



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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WARNING LETTER

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

VIA FEDERAL EXPRESS
VIA FACSIMILE

Michael R. Farris
President and CEO
LaserSight Technologies, Inc.
3300 University Boulevard
Suite 140
Winter Park, Florida 32792

Re: LaserScan LSX Excimer Laser System P980008

Dear Mr. Farris:

The Food and Drug Administration (FDA) has reviewed promotional material for the LaserScan LSX Excimer Laser found on your website at <http://www.lase.com>. This product is manufactured by LaserSight Technologies, Inc., and is a device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The LaserScan LSX Excimer Laser System was approved to perform photorefractive keratectomy (PRK) for the reduction or elimination of mild to moderate myopia (-1.0 to <-6.0 D) with ≤ 1.0 D of astigmatism in patients with documentation of a stable manifest refraction (± 0.5 D) over the past year.

Under the website subheading "Refractive/LSX," it states at the bottom of the page that "The approval is for the treatment of nearsightedness up to -6.0 diopters; however refractive surgeons in the U.S. may use the laser to treat patients for nearsightedness up to -10.0 diopters."

While FDA allowed the treatment range to be unlocked from -6.0 to -10.0D for use, it never gave approval for the device to be used at or above -6.0D. The "Warnings" sections of the approved labeling indicate that effectiveness is reduced for PRK treatment of myopia between -6.0 to -10.0D. A Warning message appears on the screen when treatments outside the approved range are entered. The message indicates that the device is not approved for treatment of myopia greater than or equal to -6.0D, and the safety and effectiveness are poorer. Your "Conditions of Approval" state that the appropriate warning statements should appear when the unlocked range is keyed in, and includes the statement that "This device is not approved for treatment of myopia greater than or equal to -6.0D." This disclaimer, however, is not intended to be used in promotional or advertising materials since LaserSight is not approved to promote this device beyond -6.0D.

In addition, the TECHNICAL SPECIFICATIONS Ablation zone is given as "3 to 9mm adjustable*" with an asterisked statement that indicates the "*US version has fixed ablation zone sizes of 5.5 mm to 8.5 mm for myopia and hyperopia, respectively..." The LaserScan LSX has been approved for a fixed ablation zone of 6.0mm, not 5.5mm, for myopia (PRK) only. Treatment of hyperopia is not an approved use for this device. An additional statement indicates the "System is LASIK-ready." The LaserScan does not yet have approval for treatment of LASIK, and should not be promoted for this unapproved use.

The LaserScan LSX is adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

The LaserScan LSX is also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use of the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the device was not found to be substantially equivalent to a predicate device. The Agency's regulations at 21 CFR 814.39 require that, after FDA approval of a device, applicants submit a PMA supplement for review and approval by FDA before making a change affecting the safety and effectiveness of the device for which the applicant has an approved PMA, unless the change is of a type for which FDA had advised that an alternate submission is permitted. In our opinion, the claims as noted above represent a change in the approved effectiveness of the device.

Various press releases under your "Investor Relations" subsite discuss international testing/uses of the laser and/or uses not approved in the United States, e.g., hyperopia and hyperopic astigmatism, LASIK trials underway for the treatment of hyperopia with astigmatism and mixed astigmatism, and a custom corneal ablation treatment under development, referred to as the Advanced Shape Technology Refractive Algorithms (ASTRA) technique. We caution you that, while it is acceptable to include this information for dissemination to investors, we would object if the information were promoted in press releases to the general public, or if the general readers of your internet site were specifically directed to the Investor site.

The LaserScan is also a restricted device. The sale, distribution, and use of the excimer laser is restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Act, under the authority of section 515(d)(1)(B)(ii) of the Act. FDA also determined that, to ensure the safe and effective use of the device, it was necessary to further restrict the device within the meaning of section 520(e) under 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 the order and (2) insofar as the sale and distribution must not violate sections 502(q) and 502(r) of the Act. The "Conditions of Approval" that accompany your PMA approval order, under the heading entitled "ADVERTISEMENT," states that "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."

The PMA approval order further states that these restrictions on the use, labeling, promotion, and advertising of the device are applicable not only to the manufacturer, but to device purchasers and users as well. The manufacturer must notify the purchasers and users of these restrictions and include them in their training programs.

Therefore, in accordance with 21 CFR 801.109(d) and 502(r) of the Act, we believe that LaserSight's promotional materials should include a brief statement of the intended uses of the device, and the relevant warnings, precautions, side effects, and contraindications from the PMA Summary of Safety and Effectiveness. Additionally, the approval conditions for PMA P980008 listed eight items (a-h) that were to be included in all promotion and advertising for this device, on indications, risks and benefits.

Please note that referring readers to the product labeling is not a substitute for the required information. Readers may be directed to the device's labeling, physician's manual, or patient information booklet for a complete listing of these items, but the advertising material must still include the brief statement of the intended uses and relevant warnings, precautions, side effects and contraindications.

Section 502(r) makes no reference or distinction as to whom this information is directed to, i.e., physician or lay consumer. Consumers, whether health care professionals or lay users, want to be able to compare devices or to compare the device with an alternative approach to treatment. Advertising is a particularly

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important source for comparative information, and provides both positive and negative information that sets one device apart from other similar devices or from alternatives.

This letter is not intended to be an all-inclusive list of deficiencies associated with your LaserScan LSX Excimer Laser System. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

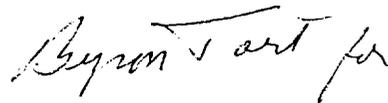
You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. 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 Ms. Patricia L. Jahnes, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-300), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Florida District Office. Please send a copy of your response to the District Director, Food and Drug Administration, 555 Winderly Place, Suite 200, Maitland, Florida, 32751.

Sincerely yours,



Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health