DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date NOV 15 1996

From Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Subject Premarket Approval of LaserVision Centers, Inc.'s - LaserVision™/VISX Excimer Laser System Model C for Phototherapeutic Keratectomy (PTK) and Photorefractive Keratectomy (PRK) - ACTION

To The Director, CDRH
ORA _____

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

(1) a premarket approval order for the above referenced medical device (Tab B); and

(2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.

Susan Alpert, Ph.D./M.D.

Attachments
Tab A - Notice
Tab B - Order
Tab C - S & E Summaries

DECISION

Approved _____ Disapproved _____ Date _____

Prepared by Ms. Marsha L. Burke Nicholas, CDRH, HFZ-460, 10/9/96, 594-2018

cc: HFC -10 (w/original attachments and one copy)
HFZ-401 DMC (with attachments)
HFZ-402 PMA (with attachments)
HFZ-460 PMA (with attachments)

P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[DOCKET NO. _____]

LaserVision Centers, Inc.; PREMARKET APPROVAL OF LaserVision^{R}/Visx Excimer Laser System Model C For Phototherapeutic Keratectomy(PTK) AND Photorefractive Keratectomy (PRK)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by LaserVision Centers, Inc., St. Louis, MO, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the stationary LaserVision^{R}/VISX Excimer Laser System Model C for Phototherapeutic Keratectomy (PTK) and Photorefractive Keratectomy (PRK). The device is to be manufactured under an agreement with VISX, Inc., Santa Clara, CA, which has authorized LaserVision Centers, Inc. to incorporate information contained in its approved premarket approval applications for the VISX Excimer Laser System (Model C) for Phototherapeutic Keratectomy (PTK) and for the VISX Excimer Laser System Model C for Photorefractive Keratectomy (PRK). FDA's Center for Devices and Radiological Health (CDRH) notified that applicant, by letter of November 15, 1996, of the approval of the application.

DATES: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

B

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. For more information on the data which supported this application, please refer to the summary of safety and effectiveness and labeling for the VISX Excimer Laser Sytem Model C for PTK (under Docket Number 96M-0486) and for the VISX Excimer Laser System Model C for PRK (under Docket Number 97M-0084).

FOR FURTHER INFORMATION CONTACT:

Morris Waxler,
Center for Devices and Radiological Health (HFZ-460),
Food and Drug Administration,
9200 Corporate Blvd.,
Rockville, MD 20850,
301-594-2018.

SUPPLEMENTARY INFORMATION: On June 3, 1996, LaserVision Centers, Inc., St. Louis, MO 63141, submitted to CDRH an application for premarket approval of the stationary LaserVision^{R}/VISX Excimer Laser System Model C for Phototherapeutic Keratectomy (PTK) and Photorefractive Keratectomy (PRK). The device is a stationary excimer laser which delivers pulses at 193 nm wavelength. The device is indicated for PTK in patients with decreased best corrected visual acuity and/or with disabling pain that are the result of superficial corneal epithelial irregularities or stromal scars in the anterior one-third of the cornea. The

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patients must have failed with alternative treatment options. For safety, the immediate postoperative corneal thickness must not be less than 250 microns. Examples of those conditions that warrant PTK are: corneal scars and opacity (from trauma and inactive infections), dystrophies (Reis-Buckler's, granular and lattice), Thygeson's superficial keratitis, irregular corneal surfaces associated with filamentary keratitis and Salzmann's nodular degeneration, residual band keratopathy after unsuccessful EDTA treatment, and scars subsequent to previous (not concurrent) pterygium excision. In addition, the device is indicated for PRK for a 6.0 ablation zone in patients who are myopic and meet all of the following criteria: (1) 1.0 to 6.0 diopters of myopia with astigmatism of $\leq$ 1.0 diopters; (2) refractive change is within $\pm$ 0.5 diopter for one year prior to the laser treatment; and (3) 18 years of age or older.

The application includes authorization from VISX, Inc., Santa Clara, CA 95051-0703, to incorporate information contained in its approved premarket approval applications for VISX Excimer Laser System (Model C) for Phototherapeutic Keratectomy (PTK) and for the VISX Excimer Laser System Model C for Photorefractive Keratectomy (PRK).

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA

substantially duplicates information previously reviewed by this panel.

On November 15, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity For Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA

grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), ((21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated:_____.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert W. May
Vice Chairman, Secretary & General Counsel
LaserVision Centers, Inc.
540 Maryville Centre Drive
Suite 200
St. Louis, MO 63141

NOV 15 1996

Re: P960019
LaserVision®/VISX Excimer Laser System Model C for Phototherapeutic Keratectomy (PTK) and Photorefractive Keratectomy (PRK)
Filed: June 3, 1996
Amended: July 9 and 18, and September 16, 1996

Dear Mr. May:

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) for the stationary LaserVision®/VISX Excimer Laser System Model C for Phototherapeutic Keratectomy (PTK) and Photorefractive Keratectomy (PRK). The device is indicated for:

1. PTK in patients with decreased best corrected visual acuity and/or with disabling pain that are the result of superficial corneal epithelial irregularities or stromal scars in the anterior one-third of the cornea. The patients must have failed with alternative treatment options. For safety, the immediate postoperative corneal thickness must not be less than 250 microns. Examples of those conditions that warrant PTK are:

   a. corneal scars and opacity (from trauma and inactive infections),

   b. dystrophies (Reis-Buckler's, granular and lattice),

   c. Thygeson's superficial keratitis,

   d. irregular corneal surfaces associated with filamentary keratitis and Salzmann's nodular degeneration,

   e. residual band keratopathy after unsuccessful EDTA treatment, and,

   f. scars subsequent to previous (not concurrent) pterygium excision.

2. PRK for a 6.0 ablation zone in patients who are myopic and meet all of the following criteria:

   a. 1.0 to 6.0 diopters (D) of myopia with astigmatism of $\leq$ 1.0 diopters;

   b. refractive change is within $\pm$ 0.5 D for one year prior to the laser treatment; and

   c. 18 years of age or older.

The stationary LaserVision®/VISX Excimer Laser System Model C for PRK will only be enabled either through the use of the VisionKey™ Card or the software controls in the device to treat simple myopia (no astigmatism) -1.0 to -6.0 D.

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VISX, Inc., 3400 Central Expressway, Santa, Clara, CA 95051 is to be the sole supplier of the stationary LaserVision®/VISX Excimer Laser System Model C for PTK and PRK. VISX, Inc. will install and set up and initially calibrate the lasers. Additionally, maintenance and repairs are to be provided by VISX, Inc. or by VISX, Inc. trained and authorized persons.

We are pleased to inform you that the PMA is approved subject to the conditions described below and in the attached "Conditions of Approval". You may begin commercial distribution of the device upon receipt of this letter. All new uses of the laser will require submission, review, and approval of a PMA supplement before you may begin commercial distribution of the modified device.

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 that 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.

As stated in your amendment dated July 17, 1996, "LaserVision Centers, Inc. has received from VISX, Inc. a copy of the approval letters for PMAs P910062 and P930016 and concurs the restrictions and conditions of approval contained therein." The restrictions listed below on the use, labeling, promotion, and advertising of the device for PRK are applicable to LaserVision Centers, Inc., as well as device purchasers and users. LaserVision Centers, Inc. must notify the 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, and 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 myopic PRK and prior to undergoing surgery, must receive from the treatment provider the "Patient Information Booklet."

3. Prospective patients, prior to undergoing surgery, must be informed of alternatives for correcting their myopia including eyeglasses, contact lenses, and other refractive surgeries such as radial keratotomy.

4. Comparison of the safety and effectiveness of this laser with any other method of refractive correction is prohibited. 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 the indications, risks and benefits:

    a. Approval is for the stationary LaserVision Centers, Inc. application for the LaserVision®/VISX Excimer Laser System Model C to correct mild to moderate nearsightedness (-1.00 D to -6.0 D when concomitant astigmatism is not greater than 1.0 D) in a procedure called photorefractive keratectomy (PRK) using an excimer laser that emits light at a wavelength of 193nm.

    b. PRK is an elective procedure with the alternative including eyeglasses, contact lenses or radial keratotomy.

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c. Approval of this application is based on clinical trials of 480 eyes treated at 6 mm and followed for two years together with safety information on more than 1600 eyes through 3 years of follow up.

d. The studies using the 6 mm treatment zone found that of the 480 eyes with at least 2 years of follow-up, 94% were corrected to 20/40 or better, and 58% were corrected to 20/20 or better without spectacles or contact lenses. In 42 of 480 eyes (9%), the best vision that could be achieved with spectacles declined by more than 1 line from pre-operative; none was worse than 20/40.

e. These clinical trials showed the following transient complications: pain (24-48 hours), foreign body sensation, tearing, photophobia, redness, itching/scratchiness, burning, dryness, headache, blurred vision, corneal swelling and pupil enlargement. These problems lasted up to several weeks.

f. The clinical trials using the 6 mm treatment zone showed that the following adverse events occurred in at least 1.0% of the patients at two years post-treatment: overcorrection >1 D (1.0%); pre-treatment Best Spectacle Corrected Visual Acuity (BSCVA) of 20/20 or better with post-treatment BSCVA worse than 20/25 (1.3%); double vision (1.3%); sensitivity to bright lights (1.7%); increase in refractive cylinder $\geq$1 D (2.9%); difficulty with night vision (3.1%); and intraocular pressure (IOP) increase of > 5 mm Hg (3.6%).

g. Long term risks of PRK beyond 3 years have not been studied.

h. This laser is not indicated to correct high myopia (nearsightedness >-6.0 D), astigmatism, or farsightedness. Also it is not indicated to correct nearsightedness of less than -6.0 D if the accompanying astigmatism is > 1.0 D. It is not to be used in procedures other than PRK or PTK as described the approved Operator's Manuals.

i. Note that the complete name for this stationary ophthalmic laser is "LaserVision®/VISX Excimer Laser System Model C for Phototherapeutic Keratectomy (PTK) and for Photorefractive Keratectomy (PRK) for the correction of Mild to Moderate Myopia (-1.0 D to -6.0 D) with Low Astigmatism ($\leq$ 1.0 D)". Two acceptable versions of this official name are: "PRK laser correction of low myopia" and "PRK laser correction of low nearsightedness". The word excimer, ultraviolet, or UV may be used instead of PRK. Also, these do not have to contain the qualifiers mild to moderate (-1.0 D to -6.0 D) or low astigmatism ($\leq$1.0 D) if the adjacent text provides this information. Names other than those appearing above require approval in a PMA supplement.

In addition to the postapproval requirements in the enclosure, LaserVision Centers, Inc. should provide the following information to the Agency as soon as the information becomes available:

1. As stated in the agreement dated August 23, 1996 (submitted in an amendment dated September 12, 1996) and signed by both you and VISX, Inc., you will provide to VISX, Inc. information to be included in the annual reports for P910062 and P930016 regarding any unscheduled maintenance visits (i.e., those beyond the usual laser maintenance schedule) to monitor laser performance and reliability. When reporting each unscheduled maintenance visit, please include the data from the PMMA calibrations performed in the 6 weeks prior to the visit.

2. As stated in the agreement dated August 23, 1996, you will provide to VISX, Inc. any instances of device tampering or usage outside of the approved indication, and any excimer systems that were exported under an 801(e) order and are now back in the U.S. VISX, Inc. will forward these reports to FDA CDRH's Office of Compliance at the address below.

OC/Division of Enforcement (HFZ-331)
Center for Devices and Radiological Health
Food and Drug Administration
2098 Oakgrove Drive
Rockville, Maryland 20850

3. You should report all complications as part of your annual reporting.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, 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 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 in final printed form.

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 Ms. Marsha L. Burke Nicholas or Morris Waxler, Ph.D. at (301) 594-2018.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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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.

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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 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 mixup 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, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

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

(2) has malfunctioned and that the device or any other 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 this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-531)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, 340
Rockville, Maryland 20850
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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Summary of Safety and Effectiveness Data

I. General Information

A. Device Generic Name: excimer laser system for phototherapuetic keratectomy (PTK)and photorefractive keratectomy (PRK)

B. Device Trade Name: LaserVision^{R}/Visx Excimer Laser System Model C for Phototherapuetic Keratectomy (PTK) and Photorefractive Keratectomy (PRK)

C. Applicant's Name and Address: LaserVision Centers, Inc.
540 Maryville Centre Drive
Suite 200
St. Louis, MO 63141

D. Premarket Approval Application (PMA) Number: P960019

E. Date of Notice of Approval to Applicant: November 15, 1996

II. Indications

The device is a stationary excimer laser which delivers pulses at 193 nm wavelength. The device is indicated for PTK in patients with decreased best corrected visual acuity and/or with disabling pain that are the result of superficial corneal epithelial irregularities or stromal scars in the anterior one-third of the cornea. The patients must have failed with alternative treatment options. For safety, the immediate postoperative corneal thickness must not be less than 250 microns. Examples of those conditions that warrant PTK are: corneal scars and opacity (from trauma and inactive infections), dystrophies (Reis-Buckler's, granular and lattice), Thygeson's superficial keratitis, irregular corneal surfaces associated with filamentary keratitis and Salzmann's nodular degeneration, residual band keratopathy after unsuccessful EDTA treatment, and scars subsequent to previous (not concurrent) pterygium excision. In addition, the device is indicated for PRK for a 6.0 ablation zone in patients who are myopic and meet all of the following criteria: (1) 1.0 to 6.0 diopters of myopia with astigmatism of $\leq$ 1.0 diopters; (2) refractive change is within $\pm$ 0.5 diopter for one year prior to the laser treatment; and (3) 18 years of age or older.

III. Center for Devices and Radiological Health (CDRH) Decision

The application includes by reference the data in PMA P910062 and P930016 for the VISX Excimer Laser System (Model C) for Phototherapeutic Keratectomy (PTK) and for the VISX Excimer Laser System Model C for Photorefractive Keratectomy (PRK) submitted by

VISX, Inc. and approved by FDA on September 29, 1995 and March 27, 1996, respectively. VISX, Inc. has authorized LaserVision Centers, Inc. to incorporate by reference the information contained in its approved PMAs. For more information on the data which supported this application, please refer to the Summary of Safety and Effectiveness Data (SSED) and labeling for P910062 (under Docket #96M-0486) and for P930016 (under Docket #97M-0084) which can be obtained from the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmic Devices Panel for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel. CDRH approved this application and final labeling on November 15, 1997.

IV. Approval Specifications

A. Postapproval Requirements and Restrictions: See Approval Order

B. Hazards to Health from Use of the Device: See Indications Contraindications, Warnings, Precautions and Adverse Events in the Labeling