



Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

**WARNING LETTER**  
**VIA EXPRESS MAIL**

SEP 28 2000

Mr. Stephen Dalton  
Senior Vice President  
LaserSight Technologies, Inc.  
3300 University Boulevard, #140  
Winter Park, Florida 32792

Dear Mr. Farris:

During an inspection of your firm's facilities located on University Boulevard and 6848 Stapoint Court on July 24 - 31 and August 2, 2000, our investigator determined that your firm manufactures ophthalmic excimer lasers. Ophthalmic lasers 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 designing, manufacturing, packaging, labeling, storage or installation are not in conformance with the Good Manufacturing Practice (GMP) requirements set forth in the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, and described below:

21 CFR 820.20(c) Management review

Failure of management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency to ensure that it satisfies the quality system requirements, as required by 21 CFR 820.20(c). For example, LaserSight started manufacturing at 6848 Stapoint Court on May 22, 2000. [REDACTED] lasers were manufactured, [REDACTED] were released, and [REDACTED] have been installed. The supplement for approval of the new manufacturing site was submitted on July 7, 2000, after the start of actual manufacturing. The investigator documented that [REDACTED] systems were distributed prior to receiving FDA approval of their PMA supplement for the manufacturing site change. Furthermore, it is documented that [REDACTED] of the systems were installed after the discovery on June 30, 2000, that LaserSight did not have the required supplement approval.

While supplement approval is not a specific requirement of the Quality System Regulation, a firm's quality system should ensure that all applicable requirements and specifications pertinent to the medical device(s) being manufactured are addressed. This should include steps to ensure that the necessary FDA clearances are obtained prior to marketing/distribution of a device.

#### 21 CFR 820.75 Process validation

Failure to review and evaluate process(es) and perform revalidation where appropriate when changes occur, e.g., move to a new site, as required by 21 CFR 820.75. For example, determinations should have been made prior to the manufacture of lasers at the new site as to the need for validating the soldering process, the Eprom programming, and the bonding operation. How was it determined, for example, that the environment in the new facility would not adversely affect the soldering process? As you are aware, particulates are a concern when performing this type of activity. For this reason, your response doesn't appear adequate in that you state the soldering process was evaluated prior to the move. Furthermore, it is well known that FDA policy requires that firms complete their process validation where appropriate, or, at a minimum, their performance qualification prior to distribution of any medical device. We would like a summary of the validation activities performed at the new site.

#### 21 CFR 820.100 Corrective and preventive action

Failure to have adequate procedures for implementing corrective and preventive action, as required by 21 CFR 820.100. While LaserSight prepared a letter to all physicians that received one of the systems distributed prior to approval of the PMA supplement, this does not address the issue of what will prevent this type of violation from occurring in the future. LaserSight needs to identify what actions/procedures must be implemented not only to address the current violation but to also prevent recurrence of this or similar problems.

Your devices are further adulterated within the meaning of Section 501(f)(1)(B) in that a PMA supplement is required for use of a different manufacturing facility and for the change in the laser head component.

#### 21 CFR 814.39 PMA supplements

Failure to submit a PMA supplement before making a change affecting the safety or effectiveness of the device, as required by 21 CFR 814.39. For example, LaserSight not only manufactured devices in its new site prior to submission/approval of its PMA supplement, but also commercially distributed and installed lasers prior to submission/approval of a supplement. Secondly, LaserSight changed the older "[REDACTED]" laser head to the newer "[REDACTED]" laser head without first submitting a supplement for this change of component.

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 its applicable regulations. The specific violations noted in this letter and in the FDA 483 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.

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We acknowledge that you have submitted to this office a response concerning our investigator's observations noted on the form FDA 483, and that you have stopped shipment of all systems from the Stapoint facility. However, it has been determined that your response is not adequate due to the reasons discussed above.

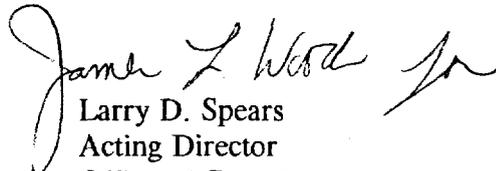
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices 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 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 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. This should include 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.

Your response should be sent to Sharon Kalokerinos, Compliance Officer, Food and Drug Administration, 2094 Gaither Road, Rockville, Maryland 20850.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Larry D. Spears".

Larry D. Spears  
Acting Director  
Office of Compliance  
Center for Devices and  
Radiological Health