



DEPARTMENT OF HEALTH AND HUMAN SERVICES

94859d

Southwest Region

Food and Drug Administration
Denver District Office
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Denver, Colorado 80225-0087
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June 14, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Avner Raz
President and CEO
Lumenis, Inc.
13 Hayetzira St.
Yokneam Industrial Park
P.O. Box 240
Yokneam, 20692 Israel

Ref # DEN-04-09

Dear Mr. Raz:

On February 17-27 and April 1, 2004, investigators from the U.S. Food and Drug Administration (FDA) conducted an inspection of your establishment located at 3959 West 1820 South, Salt Lake City, Utah. Our investigators determined that your firm manufactures a line of surgical laser systems and accessories for ophthalmic procedures, and accessories for other surgical laser systems. These products are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), [21 U.S.C. § 321(h)].

As described in the Form FDA-483 issued to your firm at the close of the inspection, the investigators found evidence that your medical devices are adulterated under 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 conformance with Current Good Manufacturing Practice (CGMP) requirements. CGMP requirements are set forth in FDA's Quality System (QS) regulation, Title 21, Code of Federal Regulations (21 CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. Failure of management with executive responsibility to ensure that the quality policy is implemented, and maintained at all levels of the organization, [21 CFR 820.20(a)]. Each manufacturer shall establish the appropriate responsibility, authority, and interrelation of

all personnel who manage, perform, and assess work affecting quality, and provide the independence and authority necessary to perform these tasks, [21 CFR 820.20(b)(1)].

Although your firm's Quality Assurance (QA) manager is responsible for verifying overall compliance with the quality system, providing specific guidance to department managers regarding implementation of the quality system, and has the authority to request corrective action, systems have not been established to ensure that all necessary quality data is available to this manager. Specifically:

- a. Failure report summaries provided to the QA manager contain the total number of failures by system, but not the type of failure by system.
 - b. The QA manager has not been given the authority to review individual product complaints which have been handled by your Customer Service Center in Santa Clara, California, for trends or the need for an investigation.
 - c. Non-conformance report information is not provided to the QA manager's representative in a format which allows trending.
 - d. The QA manager is not always informed when Medical Device Reports (MDR), for products manufactured at the Salt Lake City facility, are initiated by the Santa Clara Customer Service Center, and the QA manager does not have access to complete MDR files for products manufactured in Salt Lake City.
2. Failure to validate a process for which results cannot be fully verified by subsequent inspection or test, [21 CFR 820.75(a)].

Specifically, the ETO sterilization validation protocol for your sterile accessory probes, protocol number 200212303-02, Comparative Resistance Study, purports to comply with AAMI/ANSI/ISO 11135:1994, which requires "product used for microbiological performance qualification shall be packaged as it will be routinely presented for sterilization." Your sterile laser accessory probe products are routinely packaged in double [REDACTED] pouches prior to ETO sterilization. However, the process challenge devices and inoculated products used for the 2002 microbiological performance qualification were packaged in single [REDACTED] pouches, not in double Tyvek pouches.

3. Failure to establish and maintain procedures for implementing corrective and preventive action, [21 CFR 820.100 (a)]. Specifically,
- a. Your Corrective Action/Preventive Action procedure, SOP- 503, does not require validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device, [21 CFR 820.100 (a)(4)].
 - b. You have not adhered to the requirements of your Corrective Action/Preventive Action procedure, SOP-503, which requires the preparation of a Corrective Action Report (CAR) for recurrent nonconforming conditions, [21 CFR 820.100 (a)(5)]. Data from non-conformance reports for the period December 2003 to February 2004 indicates that there were 87 board failures, but a CAR was not generated to address this recurring problem. During the same period, the wrong

revision of a part was used in manufacturing a laser system or accessory 20 separate times, but a CAR was not generated to address the problem.

- c. You have not analyzed all complaints using appropriate statistical methodology to detect recurring quality problems or trends. Only complaints relating to Dead On Arrival (DOA) devices are subjected to trending, [21 CFR 820.100 (a)(1)].
4. Failure to establish and maintain procedures to ensure that Device History Records (DHR) for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the Device Master Record (DMR), [21 CFR 820.184]. Our investigators reviewed six DHRs for the Novus Spectra laser device. The review disclosed that components currently specified for use in the DMR were not used in the manufacture of three Novus Spectra laser devices, serial numbers [REDACTED] and [REDACTED].
5. Failure of the evaluations of nonconforming product to include a determination of the need for an investigation, and the documentation of any such investigation, [21 CFR 820.90 (a)]. Your Documenting & Controlling of Nonconforming Material, SOP-502, procedure does not require that the evaluation of non-conforming materials include a determination of the need for an investigation or that any investigation which is conducted be documented. Of the three closed non-conformance reports (NCR) reviewed by our investigators, two did not contain investigations or justifications for not conducting investigations regarding the reason for the non-conformance.
6. Failure to develop, conduct, control, and monitor production processes to ensure that your devices conform to your specifications, [21 CFR 820.70 (a)]. Where process controls are needed they shall include documented instructions, standard operating procedures, and methods that define and control the manner of production, [21 CFR 820.70 (a)(1)]. Specifically:
 - a. Although the bioburden level of accessory probes which will be sterilized is monitored, you have not established written procedures for testing frequency or acceptance levels.
 - b. Your Production Environmental Specifications procedure, WP0200055, states that “active air bioburden sampling” will be conducted quarterly in the “Environmentally Controlled Room (White Room)”; however, the procedure does not define acceptable bioburden levels.
7. Failure to establish and maintain procedures for the receipt, review, and evaluation of all complaints by a formally designated unit, [21 CFR 820.198(a)]. Our investigators observed the following when reviewing your procedures and 46 individual complaint records:
 - a. Complaints received from your distributors are not handled according to your Complaint Processing Procedure, SOP-39-257. Two complaints received from a distributor, a laser arm falling off and a safety filter falling out, were handled as

- Corrective Action Reports, and were not reviewed, evaluated or trended as complaints.
- b. Your firm's actions following the receipt of a complaint are based on the Symptom Code given a complaint; however, your Complaint Processing Procedure does not address the use of Symptom Codes.
 - c. One complaint reviewed had been assigned the wrong Symptom Code.
 - d. Three complaints did not make reference to or contain the Dead On Arrival (DOA) sheet as required by your Out of Box Failure – DOA procedure, SOP-00-39-259.
8. Failure to evaluate complaints to determine whether the complaint represents an event which is required to be reported to FDA under 21 CFR 803 or 804, [21 CFR 820.198 (a)(3)]. Two excessive laser power complaints were not evaluated for MDR reportability as required by the regulation and your Receiving, Reviewing, and Evaluation MDR Reportable Events and Complaints procedure, SOP-00-39-215.
 9. Failure to review and evaluate all complaints to determine whether an investigation is necessary, and when no investigation is made, maintain a record that includes the reason and name of the individual responsible for the decision not to investigate, [21 CFR 820.198 (b)]. Field Service Technicians from your Santa Clara, CA Customer Service Center close complaint service calls with a code designation. If the code selected by the Service Technician does not indicate that an investigation is necessary, the complaint is not reviewed by a formally designated unit such as your Technical Services unit or Quality Assurance unit.
 10. You have failed to review, evaluate, and investigate complaints involving the possible failure of a medical device to meet specifications, [21 CFR 820.198(c)]. Our investigator identified six complaints received by your firm that involved the possible failure of a medical device to meet specifications. These were not investigated. The QS Regulation excuses a firm from reviewing, evaluating, and investigation out-of-specification complaints for medical devices, but only if an investigation has already been performed for a similar complaint and another investigation is not necessary. Our investigator found no evidence that your firm had already performed an investigation for a similar complaint.

This type of deviation from the Quality Systems Regulations was also noted during our August 16, 2002 inspection of your firm and reported to your management in a letter dated January 3, 2003.

On April 28, 2004, we received a response letter, dated March 22, 2004, from Ms. Theresa M. Myers, your Quality Assurance Manager, which stated "We will send our corrective action plan as of April 1, 2004". Your response is inadequate in that it does not contain any specific steps you have taken or plan to take to address the conditions noted. In addition, we have not received any additional correspondence from your firm regarding a "corrective action plan".

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June 14, 2004

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Act and regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These include seizure, injunction and/or civil penalties.

You should 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 prevent the recurrence of similar violations. 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: 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,



B. Belinda Collins
District Director

cc: Ms. Theresa M. Myers
QA Manager
Lumenis, Inc.
3959 W. 1820 S.
Salt Lake City, UT 84104

Mr. David Plank
Director Manufacturing
Lumenis, Inc.
3959 W. 1820 S.
Salt Lake City, UT 84104