

Premarket Approval (PMA) Package for
Dockets Management Branch

PMA Number P930034/S12
Docket # 00M-0424

Summit Technology, Inc.
SVS Apex Plus Excimer Laser Workstation,
emphasis discs (K and L) and axicon

Includes:

Approval Order
Summary of Safety and Effectiveness Data (SSED)
Labeling

00M-0424

AAVI



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Eric P. Ankerud, J.D.
Vice President,
Quality, Regulatory, and Clinical Affairs
Summit Technology, Inc.
21 Hickory Drive
Waltham, MA 02154

OCT 21 1999

Re: P930034/S12
SVS Apex Plus Excimer Laser Workstation, emphasis® discs K and L, and
axicon for hyperopic photorefractive keratectomy
Filed: July 14, 1998
Amended: November 16, 1998; February 9, April 2 and 30, June 14, July 6, 8, and
29, August 25, and October 1, 1999

Dear Mr. Ankerud:

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 SVS Apex Plus Excimer Laser Workstation, emphasis® discs K and L, and axicon. These devices are indicated to perform hyperopic PRK:

- for the reduction or elimination of mild to moderate hyperopia (+1.5 to + 4.0 D) with low astigmatism (<-1.00D) at the spectacle plane;
- in patients with documentation of a stable manifest refraction ($\pm 0.5D$) over the past year; and,
- in patients who are 21 years of age or older

We are pleased to inform you that 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 upon receipt of this letter.

1. The SVS Apex Plus Excimer Laser Workstation, emphasis® discs K and L, and axicon will only be enabled for treating hyperopia up to and including +4.0 D.

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2. A post-approval study will be conducted to continue assessment of the stability of treatment, rate of loss in best corrected visual acuity, and rate of retreatment in the K108 treated subjects at 18 months. Depending on the 18 months data, 24 months data may be required for this group of patients. These data will be included in the labeling.

The sale, distribution, and use of these devices 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.

These restrictions on the use, labeling, promotion, and advertising of the device are applicable to Summit Technology, Inc., as well as device purchasers and users. Summit 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, who have been trained in laser refractive surgery (for hyperopia) 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 Hyperopic PRK 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 hyperopia 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 supplemental 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 the Summit Technology, Inc.'s application for the SVS Apex Plus Excimer Laser Workstation and emphasis® disc to perform hyperopic photorefractive keratectomy (PRK) for the reduction or elimination of mild to

moderate hyperopia (+1.5 to +4.0 D) with low astigmatism (< -1.0 D) at the spectacle plane; in patients with documentation of a stable manifest refraction (± 0.5 D) over the past year; and, in patients who are 21 years of age or older.

- b. Hyperopic PRK is an elective procedure with the alternatives including eyeglasses, contact lenses, and hexagonal keratotomy.
- c. Approval of the application is based on a U. S. study of 165 eyes followed for twelve months, together with supplemental safety and effectiveness information from the eighteen-month exam.
- d. The study found that of the treated eyes, 91.7% were corrected to 20/40 or better, and 45.8% were corrected to 20/20 or better without spectacles or contact lenses.
- e. The study showed the following adverse reactions occurred in at least 1% of the subjects at twelve month post-treatment: double images in the operative eye (1.7%), foreign body sensation (1.7%), ghost images in the operative eye (2.2%), undercorrected by > 2 D (2.4%), glare (2.8%), patient discomfort (3.4%), loss of near or distance acuity with glasses of ≥ 2 lines (4.5%), and anterior stromal haze (10.7%).
- f. Long term risks of hyperopic PRK beyond 18 months have not been studied.
- g. This laser is not indicated to correct farsightedness less than +1.5 D or more than +4.0 D. It is not to be used in procedures other than those described in the approved Operator's Manual.
- h. Note that the complete name for the approved device is "SVS Apex Plus Excimer Laser Workstation, emphasis® discs K and L, and axicon for photorefractive keratectomy (PRK) for the reduction or elimination of mild to moderate hyperopia (+1.5 to + 4.0 D) with low astigmatism (< -1.00 D) at the spectacle plane. The word excimer, ultraviolet, or UV may be used instead of PRK. Names other than those above 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

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.

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 20857. 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).

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA supplement submission with copies of all approved labeling in final printed form.

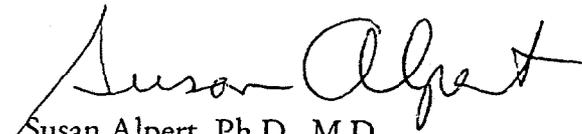
All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

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

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If you have any questions concerning this approval order, please contact Ms. Quynh Hoang at (301) 594-2018.

Sincerely yours,

A handwritten signature in black ink that reads "Susan Alpert". The signature is written in a cursive style with a large, sweeping initial "S".

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

Enclosure: "Conditions of Approval"

Issued: 3-4-98

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 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 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 Assistance (DSMA) at 301-443-8818.

SUMMARY OF SAFETY AND
EFFECTIVENESS DATA (SSED)

**SUMMARY OF SAFETY AND EFFECTIVENESS DATA
FOR A SUPPLEMENTAL PREMARKET APPROVAL APPLICATION**

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I. GENERAL INFORMATION

Device Generic Name: Ophthalmic Excimer Laser System

Device Trade Name: SVS Apex Plus Excimer Laser Workstation, emphasis® discs (K and L), and axicon

Applicant's Name and Address: Summit Technology, Inc.
21 Hickory Drive
Waltham, MA 02154 USA

Premarket Approval Application (PMA) Supplement Number: P930034/S12

Date of Notice of Approval to Applicant: October 21, 1999

The SVS Apex Plus Excimer Laser Workstation was approved on February 7, 1997 for both phototherapeutic keratectomy (P910067/S1) and myopic photorefractive keratectomy using a 6.0 mm ablation zone in patients 21 years of age or older with myopia 1.5 to 7.0 D and concomitant astigmatism ≤ 1.5 D and for whom the refractive change for the one year prior to the laser treatment is within ± 1.0 D (P930034/S2). On March 11, 1998 (P930034/S9), the indication for the laser, with the addition of emphasis® discs M, was expanded to include toric photorefractive keratectomy for the reduction or elimination of mild to moderate myopia (-1.00 to < -6.00 D) and concomitant reduction or elimination of mild to moderate astigmatism (-1.00 to < -4.00 D), in which the combined attempted correction must be < -6.00 D spherical equivalent at the spectacle plane. The sponsor submitted the current supplement to further expand the indication statement. The updated pre-clinical and clinical work to support this expanded indication is provided in this summary. For more information on the data that supported the approved indications, the Summaries of Safety and Effectiveness Data to the respective PMA applications should be requested from the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Please identify Docket # 95M-0179 for phototherapeutic keratectomy, #96M-0274 for myopic photorefractive keratectomy, or #98M-0329 for toric photorefractive keratectomy. The summaries can also be found on the FDA CDRH Internet Home Page located at <http://www.fda.gov/cdrh/pmapage.html>.

II. INDICATIONS FOR USE

The SVS Apex Plus Excimer Laser Workstation, emphasis® discs K and L, and axicon are indicated to perform hyperopic photorefractive keratectomy (PRK):

- for the reduction or elimination of mild to moderate hyperopia (+1.5 to + 4.0 D) with low astigmatism (<-1.00D) at the spectacle plane;
- in patients with documentation of a stable manifest refraction ($\pm 0.5D$) over the past year; and,
- in patients who are 21 years of age or older.

III. CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS

A. CONTRAINDICATIONS:

Hyperopic PRK treatment should not be performed in:

1. patients with uncontrolled vascular disease or auto-immune diseases because it is well known that these patients have difficulty in corneal healing and are more susceptible to corneal melting;
2. women who are pregnant and/or nursing, due to the potential for temporary fluctuation in refraction during this time;
3. patients with signs of keratoconus since eyes with this condition may have unstable corneas;
4. patients known to have a previous history of keloid formation because their corneal healing response is less predictable; or,
5. patients taking Accutane (isotretinoin) or Cordarone (amiodarone hydrochloride)

B. WARNINGS:

1. Hyperopic PRK should not be performed in patients whose refractive history is unstable since an accurate pretreatment baseline refraction for the calculation of the desired correction can not be obtained.
2. Hyperopic PRK is not recommended in patients with Herpes Simplex Virus or Herpes Zoster since cases of herpes reactivation have been

reported after use of the excimer laser. Further clinical experience is necessary regarding the use of the 193 nanometer excimer laser wavelength in patients with these conditions.

C. PRECAUTIONS:

1. Hyperopic PRK should not be performed in patients who are unable to cooperate during the treatment because of the potential difficulty in aligning the laser beam and keeping the eye steady during the treatment.
2. Prior to removing the epithelium, the practitioners should arm and test the laser to ensure that it is ready to deliver laser energy.
3. The long term safety and effectiveness of Hyperopic PRK has not been established.
4. The safety and effectiveness of Hyperopic PRK in patients who are under 21 years of age have not been established.
5. The safety and effectiveness of Hyperopic PRK in patients taking Imitrex (sumatriptan succinate) have not been studied.
6. Although the effects of Hyperopic PRK on visual performance under poor lighting conditions have not been determined, it is possible that post-procedure patients will find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog, or glare from bright lights at night.
7. Patients with known sensitivity to any of the treatment medications
8. Patients with a history of glaucoma because of the potential for a strong response to postoperative steroids.

IV. DEVICE DESCRIPTION

The Apex Plus, emphasis® discs (K and L), and axicon constitute the device that is the subject of this PMA supplement. Hyperopic correction is delivered by the laser and disc within the central 6.5 mm diameter, and by the laser and axicon from 6.5 to 9.5 mm. The optical zone or the area that provides the actual refractive correction is within the central 5.0 mm diameter.

The excimer laser is the same one previously approved for Toric PRK, but with the addition of the software for hyperopic correction. The emphasis® discs for hyperopic correction are models K and L. Ten discs are made available for corrections from +1.5 to

+ 4.0 D. The axicon is an optical lens that converts the round shape of the excimer beam into a ring shape.

V. ALTERNATE PRACTICES AND PROCEDURES

There are currently three other alternatives for the correction of mild to moderate hyperopia:

Contact Lenses
Hexagonal Keratotomy
Spectacles

Each alternative has its own advantages and disadvantages. A prospective patient should fully discuss with his/her care provider these alternatives in order to select the correction method that best meets his/her expectation and lifestyle.

VI. MARKETING HISTORY

Since 1995, Summit Technology, Inc. has sold or distributed over 300 Apex Plus worldwide. The Summit Excimer Laser System has not been withdrawn from any country or market for reasons of safety or effectiveness.

VII. ADVERSE EFFECTS OF THE DEVICE ON HEALTH

During the immediate/early postoperative period, reported problems include: postoperative pain (first 24 to 48 hours), discomfort, double vision, foreign body sensation, ghost images, and peripheral corneal epithelial defect. These signs and symptoms appear to subside several months after surgery.

The adverse reactions reported at the postoperative examinations include: anterior stromal reticular haze, loss of best spectacle near or distance acuity, undercorrection, overcorrection, glare, halo, foreign body sensation, patient discomfort, ghost images, double images, light sensitivity, ptosis, dryness/night driving difficulties, persistent central corneal epithelial defect, peripheral corneal epithelial defect, and recurrent corneal erosion.

A rates of these adverse reactions at the 6 month visit, 12 month stability time point, and 18 month visit are found in the Summary of Clinical Study of this document (section IX.F.2.d).

VIII. SUMMARY OF PRECLINICAL STUDIES

Each disc was individually verified with a lensometer. In addition, nonclinical laboratory studies were performed to evaluate the achieved profiles (depth, width, and radius of curvature) in polymethylmethacrylate (PMMA). Sets of K and L discs were tested in PMMA to verify that their profiles follow an expected linear relationship of curvature (inverse radius) versus diopter.

A hazard analysis was performed to evaluate the effect of the hardware and software modifications for hyperopia correction. The safety or effectiveness of the device was not determined to be affected by the change.

IX. SUMMARY OF CLINICAL STUDY

The sponsor performed a clinical study of the K discs in the US and England under the auspices of an IDE G900142. The data from this study served as the basis for the approval decision. Specifically, safety and effectiveness outcomes at 12 months postoperative were assessed as stability is reached by that time. Outcomes at 18 months postoperatively and data from another site in England were also evaluated for confirmation. The IDE study is described in detail as follows.

A. STUDY OBJECTIVES

The overall reason for the Hyperopic PRK procedure was defined by two main treatment goals: improving uncorrected near vision or improving uncorrected distance vision. Since safety from this type of procedure has been demonstrated previously, the effectiveness of the device for the proposed indication was the primary objective of the study.

B. STUDY DESIGN

The study was a prospective, multi-center, two-arm cohort study where the primary control was the preoperative state of the treated eye (*i.e.*, comparison of pretreatment and post-treatment visual parameters in the same eye).

C. INCLUSION AND EXCLUSION CRITERIA

Enrollment in the Hyperopic PRK study was limited to patients in need of mild to moderate spherical corrections of +1.00 to +4.00 D; preoperative distance best spectacle corrected visual acuity (BSCVA) of 20/32 or better; preoperative near BSCVA of 20/30 or better; preoperative best contact lens over refraction corrected visual acuity ("BCCVA") that did not differ more than 11 letters from the BSCVA; and refractive stability within ± 1.00 D for a period of at least one year.

Subjects entering the near vision treatment group were required to have a preoperative near uncorrected visual acuity (UCVA) of worse than 20/40. Subjects entering the distance vision treatment group were required to have distance UCVA of worse than 20/40.

Patients were not permitted to enroll in the Hyperopic Study if they met any of the following exclusion criteria: functionally monocular (i.e., BSCVA of fellow eye worse than 20/40); difference of more than 1.00 D between preoperative MRSE and cycloplegic refraction spherical equivalent; more than 1.00 D of corneal astigmatism, history of glaucoma or a preoperative intraocular pressure of 21 mm Hg or greater; irregular astigmatism; progressive retinal pathology, such as diabetic retinopathy; clinically significant cataract; signs of keratoconus; previous intraocular or corneal surgery; any systemic autoimmune disease or disseminated vasculopathies; herpes simplex or herpes zoster; or are pregnant or nursing.

D. STUDY PLAN, PATIENT ASSESSMENTS, AND EFFICACY CRITERIA

All subjects were expected to return for follow-up examinations at 1, 3, and 7 days (only required at 7 days if not re-epithelialized at 3 days), and 1, 3, 6, 9, 12, 18 and 24 months postoperatively.

Subjects were permitted to have second eyes (fellow eyes) treated a minimum of three months after treatment of the first eye. In addition, subjects were eligible for retreatment if they had a stable UCVA of worse than 20/40 and a stable MRSE greater than +1.00 D. Retreatment was not permitted until at least six months after the initial treatment.

Preoperatively, the subject's medical and ocular histories were recorded. Immediately postoperative, re-epithelialization data were collected. The objective parameters measured during the study included best spectacle corrected visual acuity (near, distance, with and without glare), uncorrected visual acuity (near and distance), manifest and cycloplegic refraction, intraocular pressure, pupil size and status of the cornea, conjunctiva, anterior chamber, lens, vitreous, retina, and externals. Corneal topography was performed on all subjects preoperatively, and postoperatively in subjects with certain adverse reactions. Specular microscopy was performed on the first 50 subjects. A patient questionnaire was to be administered to all subjects preoperatively and postoperatively at 6, 12, 18 and 24 months.

The primary efficacy variables for this study were: improvement of near or distance UCVA based on the per eye treatment goal of the procedure, and predictability of manifest refraction spherical equivalent (MRSE).

E. STUDY PERIOD, INVESTIGATIONAL SITES, AND DEMOGRAPHICS

1. STUDY PERIOD AND INVESTIGATIONAL SITES

Subjects were treated between January 31, 1997 and September 29, 1998. The database for this PMA supplement reflected data collected through March 31, 1999 and included 201 eyes: 119 first eyes and 82 second eyes. There were eight investigational sites.

TABLE 1: INVESTIGATION SITES	
Principal Investigator/Co-Investigator and Site	Number of eyes treated
Peter Hersh, MD The Cornea and Laser Vision Institute Teaneck, NJ	17
Steven Wilson, MD Cleveland Clinic Cleveland, OH	20
Jonathan Rubenstein, MD/ Robert Mack, MD Rush Presbyterian-St. Luke's Eye Center Physicians Ltd. Chicago, IL	3
Michael Gordon, MD/Perry Binder, MD Vision Surgery and Laser Center San Diego, CA	49
Vance Thompson, MD Ophthalmology, Ltd Sioux Empire Medical Center Sioux Falls, SD	43
Helen Wu, MD/Roger Steinert, MD Lawrence Memorial Eye Clinic Medford, MA	31
Edward Manche, MD Stanford University Medical Center Stanford, CA	18
Prof. John Marshall/ Christopher G. Stephenson, MD United Medical and Dental Schools Department of Ophthalmology St. Thomas' Hospital London, England	20
TOTAL	201

2. DEMOGRAPHICS

The demographics of this study were predominantly female (66%) and Caucasians (94%). The mean age of the subjects treated was 55 ± 7 years with a range from 35 to 71. The majority of patients (53%) fell in the 50-

59 age decade. Preoperative patient characteristics that were found to associate with outcomes are discussed in section IX.F.2.f.

No patient in this study was younger than 35. The sponsor provided literature references for hyperopia in the younger population. The FDA Ophthalmic Devices Advisory Panel (the Panel) has previously recommended an age limit as low as 21 for this group of patients. Younger than 21 was not deemed acceptable because stability of refraction may not be reached in young patients. Based on the available data, the approved indication was limited to 21 years of age and older.

Table 2: Preoperative Characteristics	
Distance	
UCVA 20/40 or better*	24/168 (14.3%)
UCVA 20/50 to 20/80	66/168 (39.3%)
UCVA 20/100 or worse	78/168 (46.4%)
*protocol deviation; to be excluded from PMA cohort	
Near	
UCVA 20/40 or better*	0
UCVA 20/50 to 20/80	1/26 (3.8%)
UCVA 20/100 or worse	25/26 (96.2%)
*protocol deviation; to be excluded from PMA cohort	
Manifest refraction sphere (D)	>0.0 to <=1.0 8/194 (4.1%) >1.0 to <=2.0 89/194 (45.9%) >2.0 to <=3.0 56/194 (28.9%) >3.0 to <=4.0 28/194 (14.4%) >4.0 to <=5.0 12/194 (6.2%) >6.0 to <=7.0 1/194 (0.5%) Mean 2.33 Std. Dev. 1.02
Attempted Spherical Correction (D)	+1.6D (disc K102) 70/194 (36.1%) +2.3D (disc K104) 36/194 (18.6%) +3.1D (disc K106) 35/194 (18.0%) +3.9D (disc K108) 53/194 (27.3%)
Cylinder (D)	0.00 60/194 (30.9%) -0.25 33/194 (17.0%) -0.5 59/194 (30.4%) -0.75 28/194 (14.4%)

F. DATA ANALYSIS AND RESULTS

1. PREOPERATIVE CHARACTERISTICS

Table 2 contains a summary of the preoperative acuity and refraction. Note that per protocol, subjects with preoperative refractive error greater than that specified in the inclusion criteria can be enrolled in the study as long as the correction that was being sought fell within the range specified for the study. The attempted correction is therefore not indicative of a subject's preoperative refractive error, but rather dependent on the treatment goal for each eye: to improve near or distance vision.

2. POSTOPERATIVE RESULTS

a. Accountability and definition of the PMA cohort

At the 12 month visit, 178 eyes were available for analysis, yielding an accountability rate of 92% (table 3). The 178 eyes represented the cohort available for safety analysis at twelve months.

At twelve months, the PMA cohort or the cohort available for the effectiveness analysis consisted of 165 eyes. Six protocol deviated and seven retreated eyes were excluded from this PMA cohort.

Status	1 months	3 months	6 months	9months	12 months	18 months
Discontinued (Death)	0	0	0	1	2	2
Not Eligible for Interval	0	0	0	4	5	137
Unavailable for Visit						
Overdue	0	2	1	21	1	3
Missed Visit	2	5	7	14	11	1
Lost to Follow-up	1	1	3	4	4	4
Available for Analysis	198	193	190	157	178	54
Evaluable = Avail-retreated - protocol deviations	191	186	183	148	165	51
% Accountability= Avail/(201-discont.-not eligible)	99	96	95	80	92	87

b. Stability of outcome

In the 9-12 months window, greater than 95% of eyes experienced a change of MRSE not exceeding $\pm 1.0D$. Furthermore, the mean of the pair-difference of MRSE progressively decreased over time, and reached a change of about 0.1 D in the 9-12 months window (tables 4 and 5). The changes in the 12-18 months window for the entire cohort were smaller than those observed in the previous time window; thus, stability was demonstrated by 12 months postoperative. The assessment of the efficacy was therefore performed using the outcomes of the 165 eyes evaluable at 12 months.

It was however noted that when the data are stratified by discs, the amount of change for disc K108 in the 12-18 months window was slightly higher than that observed in the previous time window. This observation was a reason behind the post approval requirement of continued monitoring of the eyes treated with this disc.

Table 4: Stability Analyses (change in MRSE over time for eyes that had every exam, through 12 months)				
Analysis	1 to 3 Months	3 to 6 Months	6 to 9 Months	9 to 12 Months
Change $\leq 1 D$ N/N (%) (95% CI)	102/131 (77.9%) (69.8,84.6)	116/131 (88.5%) (81.8,93.4)	119/131 (90.8%) (84.5,95.2)	126/131 (96.2%) (91.3,98.7)
Change (Pair-Differences)				
Mean	0.48	0.233	0.145	0.094
Std.Dev.	0.746	0.635	0.576	0.481
(95% CI)	(0.35,0.61)	(0.12,0.34)	(0.05,0.24)	(0.01,0.18)

Table 5: Stability Analyses (change in MRSE over time for eyes that had 2 consecutive exams, through 12 months)				
Analysis	1 to 3 Months	3 to 6 Months	6 to 9 Months	9 to 12 Months
Change $\leq 1 D$ n/N (%) (95% CI)	141/184 (76.6%) (69.8,82.5)	160/177 (90.4%) (85.1,94.3)	129/142 (90.8%) (84.9,95)	131/137 (95.6%) (90.7,98.4)
Change (Pair-Differences)				
Mean	0.525	0.243	0.147	0.08
Std.Dev.	0.74	0.608	0.572	0.492
(95% CI)	(0.42,0.63)	(0.15,0.33)	(0.05,0.24)	(0,0.16)

c. Effectiveness Outcomes

The analysis of effectiveness was based on the 165 eyes evaluable at the 12 months stability time point. Of the 165 eyes, there were 21 in which treatment was for near vision; hence, these 21 eyes were excluded from the presented UCVA data in table 6 since they pertained to distance vision. The near UCVA outcomes of these 23 eyes at 12 months were: 5/21 (23.8%) with 20/20 or better, 10/21 (47.6%) with 20/25 or better, and 17/21 (81.0%) with 20/40 or better.

To simplify the effectiveness analysis, the intended versus the achieved correction (predictability) of each disc was evaluated in table 6. Effectiveness by treatment goal was not scrutinized, because the sponsor was not pursuing this claim given the small number (23 eyes) treated for near vision. Effectiveness by preoperative refraction was not deemed appropriate because the amount of correction does not necessarily correlate with the patient's preoperative refraction.

Table 6 revealed better performance with lower levels of correction. MRSE \pm 1.0 D followed the same trend but remained above 75% for all discs. Overall, the effectiveness of the device was deemed acceptable.

Table 6: Summary of Key Effectiveness Variables at 12 Months by Disc					
Efficacy Variables	Disc				Cumulative n/N (%) (95%CI)
	n/N (%) (95% CI)				
	K102: 1.6D	K104: 2.3D	K106: 3.1D	K108: 3.9D	
UCVA 20/20 or better	32/56 (57.1%) (43.2,70.3)	17/34 (50.0%) (32.4,67.6)	8/24 (33.3%) (15.6,55.3)	9/30 (30.0%) (14.7,49.4)	66/144 (45.8%) (37.5,54.3)
UCVA 20/25 or better	44/56 (78.6%) (65.6,88.4)	25/34 (73.5%) (55.6,87.1)	12/24 (50.0%) (29.1,70.9)	17/30 (56.7%) (37.4,74.5)	98/144 (68.1%) (59.8,75.6)
UCVA 20/40 or better	54/56 (96.4%) (87.7,99.6)	33/34 (97.1%) (84.7,99.9)	21/24 (87.5%) (67.6,97.3)	24/30 (80.0%) (61.4,92.3)	132/144 (91.7%) (85.9,95.6)
MRSE +/- 0.50 D	42/56 (75.0%) (61.6,85.6)	17/34 (50.0%) (32.4,67.6)	13/30 (43.3%) (25.5,62.6)	20/45 (44.4%) (29.6,60)	92/165 (55.8%) (47.8,63.5)
MRSE +/- 1.00 D	54/56 (96.4%) (87.7,99.6)	28/34 (82.4%) (65.5,93.2)	23/30 (76.7%) (57.7,90.1)	34/45 (75.6%) (60.5,87.1)	139/165 (84.2%) (77.8,89.4)
MRSE +/-	56/56	33/34	28/30	43/45	160/165

	(100.0%) (93.6,100)	(97.1%) (84.7,99.9)	(93.3%) (77.9,99.2)	(95.6%) (84.9,99.5)	(97.0%) (93.1,99)
2.00 D					

d. Safety Outcomes

The analysis of safety was based on the entire 178 eyes that have had the 12 months exam. The key safety outcomes for this study are presented in table 7, with all the adverse reactions reported in tables 8 and 9. It should be noted that the safety of the device for PRK was not based on this small sample size alone, but rather on all the available data for the device for this type of procedure to date. The safety data from this study were for confirmatory purposes. Overall, the device was deemed reasonably safe.

It was observed that the loss of BSCVA ≥ 2 lines appeared to be higher in eyes treated with K108 than with the other discs, which may be due to the low N. A closer look at the 3 affected eyes revealed that none had the 18 months follow-up exam; only one had 20/40 or worse BSCVA, and, none had undergone re-treatment prior to the loss of BSCVA. Longer follow-up of these eyes was needed to determine their natural course of progression. This was the second reason behind the post approval requirement of continued monitoring of the eyes treated with the K108 disc.

Efficacy Variables	Disc				Cumulative n/N (%) (95%CI)
	n/N (%) (95%CI)				
	K102: 1.6D N=61	K104: 2.3D N=34	K106: 3.1D N=34	K108: 3.9D N=49	
Loss of > 2 Lines Distance BSCVA	1/61 (1.6%) (0,8.8)	0 (0,10.3)	0 (0,10.3)	1/49 (2.0%) (0.1,10.9)	2/178 (1.1%) (0.1,4)
Loss of 2 Lines Distance BSCVA	0 (0, 5.9)	1/34 (2.9%) (0.1, 15.3)	0	2/49 (4.1%) (0.5,14.0)	3/178 (1.7%) (0.3,4.8)
Increase of >2.0D Cylinder	0	0	0	0 (0,7.3)	0 (0, 2.1)
Distance BSCVA worse than 20/40	0	0	0	0	0 (0, 2.1)
Distance BSCVA	1/61	0	0	0	1/178

Table 7: Summary of Key Safety Variables at 12 Months by Disc					
worse than 20/25 if 20/20 or better preoperatively	(1.6%)				(0.6%) (0,3.1)

Table 8 presents a summary of the FDA defined adverse events. The benchmark for each adverse event is a rate of less than 1 % per event. For the PMA cohort which has a sample size of 178 eyes, a 0 observed rate means that the true rate can be as high as 2.1% (in simple terms, if this study of 178 eyes were to be repeated over and over again, the observed adverse event rate for each study may be different each time but it will not be higher than 2.1%). Obviously, a rate of 2.1% is higher than the 1.0% benchmark. As previously explained, FDA's assessment of the safety of the PRK procedure with this laser was not limited to the data from this one study since there are prior PRK safety data for this laser. Rather, the data from this specific study were assessed for confirmation. The observed adverse events and complications from this specific study did not appear to be different from those noted previously.

Table 8: FDA defined Adverse Events at 12 months	
Adverse Event	PMA cohort
Corneal infiltrate or ulcer	0
Persistent central corneal epithelial defect at 1 month or later	1 month: 1 (0.5%) 3 months: 1 (0.5%) 6 and later: 0
Corneal edema at 1 month or later	0
Uncontrolled IOP with increase of > 10 mm Hg above baseline, or any reading above 25 mm Hg	0
Late onset of haze beyond 6 months with loss of 2 lines (10 letters) or more BSCVA	0
Decrease in BSCVA of > 10 letters not due to irregular astigmatism as shown by hard contact lens refraction, at 6 months or later	0
Retinal detachment	0

All adverse reactions, measured or reported by patients, are presented in table 9. Events observed at the 12 months stability time point and at the two adjacent visits are included for comparison. In general, the rate of an adverse reaction tends to be highest immediately postoperative and tapers down over time. The reverse was noted for moderate "2" and marked "3" haze which seemed to occur after the one month visit and peak by the six month visit. The rate of moderate and marked haze at one month is 4.5% (9/198) and at three months was 12.4%

(24/193). An analysis of the 19 eyes at twelve months indicated that the location of haze was at the periphery and only 1 eye lost more than 2 lines of near BSCVA while none lost more than 2 lines of distance BSCVA.

Adverse Reaction	6 months N=190	12 months N=178	18 months N=54
Anterior Stromal Reticular Haze	12.6%	10.7%	5.6%
Double images in the operative eye	2.6%	1.7%	1.9%
Double vision	0.6%	0.6%	0
Foreign body sensation	2.1%	1.7%	1.9%
Ghost images in the operative eye	2.6%	2.2%	1.9%
Glare	2.8%	2.8%	1.9%
Halo	0.6%	0.6%	3.7%
Light sensitivity	0.6%	0.6%	0
Loss of near or distance BSCVA	5.8%	4.5%	5.6%
Overcorrection of hyperopia by > 2.0 D	0.5%	0.6%	0
Patient discomfort	0.5%	3.4%	1.9%
Ptosis	0.6%	0.6%	0
Recurrent corneal erosion	0.5%	0.6%	0
Undercorrection of hyperopia by > 2.0 D	0.5%	2.4%	0
Other: dryness/night driving difficulties	0.6%	0.6%	0

e. **Retreatment**

All retreatment procedures were performed at least 6 months after the initial treatment date with written approval from Summit. There were a total of 12 retreatments on the 201 eyes: 7 after six months, 2 after nine months, and 3 after twelve months.

The type of retreatment varied: 6 astigmatic keratotomy, 2 myopic PRK, and 4 hyperopic PRK. There were no major safety concerns for these retreated eyes. Since there were only 4 hyperopic retreatments performed in this trial, we do not have enough data to form any definitive conclusions regarding retreatment outcomes with this device.

It was noted that six of the 12 retreatments were for eyes treated with the K108 disc. They included hyperopic, myopic and AK corrections of residual refractive errors. Such high rate of re-

treatment could partially be due to the wide range of pre-operative refractive errors in eyes treated with K108. Nevertheless, this was the third reason for the post approval requirement of continued monitoring of the eyes treated with the K108 discs.

f. Factors associated with outcomes

These preoperative characteristics were evaluated for potential association with outcomes: gender, site, age, preoperative MRSE, and attempted MRSE.

Gender was not found to be associated with any of the safety or efficacy variables. Site was found to be statistically significant with stability of MRSE and re-epithelialization within 7 days. Age was found to be associated with re-epithelialization within 7 days. Preoperative MRSE was found to be associated with predictability within $\pm 0.5D$. Attempted MRSE was found to be associated with predictability within $\pm 0.5D$, with fewer eyes came to within $\pm 0.5D$ of the intended level in the higher attempted MRSE groups. Similar results were seen with MRSE predictability within $\pm 1.0 D$.

g. Patient Satisfaction

Patient surveys were completed on an eye-by eye basis. Information at 12 months was presented in the PMA.

Ninety percent (146/162) were either 'satisfied' or 'very satisfied' with the results of their treatment. Three did not respond. The primary reason for dissatisfaction in the 16 'not satisfied' eyes was with one's near uncorrected vision.

Ninety five percent (156/162) of patients would recommend the procedure to a friend at the time of the 12 month visit for each eye treated. Three did not respond. Six patients reported that they would not recommend the treatment to a friend.

h. Device failure

None occurred during the course of the study.

i. Confirmatory 18 months and international data

The limited safety and effectiveness data at 18 months postoperative follow the same trends observed for the earlier time

point. The key safety and effectiveness variables are presented in tables 10 and 11.

Table 10: Summary of Key Effectiveness Variables at 18 Months by Disc					
Efficacy Variables	Disc				Cumulative n/N (%) (95%CI)
	n/N (%) (95% CI)	n/N (%) (95% CI)	n/N (%) (95% CI)	n/N (%) (95% CI)	
	K102: 1.6D	K104: 2.3D	K106: 3.1D	K108: 3.9D	
UCVA 20/20 or better	9/14 (64.3%) (35.1,87.2)	2/8 (25.0%) (3.2,65.1)	3/10 (30.0%) (6.7,65.2)	2/10 (20.0%) (2.5,55.6)	16/42 (38.1%) (23.6,54.4)
UCVA 20/25 or better	11/14 (78.6%) (49.2,95.3)	6/8 (75.0%) (34.9,96.8)	5/10 (50.0%) (18.7,81.3)	54/10 (40.0%) (12.2,73.8)	26/42 (61.9%) (45.6,76.4)
UCVA 20/40 or better	14/14 (100.0%) (76.8,100)	8/8 (100.0%) (63.1,100)	8/10 (80.0%) (44.4,97.5)	9/10 (90.0%) (55.5,99.7)	39/42 (92.9%) (80.5,98.5)
MRSE +/- 0.50 D	10/14 (71.4%) (41.9,91.6)	4/8 (50.0%) (15.7,84.3)	4/12 (33.3%) (9.9,65.1)	5/17 (29.4%) (10.3,56)	23/51 (45.1%) (31.1,59.7)
MRSE +/- 1.00 D	13/14 (92.9%) (66.1,99.8)	6/8 (75.0%) (34.9,96.8)	9/12 (75.0%) (42.8,94.5)	10/17 (58.8%) (32.9,81.6)	38/51 (74.5%) (60.4,85.7)
MRSE +/- 2.00 D	14/14 (100.0%) (76.8,100)	8/8 (100.0%) (63.1,100)	12/12 (100.0%) (73.5,100)	17/17 (100.0%) (80.5,100)	51/51 (100.0%) (93,100)

Table 11: Summary of Key Safety Variables at 18 Months by Disc					
Efficacy Variables	Disc				Cumulative n/N (%) (95%CI)
	n/N (%) (95% CI)				
	K102: 1.6D	K104: 2.3D	K106: 3.1D	K108: 3.9D	
Loss of > 2 Lines Distance BSCVA	0	0	0	0	0 (0,6.6)
Loss of 2 Lines Distance BSCVA	0	0	0	1/19 (5.3%) (0.1, 26)	1/54 (1.9%) (0,9.9)
Increase of >2.0D Cylinder	0	0	0	0	0 (0,6.6)
Distance BSCVA worse than 20/40	0	0	0	1/19 (5.3%) (0.1, 26)	1/54 (1.9%) (0,9.9)
Distance BSCVA worse than 20/25 if 20/20 or better preoperatively	0	0	0	0	0 (0,6.6)

International data from Dr. David O'Brart at St. Thomas' Hospital, London, UK was provided in this PMA as confirmatory in support of the safety and effectiveness of the device. This confirmatory data included 24 months data from a study of 43 eyes. The St. Thomas study had similar inclusion criteria as the US IDE study, except in the following areas: +1.75 to +7.50 D preoperative refraction and an age limit of 21 years minimum. Treatment was with these three discs: K106 (3.1D), K110 (4.7D) and K114. St. Thomas' patients were not given the option of retreatment until the third postoperative year had passed.

The stability of the St. Thomas' cohort was reached by 12 months postoperative and confirmed with the 24 months results (table 12). Even though the range of correction in the St. Thomas data did not correspond exactly with the PMA Cohort, the observed stability was reassuring given that stability usually decreases with increasing magnitude of correction. Thus, adequate stability with the higher corrections most probably indicates adequate stability with the lower range of corrections as well.

Table 12: Stability Analyses of St. Thomas Data (change in MRSE over time for eyes that had every exam, through 24 months)					
Analysis	1 to 3 Months	3 to 6 Months	6 to 9 Months	9 to 12 Months	12 to 24 months
Change ≤ 1 D n/N (%) (95% CI)	23/42 (54.8%) (38.7, 70.2)	30/42 (71.4%) (55.4, 84.3)	37/42 (88.1%) (74.4, 96.0)	40/42 (95.2%) (83.8, 99.4)	39/42 (92.9%) (80.5, 98.5)
Change (Pair-Differences) Mean Std.Dev. (95% CI)	1.006 1.336 (0.6, 1.41)	0.372 1.378 (-0.04, 0.79)	0.351 0.643 (0.16, 0.55)	0.098 0.468 (-0.04, 0.24)	-0.09 0.526 (-0.25, 0.07)

The following safety profiles were noted for the St. Thomas' eyes. Twelve eyes (28%) lost lines of Snellen BSCVA. Only 2 eyes (5%) lost 2 lines of BSCVA with none losing greater than 2 lines of BSCVA. No change or an improvement in BSCVA was seen in 31 eyes (72%). Distance BSCVA was worse than 20/40 in 2 eyes (5%) at the 6 month postoperative examination. By the 2 year postoperative examination, 3 eyes (7%) had a distance BSCVA worse than 20/40.

Under slit lamp examination at 6 months postoperatively, 34 eyes (79%) showed clear central corneas with no evidence of central anterior stromal reticular haze. In 9 eyes (21%), slight subepithelial haze less than or equal to grade 1 was present.

One eye (2%) experienced recurrent corneal erosion presenting at 2 months postoperatively and resolving at 3 months postoperatively with subsequent management with lubricating ointment. There was no recurrence after 3 months postoperatively. Two eyes (5%) experienced irregular epithelial healing during the first month after treatment which was attributed to the age of the patients. Both were among the oldest treated and were in their seventies. Two eyes (5%) had peripheral subepithelial haze which was associated with regression.

The safety outcomes of the O'Brart data do not raise any concern for the PMA data.

X. EMPHASIS DISCS L

The L discs were introduced to fill in the gaps of the K discs. The L discs covered the treatment range of 1.0 to 4.0 D in 0.5 increments. Their names are indicative of their corrective power: L10 for 1.0D, L15 for 1.5 D, etc.

The L discs were not used in the studies summarized herein; nevertheless, they were approved with the K discs. For this approval, the sponsor must first demonstrate that all discs are manufactured with consistency, precision and accuracy, and then generate a statistical model to predict the clinical outcomes of the L discs using the results of the K discs. Since outcomes with each individual K disc were deemed acceptable and the various discs can be properly manufactured, interpolation between K discs was deemed acceptable for the purpose of predicting L discs' outcomes. Only limited extrapolation of the K disc data was allowed.

The predicted outcomes of the L discs are provided in table 13.

Probability	L10	L15	L20	L25	L30	L35	L40
Within \pm 0.5 D	0.76 (0.62, 0.86)	0.70 (0.59, 0.80)	0.65 (0.55, 0.73)	0.58 (0.50, 0.66)	0.50 (0.43, 0.60)	0.44 (0.34, 0.55)	0.38 (0.26, 0.51)
Within \pm 1.0 D	0.95 (0.87, 0.98)	0.93 (0.85, 0.97)	0.91 (0.83, 0.95)	0.87 (0.80, 0.92)	0.83 (0.76, 0.88)	0.77 (0.68, 0.85)	0.70 (0.56, 0.82)

XI. CONCLUSIONS DRAWN FROM THE CLINICAL STUDY

The data in this application supports reasonable assurance of safety and efficacy of this device for the treatment of hyperopia from +1.5 to +4.0 D sphere.

XII. PANEL RECOMMENDATION

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, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. FDA DECISION

On October 21, 1999, FDA issued an approval order to Summit Technology, Inc.

XIII. APPROVAL SPECIFICATIONS

- Post approval requirements and restrictions: see approval order.
- Hazards to health from use of device: see indications, contraindications, warnings, precautions, and adverse events in the labeling.
- Directions for use: see the labeling.

LABELING



SUMMIT TECHNOLOGY[®], INC.

**SVS APEX PLUS EXCIMER LASER WORKSTATION
PRACTITIONER INFORMATION**

HYPEROPIC PHOTOREFRACTIVE KERATECTOMY

CAUTION: RESTRICTED DEVICE: Federal Law (US) restricts this device to sale, distribution, and use by or on the order of a practitioner. Federal Law (US) restricts the use of this device to practitioners who have been trained in laser refractive surgery including laser system calibration and operation. Federal law (US) restricts the use of this device to practitioners trained in the medical management and surgical treatment of the cornea. This device is not for use in mobile clinics.

Be certain that all patients are advised of the risks inherent in the use of this medical device and in the outcomes of Hyperopic PRK before applying it to their person!

All patients must have the opportunity to read and understand the Patient Information Booklet for Hyperopic PRK.

All patients must have the opportunity to read, understand and sign an Informed Consent Document for this treatment.

Improper use of this device may result in physical harm to a patient! If in doubt about the correct way to operate this medical device, seek help! Pay attention to all warnings, cautions and contraindications in the following practitioner information document and in the SVS Apex Plus Excimer Laser Workstation User Manual.

A. Background

The following practitioner information has been developed based on the experiences of active Summit excimer laser centers to provide recommendations concerning the use of the SVS Apex Plus Excimer Laser Workstation with the emphasis® disc and axicon for Hyperopic PRK procedures.

The practitioner and staff should read the Summit Technology SVS Apex Plus Excimer Laser Workstation User Manual, the following practitioner information, and the emphasis disc package insert. **Practitioners must complete all necessary training as outlined by Summit Technology prior to performing patient treatments.**

B. Indications, Contraindications, Warnings, Precautions:

Indications For Use:

The SVS Apex Plus Excimer Laser Workstation with emphasis discs and axicon are indicated for the reduction or elimination of mild to moderate hyperopia ranging from +1.5 D to +4.0 D with less than 1.0 D of astigmatism at the spectacle plane using hyperopic photorefractive keratectomy (Hyperopic PRK) in patients with documentation of a stable manifest refraction (± 0.5 D) over the past year, and in patients who are 21 years of age or older.

Contraindications:

The SVS Apex Plus Excimer Laser Workstation used in conjunction with emphasis discs and axicon for Hyperopic PRK is contraindicated for the following:

1. Patients with uncontrolled vascular disease or auto-immune diseases because it is well known that these patients have difficulty in corneal healing and are more susceptible to corneal melting;
2. Women who are pregnant or nursing, due to the potential for temporary fluctuation in refraction with pregnancy;
3. Patients with signs of keratoconus, since eyes with this condition may have unstable corneas;

4. Patients known to have a previous history of keloid formation, because their corneal healing response is less predictable;
5. Patients taking Accutane (isotretinoin) or Cordarone (amiodarone hydrochloride).

Warnings:

The following Warnings pertain to the SVS Apex Plus Excimer Laser Workstation used in conjunction with emphasis discs and axicon for Hyperopic PRK:

1. The treatment should not be performed in patients whose refractive history is unstable since an accurate pretreatment baseline refraction for the calculation of the desired correction can not be obtained.
2. The treatment is not recommended in individuals with Herpes Simplex Virus or Herpes Zoster since cases of herpes reactivation have been reported after use of the excimer laser. Further clinical experience is necessary regarding the use of the 193 nanometer excimer laser wavelength in patients with these conditions.

Precautions:

The following Precautions pertain to the SVS Apex Plus Excimer Laser Workstation used in conjunction with emphasis discs and axicon for Hyperopic PRK:

1. The treatment should not be performed in patients who are unable to cooperate during the treatment because of the potential difficulty in aligning the laser beam and keeping the eye steady during the procedure.
2. Prior to removing the epithelium, the doctor should arm and test the laser to ensure that it is ready to deliver laser energy.
3. The long-term safety and efficacy of Hyperopic PRK has not been established.
4. The safety and effectiveness of Hyperopic PRK has not been established in patients who are under 21 years of age.

5. The effects of Hyperopic PRK on patients taking Imitrex (sumatriptan succinate) have not been studied.
6. Although the effects of Hyperopic PRK on visual performance under poor lighting conditions have not been determined it is likely that patients will find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog, or glare from bright lights at night.
7. Patients with known sensitivity to any of the treatment medications;
8. Patients with a history of glaucoma because of the potential for a strong response to postoperative steroids

C. Adverse Events

The following adverse events were reported in conjunction with Summit Technology's Hyperopic PRK Clinical Investigation that included the treatment of 201 eyes in 182 patients:

- **Immediate/Early Post-Treatment Adverse Events:**

The following events were reported in the first month after Hyperopic PRK. These events are temporary and occur in many patients during the early post-treatment period. They are associated with the normal post-treatment healing process and include: post-treatment pain or discomfort (first 24 to 48 hours); double vision; foreign body sensation; ghost images and peripheral corneal epithelial defect. The time to re-epithelialization was ≤ 7 days for 89.6% of eyes, ≤ 14 days for 97.5% of eyes and ≤ 1 month for 99.5% of eyes.

- **6, 12 and 18 Month Post-Treatment Adverse Events:**

Events reported in more than 1% of the patients included in the Summit Technology Hyperopic PRK Clinical Investigation at 6, 12 and 18 months are listed in **Table 1**:

Table 1

Event	6 Months	12 Months	18 Months
Anterior Stromal Reticular Haze	12.6%	10.7%	5.6%
Loss of Best Spectacle Near or Distance Corrected Acuity (2 lines or more)	5.8%	4.5%	5.6%
Undercorrection of hyperopia by >2.00 D	0.5%	2.4%	0%
Overcorrection of hyperopia by >2.00 D	0.5%	0.6%	0%
Glare	2.8%	2.8%	1.9%
Halo	0.6%	0.6%	3.7%
Foreign body sensation	2.1%	1.7%	1.9%
Patient discomfort	0.5%	3.4%	1.9%
Ghost images in the operative eye	2.6%	2.2%	1.9%
Double images in the operative eye	2.6%	1.7%	1.9%

- At 6,12 and 18 months after treatment the events listed in **Table 2** were reported in less than 1% of the patients included in the Summit Technology Hyperopic PRK Clinical Investigation:

Table 2

Event	6 Months	12 Months	18 Months
Light sensitivity	0.6%	0.6%	0%
Double vision	0.6%	0.6%	0%
Ptosis	0.6%	0.6%	0%
Other: dryness/night driving difficulties	0.6%	0.6%	0%
Recurrent corneal erosion	0.5%	0.6%	0%

Some events were not reported in the Summit Hyperopic PRK Clinical Investigation but should be noted:

Event

Corneal scarring	Persistent central corneal epithelial edema
Corneal ulceration/perforation	Uncontrolled IOP with increase of >5 above baseline and any reading >25 mm Hg
Corneal decompensation	Late onset haze beyond 6 months with loss of 2 lines or more BSCVA
Endophthalmitis	Decrease in distance BSCVA >2 lines not due to irregular astigmatism as shown by hard contact lens refraction at 6 months or later Retinal detachment
Hyphema	Peripheral corneal epithelial defect
Hypopyon	Corneal infiltrate or ulcer
Intraocular infection	
Persistent corneal edema	
Microbial keratitis	
Foreign body sensation	
Ghost images	
Patient discomfort	
Microbial keratitis	
Foreign body sensation	
Ghost images	
Patient discomfort	
Tearing	

Clinical Results

Key Safety and Effectiveness variables are shown at 6, 12 and 18 months in Table 3 below.

Table 3

	6 months	12 months	18 months
Efficacy Variable			
UCVA 20/20 or better*	60/159 (37.7%)	66/144 (45.8%)	16/42 (38.1%)
UCVA 20/25 or better*	97/159 (61.0%)	98/144 (68.1%)	26/42 (61.9%)
UCVA 20/40 or better*	140/159 (88.1%)	132/144 (91.7%)	39/42 (92.9%)
MRSE within $\pm 0.5D$	90/183 (49.2%)	92/165 (55.8%)	23/51 (45.1%)
MRSE within $\pm 1.0D$	142/183 (77.6%)	139/165 (84.2%)	38/51 (74.5%)
Safety Variable			
Loss > 2 lines BSCVA	2/190 (1.1%)	2/178 (1.1%)	0
Loss 2 lines BSCVA	4/190 (2.1%)	3/178 (1.7%)	1/54 (1.9%)
Increase > 2D cylinder	0	0	0
BSCVA worse than 20/40	0	0	1/54 (1.9%)
BSCVA worse than 20/25 if 20/20 or better preoperatively	0	1/178 (0.6%)	0

* For all eyes minus those intentionally undercorrected

Table 4 shows the Summary of Key Safety and Effectiveness variables at 12 months stratified by disc. Predictability of corrective power of the emphasis "L" discs was extracted from statistical modeling based upon clinical results from emphasis "K" discs.

Summary of Key Safety and Efficacy Variables Stratified by Disc
12 Months Postop

Table 4

K Disc Stratification	K102 1.6 D	K104 2.3 D	K106 3.1 D	K108 3.9 D
Efficacy Variable				
UCVA 20/20 or better*	32/56 (57.1%)	17/34 (50.0%)	8/24 (33.3%)	9/30 (30.0%)
UCVA 20/25 or better*	44/56 (78.6%)	25/36 (73.5%)	12/24 (50.0%)	17/30 (56.7%)
UCVA 20/40 or better*	54/56 (96.4%)	33/34 (97.1%)	21/24 (87.5%)	24/30 (80.0%)
MRSE within $\pm 0.5D$	42/56 (75.0%)	17/34 (50.0%)	13/30 (43.3%)	20/45 (44.4%)
MRSE within $\pm 1.0D$	54/56 (96.4%)	28/34 (82.4%)	23/30 (76.7%)	34/45 (75.6%)
Safety Variable				
Loss > 2 lines BSCVA	1/61 (1.6%)	0	0	1/49 (2.0%)
Loss of 2 lines BSCVA	0	1/34 (2.9%)	0	2/49 (4.1%)
Increase > 2D cylinder	0	0	0	0
BSCVA worse than 20/40	0	0	0	0
BSCVA worse than 20/25 if 20/20 or better preoperatively	1/61 (1.6%)	0	0	0

- **Retreatments**

There were a total of 12 retreatments on the 201 eyes treated in this study, 7 after 6 months, 2 after 9 months, and 3 after 12 months. The retreatments were carried out to enhance the refractive correction. The refractive surgery used for the enhancements was astigmatic keratotomy (AK) in 6 cases, myopic PRK in 2 cases, and Hyperopic PRK in 4 cases. The 4 Hyperopic PRK retreatments had the following outcomes:

- 1 eye was treated for emmetropia and at the last follow-up visit, 6 months after retreatment, had distance UCVA of 20/25 and MRSE of -0.125 D;
- 2 eyes were treated for monovision and at the last follow-up visit, 6 months after retreatment, had respectively near UCVA of 20/20 with MRSE of -1.25 D, and near UCVA of 20/30 with MRSE of -2.125 D;
- 1 eye was intended for an emmetropia retreatment, but ended up with monovision. At the last follow-up visit at 1 month after retreatment, it had near UCVA of 20/30, distance UCVA of 20/62.5, and MRSE of -1.75 D.

- **Factors associated with outcomes**

Gender, age, pre-operative MRSE, and attempted MRSE were evaluated for potential association with outcomes. Gender was found not to be associated with primary safety and efficacy variables. Age was found to be associated with re-epithelialization within 7 days, and pre-operative MRSE with MRSE predictability within ± 0.5 D, but sample sizes were small. Attempted MRSE correction was found to be associated with MRSE predictability within ± 0.5 Dm with slightly fewer eyes reaching ± 0.5 D MRSE predictability in the higher attempted MRSE correction groups. Similar results were seen with MRSE predictability within ± 1.0 D.

D. Ancillary Equipment

The following items will be needed when performing the Hyperopic PRK procedure with the SVS Apex Plus Excimer Laser Workstation with emphasis discs and axicon:

1. Sterile eye speculum
2. Gauze pads and tape
3. Carboxypropyl methylcellulose 1.0%
4. Agent to constrict the pupil
5. Small ophthalmic sponges
6. Topical anesthetic
7. Slit Lamp available near the laser system
8. Materials to perform the SVS Apex Plus Excimer Laser Beam Profile and Alignment Tests
9. Patient Bed or Chair capable of performing fine movements (comparable to the chair supplied by Summit Technology)
10. Standard instrument for mechanical epithelium removal (64 Beaver[®] blade)
11. emphasis discs for Hyperopic PRK
12. Disposable suction cups for handling discs
13. emphasis axicon cassette
14. emphasis cassette
15. Vacuum tweezers

E. SVS Apex Plus Excimer Laser Workstation Parameters

Ablation Zone Size:	emphasis disc: 6.5 mm axicon: 6.5 mm to 9.5 mm
Intended Correction:	Spherical Correction at the Spectacle Plane: from +1.5 to +4.0 D
Pulse Energy Density:	162 mJ/cm ² at the corneal plane Tapered from 200 mJ/cm ² to 0 mJ/cm ² with the axicon
Repetition Rate:	System set at 10 Hz.

F. Directions For Use:

Laser Preparation:

1. Turn on the SVS Apex Plus Excimer Laser Workstation and allow the system to warm up. Refer to the SVS Apex Plus Excimer Laser Workstation User Manual for start up and operating instructions regarding your laser workstation.
2. If it is the first procedure of the day, the Beam Profile and Alignment Tests (refer to the User Manual) should be performed in accordance with Summit Technology's Beam Profile and Alignment Test instructions. **This daily check should include tests of axicon and emphasis cassette alignment.**

NOTE: The axicon Alignment and axicon Profile tests must be performed and approved at the start of any day in which a Hyperopic PRK procedure is being performed.

3. If your test results meet the criteria specified in the beam profile and alignment test instructions proceed with Hyperopic PRK procedure. If your test results do **not** meet the test criteria; (1) contact Summit's Customer Service Department immediately or your Summit Service Representative and (2) do **not** use the laser on patients because of the potential for improper results.

emphasis Disc Preparation:

4. Review the manifest refraction for the eye to be treated.
5. Review the emphasis disc Look Up Table located in Section G of this Practitioner Information document or Chapter 6 of the Apex Plus User Manual and select the disc type that most closely corresponds to the desired refractive correction.
6. Check the chamber of the emphasis cassette to ensure it is free of obstructions by inserting the suction cup end of the vacuum tweezers into the chamber. Remove any obstructions.

CAUTION: Failure to remove obstructions, such as used discs or the disc alignment template, prior to insertion of the treatment disc may cause an undesired clinical result.

7. Open the appropriate disc package and carefully pick up the disc with the vacuum tweezers. Check the surface to verify that the disc type is appropriate for the attempted hyperopic correction. Place the disc in the cassette with the alignment pins on the cassette engaging the slots on the disc.

WARNING: Do not use the disc if it appears damaged in any way or becomes damaged in insertion into the cassette. Using a damaged disc could adversely affect the outcome of the treatment.

NOTE: Avoid contacting the delicate emphasis disc with any object while handling the disc. Do not contaminate the disc by contacting it with any surface. Do not manipulate the disc with anything other than the vacuum tweezers.

NOTE: Refer to Section 6 of the Apex Plus User Manual for additional information regarding emphasis disc preparation.

8. Slide the disc latch to the closed position.
9. Remove the axicon cassette from the storage box. Visually inspect the axicon for dust or debris. The axicon may be cleaned with a clean supply of nitrogen. Do not use "canned air", as the propellant may damage the optic.

NOTE: Do not insert the emphasis cassette with the disc until prompted to do so by the laser system software.

Patient Preparation

10. Approximately 30 minutes prior to the procedure, topical anesthetic and an agent to constrict the pupil should be applied to the operative eye. Additional topical anesthetic should be applied until the epithelium removal has been initiated.
11. Place the patient on the patient chair with the operative eye centered under the excimer laser delivery system.
12. Topical anesthetic may be given to the eye not scheduled for treatment to relax the reflexes.

13. Patch the patient's eye **not** scheduled for treatment. A patch may also be placed on the side of the head next to the eye to be treated to collect excess fluids.
14. Place the speculum in the eye to be treated.
15. Turn on the HeNe aiming beams.
16. The patient should be instructed to keep his operative eye focused on the flashing green fixation target inside the red fixation ring in the laser downtube.
17. Position the patient with the HeNe aiming beams so that the two central spots intersect on the anterior surface of the cornea centered over the pupil. The 3 and 9 o'clock diverging HeNe beams should appear on the iris equally spaced from the center of the pupil.

NOTE: The HeNe aiming beams mark the image plane of the excimer beam. The desired vertical area of effect is located where the two HeNe beams appear as one spot. In order to ensure that the patient is not exposed to hazardous levels of laser energy, the HeNe beams should not be fired at the patient continuously for longer than 390 seconds.

NOTE: Do **not** lean on the operating microscope or the excimer laser system during any portion of the procedure.

Patient Training

Patient training allows patients to become familiar with fixating the eye on the green fixation target as well as introducing the patient to the light, noise and smell produced by the laser system during laser energy delivery. The SVS Apex Plus Excimer Laser Workstation provides two patient training sequences: Patient Training A and Patient Training B. Patient Training A is a simulated PRK where the laser energy is delivered on a coating of 1% methylcellulose. Patient Training B is a 25 pulse PTK designed to be delivered on dry epithelium. The patient should be made aware that there is no pain associated with the laser beam striking the cornea.

NOTE: Neither Patient Training A nor Patient Training B is a refractive procedure.

Training "A"

1. Program the laser for Patient Training A. Arm and test the laser.
2. Apply 1% methylcellulose to the eye to ensure that the entire cornea is covered. This layer of methylcellulose will inhibit laser ablation of the cornea.
3. Begin firing the laser and closely observe the patient's ability to fixate during laser delivery. If the sound of the ablation changes, stop firing the laser as you may be ablating epithelium.
4. Repeat this procedure 2 to 3 times, as necessary, until the patient fixates adequately during laser delivery.

NOTE: If the patient cannot fixate after two to three training sessions, the practitioner may reschedule the clinical procedure.

Training "B"

1. Patient training B should be performed on dry epithelium. Delivering laser energy to the dry epithelium will produce a circular ablation on the patient's epithelium. This final training session allows the practitioner to ensure that the patient is able to fixate and introduces the patient to the noise, smell and sensation of the laser striking the cornea.
2. Using a small ophthalmic sponge, remove all remaining methylcellulose from the eye and from around the eye speculum.
3. Program the laser for Patient Training B. Arm and test the laser.
4. Make sure that the patient is aligned correctly and begin firing the laser. Closely observe the ability of the patient to fixate

during laser delivery. This training will most closely mimic the actual procedure.

NOTE: Do not perform more than one Patient Training B session on the dry epithelium.

OPERATIVE TECHNIQUE:

1. Program the laser for the Hyperopic PRK procedure.

NOTE: Refer to the "Sample Procedures" in section 6 of the Apex Plus User Manual for screen-by-screen instructions on the Hyperopic PRK procedure.

2. Enter the attempted hyperopic correction (the value from the Look Up Table that most closely corresponds to the patient's refraction) and press ENTER.
3. The system responds with a prompt to insert an emphasis disc. This should be the same disc type identified in the emphasis disc Look Up Table (located in section G of this document or section 6 of the Apex Plus User Manual). Press ENTER to proceed.

NOTE: You have entered a value outside of the approved indication range. The system will display the following screens: "The limited experience in the range of refractive errors below +1.5 D has not been sufficient to detect actual complication and/or adverse event rates and the effectiveness of PRK may be limited." "Do you wish to proceed with a Hyperopic PRK treatment below +1.5 D? <Press (1) if Yes, press (2) if No>." Contact Summit Customer Support for emphasis disc information.

4. Reconfirm that the emphasis disc installed in the emphasis cassette is the disc type requested in step 3 by entering the disc type again.

5. The system will present all parameters to be used in this excimer refractive procedure including the number of pulses recommended for the axicon ablation for your review and confirmation. Press Enter to confirm.
6. Arm and test the laser BEFORE beginning epithelium removal to ensure that the laser will complete the test mode, allowing the delivery of laser energy.

NOTE: If the laser remains armed for more than 20 minutes without firing, the system will automatically disarm and you will need to clear the laser and rearm and retest the system. Firing the laser will NOT reset the timing mechanism.

7. Reposition the patient's eye under the laser. Epithelial removal should occur with the patient under the laser to minimize the time period between epithelial removal and laser ablation. While the goal is to remove the epithelium approximately 1 mm beyond the largest ablation zone, *it is more important to leave a cuff of epithelium in place to ensure healing-even if the "cuff" impinges into the ablation zone.* Since the axicon creates a blend zone extending to 9.5 mm, there will frequently be some epithelium within this ablation zone. However, since the blend zone does not contribute to the retinal image, there should be little impact on the success of the procedure.

NOTE: Do not use alcohol, cocaine or any other substances to remove the epithelium. Application of these substances may influence the ablation rate of the excimer laser energy and could lead to a poor procedural result.

8. Mechanically remove the epithelium using a standard instrument (such as a 64 Beaver blade) designed for epithelium removal. Be sure to leave at least 1 mm of epithelium around the limbus to promote reepithelialization. Take great care not to damage Bowman's layer. The area of epithelium removed should be slightly larger than the area to be treated (the axicon outer diameter is 9.5 mm). Remove the epithelium in a circumferential manner, starting at the outer diameter and moving towards the center. Clean Bowman's layer very carefully to remove all debris with a small ophthalmic sponge.

9. Once the epithelium has been removed, apply 1 drop of methylcellulose or topical anesthetic to a small ophthalmic sponge and continue cleaning Bowman's layer. The methylcellulose is used to smooth out any surface irregularities commonly present in Bowman's layer. The cleaning should continue until **all** methylcellulose has been removed.

NOTE: It is important that all epithelium is removed prior to performing the Hyperopic PRK procedure. Histology has shown that small particles of epithelium may remain even when they can not be seen through the operating microscope.

NOTE: No additional drops should be placed on Bowman's layer once the cleaning procedure has been completed. Application of liquids at this time will impact the desired clinical result.

10. Ask the patient to continue fixating on the green fixation light in the red fixation ring located in the laser downtube. Position the patient with the HeNe aiming beams so that the two central spots intersect on the anterior surface of the cornea centered over the pupil. The 3 and 9 o'clock diverging HeNe beams should appear on the iris equally spaced from the center of the pupil.
11. Turn the coaxial illuminator all the way down or off and position the oblique illuminator on the patient's operative eye. The oblique light should be used at a low intensity, so that the HeNe aiming beams appear clearly on the patient's iris and corneal surface.

NOTE: During laser energy delivery, the physician should concentrate on the position of the HeNe's on the iris. Do not be distracted by watching the laser energy impacting the cornea.

12. Press the footswitch until the laser stops firing. The total number of laser pulses for the desired refractive correction should be delivered in one continuous application.

NOTE: The first 60 pulses (approximately) of any disc procedure are absorbed by the disc.

13. The physician should observe the procedure through the operating microscope. While the laser is firing, the physician should closely observe the fixation of the patient's eye. If the patient's eye moves during the procedure, firing of the laser should be stopped. The patient should be instructed to re-fixate and the treatment resumed. The laser system will keep track of how many pulses have been delivered and how many are remaining.

NOTE: As stated previously, during laser energy delivery, the physician should concentrate on the position of the HeNe's on the iris. The physician should not be distracted by watching the laser energy impacting the cornea.

NOTE: Do **not** lean on the operating microscope or the excimer laser workstation during laser delivery.

14. After all required emphasis disc pulses have been fired, remove the emphasis cassette as prompted by the system software. Press ENTER to continue.
15. Insert the axicon cassette. Press ENTER to continue.
16. The system will present the number of pulses necessary to perform the appropriate axicon ablation, based on the emphasis disc used. Press ENTER to continue.
17. Re-establish patient alignment.
18. Press the footswitch until the laser stops firing. The total number of axicon laser pulses should be delivered in one continuous application.

POSTOPERATIVE TECHNIQUE:

1. The patient should be moved to the slit lamp to allow the physician to examine the operative eye after the laser procedure. If the edges of remaining epithelium surrounding the laser ablation have been folded back or are overlapping they should be smoothed back into their original position to facilitate re-epithelialization.

2. Remove the eye speculum.
3. The operative eye may be patched or a contact lens may be placed on the eye for the first postoperative night.
4. Most patients will experience postoperative pain for the first 24 hours after the Hyperopic PRK procedure. Postoperative pain medication may be prescribed at the practitioner's discretion.
5. Physicians should refer to the existing peer review literature on postoperative medication to determine the appropriate course of action.

G. Look-up Table for Hyperopic PRK:

Emphasis® Disc type: Sphere vs. Cylinder at Corneal Plane (cyl = cylinder, sph = sphere)										
Hyperopic PRK Disc Look Up Table										
	sph +1.5	sph +1.6	sph +2.0	Sph +2.3	sph +2.5	sph +3.0	sph +3.2	sph +3.5	Sph +3.9	sph +4.0
Cyl <-1.0	L15	K102	L20	K104	L25	L30	K106	L35	K108	L40

Note: Predictability of corrective power of the emphasis "L" discs was extracted from statistical modeling based upon clinical results from emphasis "K" discs.

PATIENT INFORMATION

HYPEROPIC PHOTOREFRACTIVE KERATECTOMY (HYPEROPIC PRK)

SVS Apex Plus Excimer Laser Workstation

CAUTION: Federal Law (US) restricts this device to sale by or on the order of a physician or properly licensed practitioner.

Please speak with your doctor regarding this procedure for the correction of your farsightedness. It is important that you read this entire booklet and carefully discuss its contents with your doctor. Ask any questions you may have before you agree to the surgery.



Summit Technology®, Inc.
21 Hickory Drive
Waltham, Massachusetts 02451
Phone 781-890-1234
Fax 781-890-0313

IMPORTANT INFORMATION

- Hyperopic PRK is a permanent procedure; it is not reversible.
- Some jobs, such as pilots, have vision requirements that procedures such as Hyperopic PRK cannot provide and eyeglasses may still be needed after surgery.
- Your vision must be stable for at least one year before the surgery. You will need written proof that your farsightedness (hyperopia) has changed less than 0.5 diopter during this time. A diopter is a unit of measurement of optical strength or power.
- Hyperopic PRK is not a laser version of surgical refractive procedures; it is completely different.
- Alternatives to Hyperopic PRK include eyeglasses and contact lenses, or non-laser surgical procedures.
- The following risks of Hyperopic PRK should be noted:
 - Transient complications: pain or discomfort (24-48 hours), double vision, feeling something in the eye, and delayed healing. These problems may last up to several weeks.
 - Complications and adverse events at 12 months occurring in at least 1% of subjects: foreign body sensation (1.7%), double vision (1.7%), ghost images (2.2%), undercorrection of farsightedness by more than 2 diopters (2.4%), glare (2.8%), patient discomfort (3.4%), decrease in vision with glasses by 2 or more lines on the eye chart (4.5%), haze (10.7%).
- The following benefits of Hyperopic PRK should be noted:
 - Reduced dependence on eyeglasses or contact lenses
 - Hyperopic PRK may be an alternative to eyeglasses in some patients who are intolerant of contact lenses
 - Hyperopic PRK is an alternative to eyeglasses or contact lenses to correct farsightedness
- You should have a complete eye examination before considering Hyperopic PRK. Additionally you should discuss the complications, risks and the time required for healing with one or more eye surgeons.

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INTRODUCTION

The following information is being provided to you because you are thinking about having Hyperopic Photorefractive Keratectomy (Hyperopic PRK) laser surgery. The SVS Apex Plus Excimer Laser Workstation is indicated for use in the reduction or elimination of mild to moderate (+1.5 to +4.0 diopters) farsightedness (hyperopia) with low astigmatism (<-1.0 diopters). You must have documentation of a stable refraction (± 0.5 diopter) over the past year and be 21 years of age or older. An excimer laser is a surgical instrument that produces a powerful beam of light that can remove tissue from the eye. Options for correcting hyperopia (farsightedness) include eyeglasses and contact lenses, other refractive surgical procedures and Hyperopic PRK.

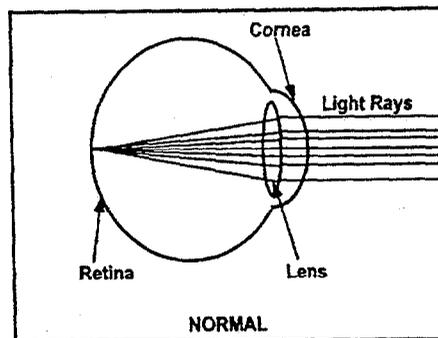
If you are farsighted ~~in both eyes.~~ This patient booklet will help you make an informed decision about Hyperopic PRK to correct your farsightedness. Please read this booklet completely and discuss any questions with your doctor in order to decide if Hyperopic PRK is right for you. Only a qualified eye doctor can determine whether or not you are suitable for Hyperopic PRK. The goal of Hyperopic PRK is to reduce your need for eyeglasses or contact lenses by reshaping the cornea through laser surgery. ✓

HOW THE EYE FUNCTIONS

Your eye focuses light to form images or pictures, much like a video camera. Your eye changes these images into electrical signals and sends them to your brain. If your eye is out of focus, what you see will be blurred

The cornea at the front of the eye bends the light rays onto your retina. This clear tissue is responsible for two-thirds of the focusing power of your eye. The lens within your eye is responsible for the other third as it focuses light onto your retina. (see Diagram 1).

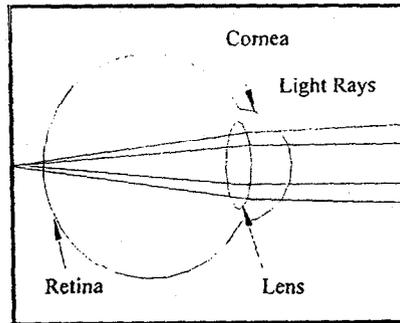
DIAGRAM 1



THE FARSIGHTED EYE (HYPEROPIA)

The excimer laser is approved for treatment of mild to moderate hyperopia, also known as farsightedness. Farsightedness occurs when light rays entering the eye are focused behind your retina instead of directly on it (see Diagram 2). The tendency to develop farsightedness runs in families. Farsightedness usually starts in childhood and typically stabilizes in the late teens or early adulthood. It can be corrected with eyeglasses, contact lenses, or refractive surgery (eye surgery that corrects vision). The first two options, eyeglasses and contact lenses, can be adjusted if your vision changes over time.

DIAGRAM 2



THE FARSIGHTED EYE

THE PRESBYOPIC EYE

A person who never needed eyeglasses in youth and who reaches an age when the eye's focusing power decreases will probably require vision correction to see objects close up. This is called presbyopia. These individuals are most likely over the age of forty and require the use of reading glasses. You should understand the difference between hyperopia and presbyopia before considering Hyperopic PRK. Hyperopic PRK cannot correct presbyopia.

A person who has been farsighted throughout most of life may or may not need correction to improve their near vision. It is possible to be farsighted and need near vision correction as the focusing power of the lens decreases with age. This condition is called presbyopic hyperopia.

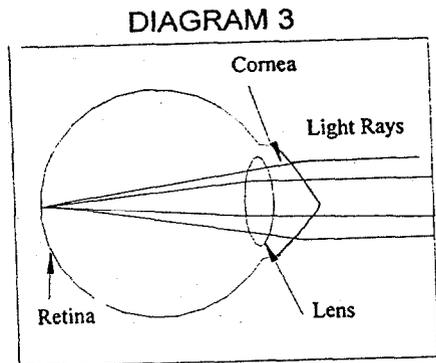
CHECKING YOUR FOCUS

During your eye exam, the doctor observes where your eye focuses light relative to your retina. When your doctor corrects your vision, light is focused properly on the retina. The amount required to correct your vision is in units called diopters (D). Hyperopic PRK can correct up to +4 D of farsightedness

WHAT IS HYPEROPIC PRK?

Hyperopic PRK is a surgical treatment for farsightedness in which the SVS Apex Plus Excimer Laser reshapes the front surface of the cornea by removing microscopic amounts of tissue.

Diagram 3 illustrates the eye after Hyperopic PRK.



THE FARSIGHTED EYE
FOLLOWING HYPEROPIC
PRK

WHAT IS AN EXCIMER LASER?

An excimer laser is a surgical instrument that produces a powerful beam of light. Laser light is directed and controlled precisely and delivered in brief, intense pulses. The excimer laser produces a beam of ultraviolet light in pulses that last only a few billionths of a second. Each pulse removes a microscopic amount of tissue from the surface of the cornea, thereby changing the shape of the cornea.

INDICATIONS FOR USE

The SVS Apex Plus Excimer Laser Workstation with emphasis discs and axicon are indicated for use in the reduction or elimination of mild to moderate hyperopia ranging from +1.5 to +4.0 D with low astigmatism (less than -1.0 D) at the spectacle plane using hyperopic photorefractive keratectomy (Hyperopic PRK) in patients with documentation of a stable manifest refraction (± 0.5 D) over the past year who are 21 years of age or older.

CONTRAINDICATIONS

You should NOT have Hyperopic PRK if:

- you have an uncontrolled vascular, auto-immune or immunodeficiency disease (for example, rheumatoid arthritis, lupus or AIDS), because it is well known that patients with these diseases have difficulty in corneal healing and are more susceptible to corneal melting
- your farsightedness is changing
- you are pregnant or nursing, because of the potential for temporary changes in vision under these conditions
- you show signs of keratoconus, (a corneal disease), because eyes with this condition may have unstable corneas;
- you have a tendency to form scars (keloids), because your corneal healing response is less predictable
- you are taking Accutane (isotretinoin) for treatment of acne or Cordarone (amiodarone hydrochloride) to control heart rhythm

WARNINGS

is not recommended

- Hyperopic PRK if you have had a *Herpes simplex* or *Herpes zoster* infection in your eyes, as laser treatment may cause the infection to return.
- Hyperopic PRK is not recommended if you are unable to keep your eye steady during the procedure.

PRECAUTIONS

- You may find it more difficult than usual to see in very dim light, rain, snow, fog or glare from bright lights at night
- You should talk to your doctor if you are taking Imitrex (sumatriptan succinate) for the treatment of migraine headache.
- You should talk to your doctor if you have a known sensitivity to any of the medications required for the laser procedure.
- You should talk to your doctor if you have a history of glaucoma, because of the potential for a strong response to post operative steroids.
- You should know that the long term safety and effectiveness of Hyperopic PRK has not been established.
- You should know that the safety and effectiveness of Hyperopic PRK in patients under 21 years of age has not been established.

BENEFITS

- Hyperopic PRK performed with the SVS Apex Plus Excimer Laser Workstation is effective in reducing or eliminating farsightedness in the range of +1.5 D to +4.0 D when astigmatism is less than -1.0 D.
- Hyperopic PRK may reduce or eliminate dependency on eyeglasses and contact lenses.
- Hyperopic PRK may reduce overall farsightedness.
- Hyperopic PRK provides an alternative to eyeglasses for some patients intolerant of contact lenses.
- If you are reluctant to wear eyeglasses, for occupational and lifestyle issues, Hyperopic PRK is a new option to reduce or correct your farsightedness.

The Hyperopic PRK clinical treatment performed with the SVS Apex Plus Excimer Laser Workstation is an alternative means of correcting farsightedness with a reasonable assurance of safety and effectiveness.

RISKS

As with any surgical procedure, there are risks associated with Hyperopic PRK. It is important to discuss these risks with your doctor before you make the decision to have laser surgery. The following events were reported in the clinical studies of Hyperopic PRK using the SVS Apex Plus Excimer Laser Workstation.

- First Month after Surgery

These events are associated with the normal post-treatment healing process and include: post-treatment pain or discomfort (first 24 to 48 hours), double vision, feeling something is in the eye, shadow images, and delayed (longer than usual) healing. These events are temporary and occur in many patients during the early post-treatment period.

- Six Months after Surgery

At 6 months after treatment the following events, presented in alphabetical order, were reported in more than 1% of patients included in the Summit Technology Hyperopic PRK Clinical Investigation:

Anterior Stromal Reticular Haze: a misty or cloudy blurring that may or may not interfere with visual acuity.

Double images: seeing a single image as two images.

Foreign body sensation: a feeling that something is in the eye.

Ghost images: seeing a shadow around objects.

Glare: after treatment glare may occur, especially from bright lights.

Loss of Best Spectacle Corrected Visual Acuity (distance or near): a decrease of 2 or more lines of vision on the eye chart while wearing eyeglasses or contact lenses.

- One Year after Surgery

At 12 months after treatment the following events, presented in alphabetical order, were reported in more than 1% of patients included in the Summit Technology Hyperopic PRK Clinical Investigation:

Anterior Stromal Reticular Haze: a misty or cloudy blurring that may or may not interfere with visual acuity.

Glare: after treatment glare may occur, especially from bright lights.

Loss of Best Spectacle Corrected Visual Acuity (distance or near): a decrease of 2 or more lines of vision on the eye chart while wearing eyeglasses or contact lenses.

Overcorrection of Hyperopia: a correction that results in the eye becoming nearsighted (myopic) possibly requiring the use of corrective lenses.

Undercorrection of Hyperopia: a correction where some degree of farsightedness may remain, possibly requiring the use of corrective lenses.

The following events at 12 months after surgery occurred in less than 1% of patients: patient discomfort, ptosis (drooping of eyelid), recurrent corneal erosion, tearing, double vision, halo, light sensitivity.

Hyperopic PRK has been studied for 18 months in the U.S. The procedure is performed using a computerized laser to correct hyperopia (farsightedness). The excimer laser is well suited for corneal reshaping, because the removal of microscopic amounts of tissue can produce the results you need to correct your farsightedness.

ARE YOU A GOOD CANDIDATE FOR HYPEROPIC PRK?

If you are considering Hyperopic PRK:

- you should be 21 years of age or older
- you should have healthy eyes which are free from disease or corneal abnormality (for example: scarring or infection)
- you should have farsightedness in the range of + 1.5 D to +4.0 D of correction with low astigmatism of less than -1.0 D
- your vision has been stable (changed by less than 0.5 D) for at least one year before surgery
- you should become familiar with the risks and benefits of Hyperopic PRK as compared with other available treatments for hyperopia.

Speak to your doctor about your reasons for choosing Hyperopic PRK and whether you are a suitable candidate for this procedure.

HOW IS HYPEROPIC PRK PERFORMED?

A specially-trained eye doctor uses the beam from the computerized laser to remove microscopic amounts of corneal tissue, precisely reshaping the cornea.

Prior to the laser treatment, some drops are placed on the eye to numb it. Use of the laser beam lasts about 15-60 seconds. The laser removes a microscopic portion of the surface tissue to reshape the cornea. This treatment is performed on one eye at a time. The second eye can be treated if all goes well and vision stabilizes without complications or adverse reactions. Hyperopic PRK of the second eye can be done three months or sooner after the first eye, at the surgeon's discretion.

After this treatment, most people report that they no longer need to wear eyeglasses or contact lenses. In the Summit Technology Hyperopic PRK Clinical Investigation: 86% of the eyes treated had 20/40 or better vision at 12 months after treatment; 64% of patients reported that they were able to function normally without any eyeglasses or contact lenses; the percentage of patients able to read ordinary newsprint without corrective lenses increased from 2% to 55% after Hyperopic PRK treatment. The remaining people experienced an improvement in vision without eyeglasses or contact lenses, but still needed to wear eyeglasses or contact lenses for some tasks.

Hyperopic PRK does not eliminate the need for reading eyeglasses. In some patients, reading eyeglasses may be required after treatment even if they were not worn before treatment.

Important: Keep in mind that your vision may take months to clear up and stabilize. Changes due to refractive surgery are permanent and cannot be undone or easily modified if your vision or focus changes or if the initial surgery is not successful (which occurs in a small percentage of cases).

WHAT YOU NEED TO KNOW

Before Surgery

If you are interested in having Hyperopic PRK you will need to have a pre-treatment examination to determine if your eye condition is right for the treatment.

Your pre-treatment examination will involve a complete medical and eye history, in which both eyes will be examined by a vision and eyeglass check, a microscopic examination, a glaucoma test, and possibly the computerized mapping of your cornea.

Important: If you wear contact lenses, it is important to stop wearing them at least two weeks before your pre-surgical examination. Failure to do so may produce poor surgical results.

Before the surgery please talk with your doctor about any medications you take. Also, talk with your doctor about eating or drinking immediately prior to the surgery. You should arrange for someone to drive you home after the surgery and to your next doctor's appointment. You should not drive until the doctor gives you permission to do so.

The Day of Surgery

Just prior to the surgery you will be given some drops in your eyes. You will be escorted into the room that contains the laser system. You will see a large machine with an arm sticking out that has the microscope attached to it. Also you may see a computer screen, a surgeon's chair and the reclining patient chair. You will be asked to sit in the patient chair. You will be laying face up toward the microscope and the ceiling. Your eye will be numbed with more drops.

Overall the surgery will take approximately 10-20 minutes, however the use of the laser beam lasts only 15-60 seconds. The doctor will place an instrument between your eyelids to hold them open during the treatment. Try to keep both eyes open without trying to shut or squeeze your eyes closed since this will allow you to relax more. The doctor will ask you to look up through the bottom of the microscope. You will see colored lights in the center of the microscope tube. The fixation light is very important in keeping your eye positioned properly during the laser surgery. **The doctor will instruct you how and when to look at these colored lights.** The doctor will then take you through a practice session with the laser to familiarize you with the sights and sounds of the treatment so that you will be prepared for what to expect during the actual treatment. Remember you and your doctor are a team; cooperate with your doctor to get the best possible result.

After the training session, the treatment will begin with the doctor using either a surgical instrument or the laser to remove the outermost layer of the cornea called the epithelium. Only after the doctor has repositioned your head in the chair, refocused the microscope and asked you to stare at the colored lights will the laser treatment be performed.

Important: It is very important to keep looking directly at the colored fixation lights during the laser treatment. The success of the surgery depends upon you staring at the lights throughout the treatment.

After your treatment, your doctor may place some drops or ointment into your eye. Your eye may then be patched for protection and comfort. The treatment itself is painless because of the numbing drops. When these eye drops wear off, your eye will likely hurt for one to two days. The doctor may recommend medicine to make you more comfortable during this time.

FIRST DAYS AFTER SURGERY

If a patch is used it is usually removed the next day. You may be sensitive to light and glare and have the feeling that something is in your eye for the first few weeks while the outer layer of your cornea grows back completely. Sunglasses may be worn to make you more comfortable during this time. Initially your eye may be overcorrected and objects may be blurry. This is part of the normal healing process after Hyperopic PRK and it may take up to three months for your vision to stabilize. All eyes get some degree of haze or cloudiness after surgery. The haziness may or may not affect your vision; it tends to decrease as your eyes heal and should eventually disappear completely.

QUESTIONS TO ASK YOUR DOCTOR

- What are the other options for correcting hyperopia?
- Will I need to limit my activities after the treatment? If yes, for how long?
- What are the benefits of Hyperopic PRK for my level of vision?
- If Hyperopic PRK does not correct my vision, could my vision be worse than before surgery? Could my vision gradually decline?
- If needed, will I be able to wear contact lenses after Hyperopic PRK?
- How is Hyperopic PRK likely to affect my need to use eyeglasses or contact lenses when I am older?
- Will my cornea heal differently if I injure it after having Hyperopic PRK?
- If I have both my eyes done, what vision problems will I experience between the treatment of my first eye and second eye?
- What vision problems will I experience if I have Hyperopic PRK only in one eye?

This information is not intended to be a substitute for a thorough discussion with your doctor about whether this treatment is right for you.

PATIENT ASSISTANCE INFORMATION

Primary Eye Doctor

Name: _____

Address: _____

Telephone No: _____

Treatment Doctor

Name: _____

Address: _____

Telephone No: _____

Treatment Location

Name: _____

Address: _____

Telephone No: _____

Laser Manufacturer

Summit Technology, Inc.

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GLOSSARY

anterior stromal reticular haze:	Corneal haze that occurs at the borders of the treatment area.
astigmatism:	Refractive error which prevents light rays from coming to a single point of focus on the retina because of different degrees of bending of light by the eye.
cornea:	Transparent front portion of the eye that covers the iris, pupil, and anterior chamber, and provides most of the eye's focusing power.
diopter:	Unit of measurement of optical strength or refractive power of lenses.
double vision:	Seeing an image as two images
drooping of eyelid (ptosis):	Sagging of the upper eyelid
excimer laser:	A medical device that produces a very powerful and pure beam of light of a single specific wavelength (color) that is used to remove tissue from the clear front part of the eye (cornea). This is performed using a computer to re-shape the cornea to correct refractive errors. This re-shaping allows incoming light rays to focus more accurately on the retina.
farsightedness (hyperopia):	Condition in which the eye is "underpowered", so that parallel light rays from a distant object strike the retina before coming to a sharp focus; true focal point is said to be "behind the retina".
foreign body sensations:	A feeling that something is in the eye.
ghost images:	Seeing a shadow around objects
glare:	Sensation produced by bright lights that is greater than normal
halos:	A hazy ring around bright lights seen by some patients.

keratoconus: A hereditary, degenerative corneal disease characterized by generalized thinning and cone-shaped protrusion of the central cornea.

late onset of corneal haze: Foggy cornea causing images to appear smudged or unclear occurring 6 months after surgery or later

lens: A transparent, colorless tissue located in the front third of the eye which helps bring light rays into focus on the retina.

light sensitivity: When light hurts your eyes

manifest refraction: A test in which a series of lenses in graded power are used to determine which lenses provide the sharpest, clearest vision. This test results in the prescription for eyeglasses or contact lenses.

nearsightedness (myopia): "Overpowered" eye in which parallel light rays from a distant object are brought to focus in front of the retina.

pupil: The opening at the center of the iris of the eye transmits light. The pupil varies in diameter depending upon the brightness of incoming light.

pupil enlargement: When the diameter of the opening in the eye (pupil) is larger than normal

PRK: An acronym for "photorefractive keratectomy". This is a surgical procedure in which a thin portion of the clear front part of the eye (cornea) is removed using an excimer laser to re-shape the cornea to correct refractive errors of the eye.

refractive error: Light rays are not brought to a sharp focus on the retina, thus producing a blurred image.

refractive surgery: Several procedures used for altering the shape of the cornea and thus how it bends light, in order to change or correct the eye's refractive error.

retina: The thin lining of tissue at the back of the eye that converts images from the lens into electrical impulses sent to the brain.

**retinal
detachment:**

When the thin lining of tissue at the back of the eye (retina) becomes loose and separates from the back of eye

RK:

An acronym for "radial keratotomy". This is a surgical procedure in which radial cuts are made in the cornea. This allows the cornea to flatten and thereby reduces nearsightedness.

shadow images: Same as ghost images

tearing: Excessive watering of the eye

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