DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 28 2001

Ned Luce
Regulatory Affairs
LaserSight Technologies, Inc.
3300 University Blvd., Suite #140
Winter Park, FL 32792

Re: P980008/S005
LaserSight LaserScan LSX Excimer Laser System for Laser-Assisted In Situ Keratomileusis (LASIK)
Filed: December 19, 2000
Amended: December 29, 2000; January 24, February 8, April 19, May 11, July 10 and 12, August 1, and September 4 and 27, 2001

Dear Mr. Luce:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) supplement for the for the LaserSight LaserScan LSX Excimer Laser System for Laser-Assisted In Situ Keratomileusis (LASIK). This device is indicated for LASIK:

- for the reduction or elimination of myopia ranging from –0.5 to less than –6.0 diopters (D) spherical equivalent, with astigmatism less than or equal to 4.5 D, as measured at the spectacle plane;

- in patients with documentation of a stable manifest refraction defined as ≤ 0.50 D, or ≤ 10% of preoperative spherical equivalent refraction (SER) shift over one year prior to surgery; and,

- in patients who are 18 years of age or older.

The PMA supplement is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device as modified upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the

labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

These restrictions on the use, labeling, promotion and advertising of the device are applicable to LaserSight Technologies, Inc. as well as device purchasers and users. LaserSight must notify purchasers and users of these restrictions and include them in your training programs:

1. Only practitioners who are experienced in the medical management and surgical treatment of the cornea, who have been trained in laser refractive surgery including laser system calibration and operation, may use the device as approved in this order.

2. Prospective patients, as soon as they express an interest in LASIK for myopia with or without astigmatism and prior to undergoing surgery, must receive from the treatment provider the Patient Information Booklet (as described in your final submission to this PMA supplement.)

3. Prior to undergoing surgery, prospective patients must be informed of the alternatives for correcting their myopia and/or astigmatism, including eyeglasses, contact lenses and other refractive surgeries.

4. Comparison of the safety and effectiveness of this laser with any other method of refractive correction is prohibited. This prohibition is based on the fact that the data submitted for PMA supplement approval do not compare the clinical outcome of this device with any other method of refractive correction. Such comparisons of safety and effectiveness are misleading and would misbrand your laser in accordance with section 502(a) of the act. All promotion and advertising for this device must include the following information on indications, risks, and benefits:

   a. Approval is for LaserSight Technologies, Inc.'s application for LaserScan LSX Excimer Laser System to perform laser-assisted in situ keratomileusis (LASIK) for the reduction or elimination of myopia from 0.5 to less than 6 diopters (D) spherical equivalent with astigmatism less than or equal to 4.5 D, as measured in the spectacle plane in patients with documentation of a stable manifest refraction (± 0.5 D or ± 10% of preoperative spherical equivalent shift) over the past year; and in patients who are 18 years of age or older.

   b. LASIK is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy, radial keratotomy or automated lamellar keratectomy.

   c. Approval of this application is based on a U.S. study of 204 eyes treated, 123 of which were followed for six months. In this study 14 eyes were retreated. Of the 14 retreated eyes 0 eyes reached the 6 month follow-up visit for analysis.

d. The study found that of the 183 eyes treated < -6.0 D spherical equivalent, excluding data collected after retreatment, and based on refractive data at the 6 month follow-up examination for 107 eyes, 93.5% were corrected to 20/40 or better and 49.5% were corrected to 20/20 or better without spectacles or contact lenses.

e. The study showed that no adverse events occurred in 1% or more of the subjects at 6 months post treatment. Patients with astigmatism rated the following significant subjective adverse events as occurring "often" or "always" both before treatment and 6 months after treatment: foreign body sensation (2.1% before, 9.1% after), burning feeling (3.5% before, 5.5% after), watery eyes (6.3% before, 5.5% after), halos/starbursts (12.5% before, 3.6% after), double vision (0.7% before, 0% after), clarity changes (6.3% before, 9.1% after) and night vision problems while driving (27.8 before, 25.5% after).

f. Long term risks of LASIK for myopia with or without astigmatism beyond 6 months have not been studied.

g. This laser is not indicated to correct nearsightedness less than -0.5 D or -6.0 D or greater spherical equivalent, or astigmatism greater than 4.5 D. It is not to be used in procedures other than LASIK as described in the Operator's Manual.

h. Note that the complete name for the approved device is "LaserScan LSX Excimer Laser System for Laser-Assisted In Situ Keratomileusis (LASIK) for the reduction or elimination of myopia from -0.5 to less than –6.0 diopters (D) spherical equivalent with astigmatism less than or equal to 4.5 D." Other names require approval in a PMA supplement.

In addition to the postapproval requirements in the enclosure, you must report to FDA CDRH's Office of Compliance at the address below of any instances of device tampering or usage outside of the approved indications, and any excimer systems that were exported under an 801(e) order and are now back in the U.S.

OC/Division of Enforcement (HFZ-331)
Center for Devices and Radiological Health
Food and Drug Administration
2098 Gaither Road
Rockville, MD 20850

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/cdrh/pmapage.html. Written requests for this information can also be made to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling affected by this supplement in final printed form. As part of our reengineering effort, the Office of Device Evaluation is piloting a new process for review of final printed labeling. The labeling will not routinely be reviewed by FDA staff when PMA supplement applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment. Please see the CDRH Pilot for Review of Final Printed Labeling document at http://www.fda.gov/cdrh/pmat/pilotpmat.html for further details.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Karen F. Warburton at (301) 594-1744.

Sincerely yours,

A Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director, Division of Ophthalmic, and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Issued: 8-21-01

CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It

allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1)Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a)unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b)reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each



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identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1)A mix-up of the device or its labeling with another article.

(2)Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a)has not been addressed by the device's labeling or

(b)has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3)Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996 and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to the FDA whenever they receive or otherwise become aware of



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information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

(1)May have caused or contributed to a death or serious injury; or

(2)Has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for a PMA, the manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) using FDA Form 3500A, i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer is responsible for submitting a baseline report on FDA Form 3417 for a device when the device model is first reported under 21 CFR 803.50. This baseline report is to include the PMA reference number. Any written report and its envelope is to be specifically identified, e.g., "Manufacturer Report," "5-Day Report," "Baseline Report," etc.

Any written report is to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, Maryland 20847-3002

Copies of the MDR Regulation (FOD # 336&1336)and FDA publications entitled "An Overview of the Medical Device Reporting Regulation" (FOD # 509) and "Medical Device Reporting for Manufacturers" (FOD #987) are available on the CDRH WWW Home Page. They are also available through CDRH's Fact-On-Demand (F-O-D) at 800-899-0381. Written requests for information can be made by sending a facsimile to CDRH's Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at 301-443-8818.