U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Omega Laser Systems 2/17/16

Department of Health and Human Services

Public Health Service
Food and Drug
Administration
10903 New Hampshire
Avenue
Silver Spring, MD 20993

WARNING LETTER
FEB 17, 2016

VIA UNITED PARCEL SERVICE

Jessica Nelson
General Manager
Omega Laser Systems
2 Deans Hall Business Park
Oak Road, Little Maplestead
Halstead, Essex, C09 2RT
United Kingdom

Dear Ms. Nelson:

During an inspection of your firm located in Essex,United Kingdom on September 7, 2015, through September 10, 2015, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures Omega Laser Systems. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning of 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 conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

Your firm's response from Jessica Nelson, General Manger, dated November 30, 2015, to the Form FDA 483 (FDA 483) was not reviewed because it was not received within fifteen business days of issuance of the FDA 483. The response will be evaluated along with any other written material provided in response to the violations cited in this Warning Letter. These violations include, but are not limited to,the following:

1. Failure to establish and maintain adequate procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30(a).For example:your firm failed to adequately document the design plan,design input,design output,design review,design verification,design validation,and related activities for the Omega XP-Clinic Laser System; 660 nm 50 mw Probe; and 60 Diode Cluster Probe. Your firm failed to demonstrate that these design control activities are performed.

2. Failure to establish and maintain adequate procedures for the identification, documentation, validation, or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i). For example: your firm has not validated or documented software changes for the Omega

XP Laser System; Omega XP-Clinic Laser System; and Omega Excel Laser System.

3. Failure to establish and maintain adequate procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example, your firm's "Customer Complaints Procedure," PRM 03.3.2, does not ensure that:

a. Complaints are processed in a uniform and timely manner.

b. Oral complaints are documented upon receipt.

c. Complaints are evaluated for MDR reportability.

4. Failure to establish and maintain adequate calibration procedures including specific directions and limits for accuracy and precision, and provisions for remedial action, as required by 21 CFR 820.72(b). For example:

a. Your firm's **(b)(4)**, does not include specific directions and limits for accuracy and precision, and provisions for remedial action.

b. Your firm failed to ensure that the test and measuring equipment used in the finished device acceptance and release activities are calibrated **(b)(4)** records of such calibrations are maintained, as required by **(b)(4)**.

5. Failure to establish and maintain adequate procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a). For example: your firm failed to adequately document its review, evaluation, investigation, and disposition of nonconforming devices found during final acceptance activities, as required by "**(b)(4)**, Issue 2.

6. Failure to establish and maintain adequate procedures for implementing corrective and preventive action (CAPA), as required by 21 CFR 820.100(a)(1). For example: your firm failed to adequately analyze its quality data using appropriate statistical methodology to identify the existing and potential causes of nonconforming product or other quality problems, as required by your firm's CAPA procedure, **(b)(4)**, Issue 2.

7. Failure to establish and maintain adequate instructions and procedures for performing and verifying that the servicing meets the specified requirements, as required by 21 CFR 820.200(a). For example:

a. Your firm's "Service and Repairs Procedure," **(b)(4)**, does not include the requirement for:

i. Analyzing service or repair reports with appropriate statistical methodology.

ii. Evaluating and considering the return and service report that represent an event which must be reported to the FDA as a complaint.

b. Your firm failed to adequately document the retest and inspection data after the completion of service or repairs numbers **(b)(4)**.

8. Failure to establish and maintain procedures for acceptance of incoming product, as required by 21 CFR 820.80(b). For example: your firm's "Receiving Inspection and Verification Procedure," **(b)(4)**, does not define the inspection, test, or verification; acceptance criteria for the incoming product; and how the acceptance and rejection is documented. Your firm's incoming product receiving records **(b)(4)** does not document the type of inspection, sample size used, inspection results and acceptance/rejectionof the goods.

9. Failure to document acceptance activities under 21 CFR 820.80, as required by 21 CFR 820.80(e). For example: your firm failed to document and maintain the following finished device acceptance activities as part of the device history records of the Omega XP Laser Systems, Omega XP-Clinic Laser Systems, and various Omega Laser Probes:

a. The test result reports of the electrical safety testing such as earth continuity test, insulation test, leakage current test, and enclosure leakage test.

b. The validity status and identity of the test equipment used in electrical safety,

battery calibration, and laser output measurement testing.

Our inspection also revealed that the Omega Laser Systems are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g). The device is also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). For a device requiring premarket approval, the notification required by section 510 (k) is deemed satisfied when a PMA is pending before the agency. [21 CFR 807.81(b)] The kind of information that your firm needs to submit in order to obtain approval or clearance for the device is described on the Internet at **http://www.fda.gov /MedicaiDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice /default.htm.The (http://www.fda.gov/MedicaiDevices /DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm.The)** FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed.

Specifically, the Omega XP Laser System (K043353) received clearance with intended use as "to emit energy in the infrared spectrum to provide temporary relief of pain associated with rotator cuff tendonitis." However, your firm has been promoting Omega XP Laser System with additional intended uses, including pain relief and management, wound healing, physiotherapy, podiatry, smoking cessation, dermatology, that are not cleared under K043353.

Our inspection also revealed that the Omega Excel/XP Clinic Laser System is misbranded under Section 502(t)(2) of the Act, 21 U.S.C. §352(t)(2), in that your firm failed or refused to furnish material or information regarding the devices that is required by or under Section 519 of the Act, 21 U.S.C. §360i, and 21 CFR Part 803-Medical Device Reporting (MDR). Significant deviations include, but are not limited to:

10. Failure to develop, maintain and implement written MDR procedures, as required by 21 CFR 803.17. For example: "Management and Corporate Planning Quality Control Vigilance Procedure," PRM 03.3.1, Issue 2, which your firm identified as the MDR procedure does not contain information that would indicate that it was an MDR procedure created in accordance with the requirements in 21 CFR 803.17.

Given the serious nature of the violations of the Act, Omega Laser Systems manufactured by your firm are subject to refusal of admission under section 801(a) of the Act, 21 U.S.C. §381(a), in that they appear to be adulterated. As a result, FDA is taking steps to refuse entry of these devices into the United States, known as "detention without physical examination," until these violations are corrected. In order to remove the devices from detention, your firm should provide a written response to this Warning Letter as described below and correct the violation described in this letter. We will notify you regarding the adequacy of your firm's response and the need to re-inspect your firm's facility to verify that the appropriate corrections and/or corrective actions have been made.

U.S. federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class Ill devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected.

Please notify this office in writing, within fifteen business days from the date you receive this letter, of the specific steps your firm has taken to correct the noted violations, including an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective action (which must address systemic problems) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementationof those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Please provide a translation of documentation not in English to facilitate our review. We will notify you regarding the adequacy of your firm's response and the need to re-inspect your firm's facility to verify that the appropriate corrections and/or corrective actions have been made.

Your firm's response should be sent to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Field Inspections Support Branch, White Oak Building 66, Rm 3523, 10903 New Hampshire Ave., Silver Spring, MD 20993. Refer to CMS case #481532 when replying. If you have any questions about the contents of this letter, please contact: Shumaya Ali, Acting Chief, Foreign Enforcement Branch, at **feb@fda.hhs.gov (mailto:feb@fda.hhs.gov)**(email) or +1(240) 402-4020 (telephone).

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems.

Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely yours,
/S/
CAPT Sean Boyd, MPH, USPHS
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

cc
Neil Camera
Advanced Medical Technologies, Inc.
101 Waterside Dr.
Centerville, MA 02632

More in 2016 (/ICECI/EnforcementActions/WarningLetters/2016/default.htm)