FDA) as required by the Medical Device Reporting (MDR) Regulation, as specified in 21 CFR 803. Specifically, you failed to submit MDR reports to FDA after receiving information which reasonably suggested that one or more of your commercially distributed devices would likely cause or contribute to a death or serious injury if a malfunction were to recur. According to the Customer Call Report, claim # 527462, dated August 4, 1997, the PD 1200 Defibrillator malfunctioned during routine maintenance in that the unit discharged when only one of the discharge buttons was pressed. This malfunction for the device would be likely to cause or contribute to a death or serious injury and is, therefore, reportable. Also, according to the August 26, 1997, Customer Call Report, claim #527982, the PD 1600 Defibrillator shut down during routine maintenance after three (3) discharges with good batteries. This malfunction for the device would be likely to cause or contribute to a death or serious injury and is, therefore, reportable. For your information, your MDR procedures do not reflect the language of the new MDR regulations that became effective on July 31, 1996. Further, at no point in the new regulation or even in the previous regulation was there any reference to device malfunctions not being complaints to be evaluated for MDR reportability if the device had been in use for more than one year.

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 FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

In order to facilitate FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts, and to resume marketing clearance for Class III devices for which a 510(k) has been submitted, and to issue Certificates to foreign Governments for products manufactured at Zoll Medical Corporation, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that he/she has conducted an audit of your establishment's manufacturing and quality assurance systems relative to the requirements of the device QSR regulation (21 CFR, Part 820). You should also submit a copy of the consultant's report, and certification by your establishment's CEO (if other than yourself) that he or she has reviewed the consultant's report and that your establishment has initiated or completed all corrections called for in the report. The attached guidance may be helpful in selecting an appropriate consultant.

The initial certifications of audit and corrections and subsequent certifications of updated audits and corrections should be submitted to this office by the following dates:

- Initial certifications by consultant and establishment - May 31, 1998.
- Subsequent certification - May 31, 1999.

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 premarket submissions for Class III devices to which the QSR deficiencies are reasonably related will be cleared until the violations related to the subject devices have been corrected.

We have received your letter dated October 27, 1997, responding to the FD-483 issued to you on October 7, 1997, at the close of the inspection. The response is currently under review and we will respond to its adequacy at a later date.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations 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 penalties.

Please notify this office in writing within fifteen (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 systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (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 Bruce R. Ota, Compliance Officer, Food and Drug Administration, One Montvale Avenue, Stoneham, Massachusetts 02180.

Sincerely,



John R. Marzilli
District Director
New England District Office

Attachment: Selecting A Consultant