



Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
P.O. Box 3012
Bothell, WA 98041-3012

June 3, 1998

Telephone: 425-486-8788
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VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 98-12

Mr. Shimon Eckhouse
President/CEO
ESC Medical Systems, Ltd.
Industrial Zone
Area 6
P.O. Box 240
Yokneam Israel 20692

WARNING LETTER

Dear Mr. Eckhouse:

During an inspection of Luxar Corporation, 22011 30th Avenue SE, #B, Bothell, WA from April 27 to May 11, 1998, Teri L. Colbert, Engineer, determined that this establishment manufactures the NovaPulse LX-20SP Laser. The NovaPulse LX-20SP Laser is a device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that this device is 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 as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Final acceptance and in-process activities do not insure that acceptance criteria are met. For example, LX-20SP serial numbers [REDACTED] and [REDACTED] did not meet the final acceptance or assembly specifications and were released for distribution.
2. Final acceptance activities do not insure that the associated data and documentation are reviewed.
3. Personnel have not been trained to adequately perform their assigned responsibilities. For example, technicians tested and approved LX-20SP laser systems that did not meet in-process and final testing specifications.

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4. Nonconformities related to product, processes, and the quality system were not analyzed in accordance with the firm's corrective and preventive action procedure.

We acknowledge that David V. Plank, Director of Quality Assurance, Luxar Corporation, has submitted to this office two written responses dated May 22 & 28, 1998, concerning the observations noted on the Form FDA 483 (enclosed). It appears that the responses are adequate. A follow-up inspection will be required, however, to assure that corrections are adequate.

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 Luxar Corporation's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Until it has been determined that corrections are adequate, 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 pending submissions for premarket clearance for devices to which the QSR violations are reasonably related will be cleared. Also, no requests for Certificates For Products For Export will be approved.

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 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Mr. Shimon Eckhouse, President/CSO
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Your reply should be directed to Thomas S. Piekarski, Compliance Officer, at the above mailing address.

Sincerely yours,


Roger L. Lowell
District Director

Enclosure:
FDA 483

cc: (w/o Enclosure)
John Holly
Senior Vice President of Operations
Luxar Corporation
22011 30th Avenue SE, #B
Bothell, WA 98021

Mr. Moshe Levine
President of North American Operations
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