DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

94689d

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-04-29

April 20, 2004

Timothy J. Shea, President
Surgilight, Inc.
12001 Science Drive
Suite 140
Orlando, Florida 32826-2916

Dear Mr. Shea:

During an inspection of your establishment located in Orlando, Florida on January 12-26, 2004, FDA Investigators R. Kevin Vogel, Leo Lagrotte, and Electro Optics Specialist, Max Lager determined that your establishment is a manufacturer of the Optivision Laser System intended for laser presbyopia reversal (LAPR), which is defined as a medical device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The investigator documented significant violations from the Quality System (QS) Regulations, Title 21, Code of Federal Regulations (CFR), Part 820. These violations cause the device you manufacture to be adulterated within the meaning of Section 501(h) [21 U.S.C. §351(h)] of the Act.

The investigator noted the following violations of the QS regulations:

1. Your firm's management with executive responsibility failed to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure the quality system satisfies the requirements of this part and the established quality policy and objectives as required by 21 CFR 820.20(c). Your firm failed to correct numerous deficiencies of the Quality System Requirements that were observed during previous FDA inspections dated April 2002 and 2003 and the current inspection: including FDA 483, Item #s 2, 3b, 5, 6, 8 & 9. During the current inspection, complaints concerning energy malfunctions of the Optivision Laser System and in-house failures of the handpiece fiber assemblies or tips were not adequately reviewed, evaluated and documented during quality review meetings when the firm's president was present (FDA 483, Item #7).

2. Your firm's internal quality audits failed to verify that the quality system is effective in fulfilling quality system objectives as required by 21 CFR 820.22. Your firm's internal audits failed to address numerous deficiencies of the Quality System Requirements observed during the present FDA inspection and previous FDA inspections. Your firm failed to include audit criteria covering validation/qualification and Medical Device Reporting (MDR) requirements. This observation was observed during the April 2003 inspection and was not corrected (FDA 483, Item #8).

3. Your firm failed to validate and approve processes whose results cannot be fully verified by subsequent inspection and test according to established procedures as required by 21 CFR 820.75(a). Your firm failed to validate the following operations :

    a) Complete validation of cleaning instructions included in the Optivision Service and Operational Manual for laser tips.
    b) Validation study to assure that polished tips obtained from Premier Laser Systems will retain 90% of initial transmission efficiency when exposed to recommended steam sterilization cycles is inadequate because (i) only five contact tips were assessed during the sterilization testing and no statistical rationale was provided that this was a valid sample. Further, these five contact tips exhibited degradation of coating but reportedly did not cause failure to reach 90% transmission goal (This observation was repeated from the April 2003, FDA 483); (ii) Sterilization validation failed to include 50 resterilizations of contact laser fiber tips even though management states that the tips could be used up to 50 times; (iii) there is no specification for water quality for steam sterilization cycles recommended for laser fiber tips to assure debris (minerals, etc.) does not compromise quality of tips.
    c) Validation of Borland Compiler is incomplete because software used to control passwords was not addressed (FDA 483, Item #3).

4. Your firm failed to analyze all data from quality sources to identify existing and potential causes of nonconforming product and other quality problems as required by 21 CFR 820.100(a)(1). Trend analysis was not conducted of in-process rejects as non-conformances and fiber failures are not documented in the quarterly trend report of nonconformances. One fiber was observed hanging in the testing room during this inspection and was labeled as a burned fiber. Surgilight personnel stated the component failed during in-house testing (FDA 483, Item #12).

5. Your firm failed to implement corrective and preventive action procedures for investigating the cause of nonconformities relating to product, processes, and the quality system as required by 21 CFR 820.100(a)(2).

Your firm failed to follow SOP (RMA procedure, Section 5.14 dated March 14, 2003) requiring that there be specific findings documented concerning failed fibers, not just a description of broken, burnt or damaged. This observation was made during the April 2002 and 2003 inspection (FDA 483, Item #13).

6. Your firm failed to take appropriate action to correct and prevent the recurrence of identified nonconforming product and other quality problems as required by 21 CFR 820.100(a)(3). Your firm received a minimum of 34 reports of low or high energy, broken fibers, or burned fibers for the Optivision Laser fiber delivery systems from the field and no evaluation or investigation was performed and/or documented (FDA 483, Item #1).

7. Your firm failed to review, evaluate, and investigate all complaints involving the possible failure of a device to meet any of its specifications as required by 21 CFR 820.198(c). The following are examples of Return Material Authorizations (RMA), Field Service Reports, and complaints that were not adequately investigated:

    a) RMA #110601-03A dated December 15, 2003, reports that one fiber and one tip were burned in Greece. No investigation was conducted.
    b) Field Service Report dated March 26, 2002 references energy settled down after move to air conditioned room, that two fibers broke at the handpiece, that during set up the next day, the SMA funnel came out with the fiber, and the system went into fault #14, water flow. Report was not treated as a complaint. Complaint #s 96 dated March 13, 2003, and 107 dated June 13 & 17, 2003, both of which reported no or low energy output at the fiber tip and no investigation was documented.
    c) Complaint #4 dated October 15, 2001, references fiber was defective.
    d) Complaint #5 dated September 20, 2001, references laser system failed to power up. Firm repaired high voltage cable connect (J3-J15), the red wire which was found to be broken. There was no determination as to what caused the failure.
    e) Complaint #s 9 and 10 dated October 15, 2001, reference a reconfiguration of the footswitch for two systems but do not identify why or what reconfiguration was done.
    f) Complaint #17 dated December 17, 2001, references software locked up due to possible computer time and/or patient file recreation. Failure not determined.
    g) Complaint #21 dated January 18, 2002, references that fiber did not fit flush with the handpiece and caused breakage of fiber at tip. No investigation completed.

h) Complaint #38 dated May 31, 2002, references that fiber broke and no investigation completed.
i) Complaint #100 dated April 24, 2003, references System Fault #16, temperature. No investigation documented.
j) Complaint #s 106 dated June 3, 2003, and 72 dated November 27, 2002, reference aiming beam shutter stuck closed on power up. No investigation documented.
k) Complaint #109 dated June 17, 2003 references high energy and no investigation was conducted. (FDA 483, Item #9).

8. Your firm failed to establish and maintain complete procedures to ensure that all purchased or otherwise received product and services to conform to specified requirements as required by 21 CFR 820.50. All components to manufacture laser systems including handpiece assemblies and tips were received from Premier Laser Systems. The firm only studied three laser systems to verify that pulse-to-pulse stability met specifications (+/- 10%). The three systems fail to be statistically relevant to verify that Premier is a reliable supplier. Your firm also failed to include fibers and tips in the study and there is no written protocol describing the study (FDA 483, Item #10).

9. Your firm failed to implement procedures to verify that design outputs meet design inputs as required by 21 CFR 820.30(f). Your firm failed to verify that the fiber delivery system could withstand multiple uses. The firm received 34 reports of events involving low and high energy, broker fibers and burned fibers. Fibers with hairline cracks can result in power fluctuations and may affect surgical procedures. Your firm's design plan refers to several items previously completed by Premier, but most of these items have never been verified (FDA 483, Item #2). This observation was previously listed on a FDA 483 during both the April 2002 and 2003 inspections and no corrective action was taken.

10. Your firm's design validation failed to ensure that modified software designed for use with the Scan 195 was appropriate for use with the Optivision Laser System as required by 21 CFR 820.30(g). The software controls the password to allow use of the device when programmed for a specific period of time. A portion of the source code also included questions that were not answered by validation or verification (FDA 483, Item #4).

11. Your firm failed to conduct design validation and risk analysis as required by 21 CFR 820.30(g). Failure of the sapphire fiber during surgery was not included in any risk analysis conducted. There also was a failure to include steam sterilization of the tips and sterile drapes as part of the risk analysis procedures. This item was observed during the April 2002 inspection and was not corrected (FDA 483, Item #5).

12. Your firm failed to include a mechanism to address incomplete, ambiguous, or conflicting requirements as required by 21 CFR 820.30(c). The design input requirements for the fiber delivery system are incomplete except for statements, such as "Transmission > +50%," "Handpiece for easy handling," "Removable from laser," "Fiber status monitoring," and "non-conducting material." This observation was made during the April 2002 and 2003 inspections and was not corrected (FDA 483, Item #6).

13. Your firm failed to identify, document, validate/verify, review, and approve design changes prior to implementation as required by 21 CFR 820.30(i). Reconfiguration of the footswitch made, as a result of Complaint #s 9 & 10 dated October 15, 2001, was implemented without the design change being documented, verified and approved prior to implementation (FDA 483, Item #11).

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. 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.

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. Additionally, no premarket submissions for Class III devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the steps you have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed, (2) any documentation indicating the corrections have been achieved, and (3) 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.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

Emma Singleton
Director, Florida District

cc: Charlotte Cozean
12001 Science Dr., Suite 140
Orlando, Florida 32826