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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94102-7070
Telephone: 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our ref: 29-51700

April 15, 1997

Sister Julie Heyer, CEO/President
Dominican Santa Cruz Hospital
1555 Soquel Drive
Santa Cruz, CA 95065

WARNING LETTER

Dear Sister Heyer:

During an inspection of Dominican Santa Cruz Hospital located in Santa Cruz, California between February 20, 1997 and February 26, 1997, Investigator Patricia A. Cruz determined that ethylene oxide sterilization of electrosurgical probes is performed under contract with [REDACTED]

Electrosurgical probes are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act). As a contract sterilizer for these probes, Dominican Santa Cruz Hospital is obligated to comply with provisions of the Good Manufacturing Practice Regulations for Medical Devices (GMP), as set forth in Title 21, *Code of Federal Regulations* (CFR) Part 820. The deviations noted by the investigator cause the probes to be adulterated within the meaning of section 501(h) of the Act, as follows:

1. Your contract sterilization facility assumed responsibility for proper sterilization of the [REDACTED] probes when it decided to apply its own parameters to the sterilization process. However, the hospital did not determine whether the process would be adequate for the devices being sterilized. Further, your facility has been unable to ensure that the

products have undergone adequate sterilization, as installation qualification studies have not been conducted on the [REDACTED] Gas Sterilizer. [21 CFR Part 820.100(a)(1)]

2. You have no written procedures for sterilization of [REDACTED] medical devices. The hospital has an unwritten procedure that [REDACTED] devices are sterilized using the "warm" cycle (55°C for 2 hrs. and 22-37 minutes). However, batch records show that devices are not always sterilized for the specified time. [21 CFR 820.100(b)] For instance, the following variation was found in sterilization times:

Load #13, dated 2/3/97:	5 hrs., 25 mins.
Load #12, dated 12/27/96:	4 hrs., 57 mins.
Load #13, dated 12/18/96	4 hrs., 20 mins.
Load #1, dated 1/4/97	6 hrs., 10 mins.

3. Review of thirty records for processing of electrosurgical probes between December 1996 and February 1997 found that the actual parameters achieved during each sterilization run are neither monitored nor recorded. [21 CFR 820.100(b)(2), 820.184]
4. Product load configuration and heat penetration studies have not been done on the [REDACTED] Gas Sterilizer. Yet, your facility simultaneously processes loads of disparate devices along with [REDACTED] electrosurgical probes. [21 CFR 820.100(a)(1)]
5. The placement of biological indicators within each sterilization load is not defined in your written procedures for Biological Indicator Monitoring. [21 CFR 820.100(b)(1)]
6. The measuring equipment on the gas sterilizer, such as humidity sensors, temperature sensors and pressure gauges, is not calibrated on a routine basis. Measuring equipment was calibrated when the sterilizer was installed six to seven years ago and has not been calibrated since that time. [21 CFR 820.61].
7. Three methods for aeration of [REDACTED] probes after ethylene oxide processing are being used by Dominican Santa Cruz Hospital:
 - a. Using the Gas Sterilizer's aeration cycle for eight hours at 131° F.
 - b. Using the Aeration Cabinet for eight hours. at 145° F.

- c. Using the Gas Sterilizer's aeration cycle at 131° F for part of the eight hour cycle and completing the eight hour cycle in the Aeration Cabinet at 145° F.

Your facility has no written procedure in place for aeration of these devices [21 CFR 820.100]

8. Testing has not been done to ensure that aeration cycles, performed either in the Gas Sterilizer and/or Aeration Cabinet, reduce ethylene oxide residues to a safe level. [21 CFR 820.100(a)(1)].
9. The target aeration parameters used by your facility are eight hours at 131° F (using Gas Sterilizer) or 145° F (using Cabinet) for [REDACTED] devices. There is no apparent basis for selection of these parameters. Further, review of your sterilization records show that the devices are not always aerated to these parameters [21 CFR 820.100(b), 820.184].

In addition, Dominican Santa Cruz Hospital has caused the [REDACTED] electro-surgical devices to be misbranded because the devices are processed without a valid registration as a medical device processing facility as required by Section 510 of the Act.

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 (Inspectional Observations) issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm'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.

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 devices to which the GMP deficiencies are reasonably related will be cleared until violations have been corrected. Also, no requests for Certificates for Products For Export will be approved until 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 the Food and Drug

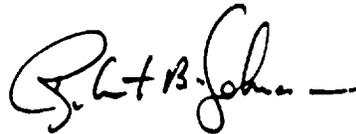
Dominican Santa Cruz Hospital
Santa Cruz, California

4

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 working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be directed to: Andrea Scott, Compliance Officer, U.S. Food and Drug Administration, 96 North Third Street, Suite 325 San Jose, California 95112.

Sincerely,



Patricia C. Ziobro
District Director
San Francisco District