Summary of Safety and Probable Benefit
VISX, Inc. Star S3 Excimer Laser System for Off-Center Ablations for Prior Refractive Surgeries

I. General Information

Device Generic Name:	Excimer Laser System for Refractive Surgery
Device Trade Name:	VISX Star S3™ Excimer Laser System
Applicant's Name and Address:	VISX, Inc. 3400 Central Expressway Santa Clara, California 95051

Humanitarian Device Exemption (HDE) Number: H000002

Date of Humanitarian Use Device Designation: March 9, 2000

Date of Panel Recommendation: Not Applicable (See Section XI for discussion)

Date of Good Manufacturing Practices Inspection: September 21, 1998

Date of Notice of Approval to Applicant: December 19, 2001

II. Indications for Use

The C-CAP™ is indicated for the treatment of asymmetrical ablation patterns from previous laser refractive surgery caused by decentration of the treatment as viewed on the Zeiss Humphrey® topography unit and treated with the STAR S3 ActiveTrak™ Excimer Laser System in patients:

- who exhibit symptomatology supportive of visual defect: reduced best spectacle-corrected visual acuity, debilitating glare, monocular diplopia (double vision), and/or debilitating halos; and,

- who pre-operatively have at least a 6 µm difference on the elevation topography, from the lowest point to the highest point, over a 6.5mm diameter or over the patient's pupil diameter as measured by the Zeiss Humphrey topographer, whichever is larger.

III. Device Description

The VISX Star S3™ Excimer Laser System with Eyetracker is an argon-fluoride laser driven system designed to provide refractive changes to the corneal tissue in well designed software controlled conditions to bring about refractive error reductions in a number of different refractive conditions including myopia, hyperopia, and myopic

astigmatism using a technique called photorefractive keratectomy (PRK) or Laser Assisted Keratomileusis (LASIK) to achieve desired outcomes. The laser can be programmed to provide specific design profiles in the correction of refractive ametropias as described above. Along with the experience seen with excimer laser treatment, is the complication of a certain small number of patients that experience symptomatic ablation decentrations. A proprietary software algorithm, the C-CAP Method™ (Custom Contoured Ablation Patterns), to ameliorate the symptoms associated with the unusual condition of de-centered ablations has been developed. As each patient requires an individually planned and created ablation based on the corneal topography, this surgery is customized and specific to each cornea. The device has the additional capability of relocating the primary optics aimed at the cornea to predefined locations off the central visual axis and onto the affected regions of the cornea. A specific algorithm system uses various other inputs to define the unique requirements of the de-centered ablation in order to treat the symptoms associated with it and restore a more regular aspheric corneal shape.

The eye tracker pauses treatment when an eye movement >0.2 mm occurs between two sampled positions, or when it detects significant non-circularity of the pupil. The operator can turn the tracker on or off at any time. The delay between the tracker acquisition of a positional signal and the beam positional response is about 67 msec, less than the interpulse interval of the laser beam.

The VISX Star S3™ Excimer Laser System utilizes the Humphrey® Systems Ablation Planner in analyzing the decentered ablation pattern and applies the VISX software program in determining the shape, location, size, and depth of the de-centered ablation to provide the appropriate parameters of correction.

IV. Contraindications/Warnings/Precautions

CONTRAINDICATIONS

Treatment using the C-CAP Method™ is contraindicated:

- in patients with abnormally thin corneas or in patients where the anticipated treatment would violate the posterior 280 microns (µm) of corneal stroma;
- in patients with collagen, vascular, autoimmune, or immunodeficiency diseases.
- in pregnant or nursing women;
- in patients with signs of keratoconus or suspected keratoconus; and,
- in patients who are taking one or both of the following medications: Isoretinoin (Accutane®) or Amiodarone hydrochloride (Cordarone®);

WARNINGS and PRECAUTIONS can be found in the Professional Labeling (See Attachment 1)

V. Adverse Effects of the Device on Health

REPORTED ADVERSE EVENTS

Although there has been very limited clinical use of the device using the C-CAP method, there was no evidence of any known adverse reactions when the device was used for the C-CAP method in the correction of off-center ablations. All cases for treatment have already experienced an adverse event in the form of an off-center ablation resulting in debilitating vision including uncorrected refractive error (including residual astigmatism), severe haloes and glare. The treatment for these conditions is to correct the adverse event by using the C-CAP method.

POTENTIAL ADVERSE EVENTS

- irregularity in vision outcomes
- corneal haze

VI. Alternative Practices and Procedures

There are no software mechanisms in the United States available to treat visual irregularities resulting from decentered treatments. Alternative treatment options for the C-CAP Method™ for decentered ablations are less precise manual manipulations of a Contour Ablation Pattern (Manual CAP) or penetrating keratoplasty (PKP), both of which provide little confidence that appropriate satisfactory treatment outcomes would be attainable.

VII. Marketing History

C-CAP Method™ is available internationally and has been used to treat a total of 88 cases, 3 of which were for decentered ablations. This treatment method for the indications stated above has not been available in the United States.

VIII. Prior Summaries of Safety and Effectiveness with the VISX STAR S3Ô Excimer Laser System (with Eye Tracker)

The STAR S3 with Eye Tracker was approved on April 20, 2000 to treat patients with myopia with or without astigmatism (P990010/S1) and on October 18, 2000 (PRK) and April 27, 2001 (LASIK) for hyperopia with or without astigmatism. All software development has been documented in support of the software delivery algorithms used to support all ablation profile shapes and modifications within the algorithms that have been approved for the use of the device for previously approved indications. Engineering and design data demonstrating how the device identified the accurate location of off-center ablations and the calculations used to derive the ablations necessary to treat previous de-centered ablations were submitted in this HDE amendment and found to be acceptable.

The addition of the Humphrey Topographer and Ablation Planner software (Humphrey® ATLAS™ Corneal Topography System with MasterVue™ Software) is an essential component of the C-CAP device. The Humphrey System was cleared for marketing in 510(k) K944523. Validation work on the Humphrey Ablation Planner was conducted using simulation conditions and under standard software system analyses including a system hazard analysis. The values input into the Ablation Planner are directly associated with values provided by the VISX Software algorithm program for C-CAP.

The Planner was validated to ensure accurate reproduction of the algorithm demands of the system.

IX. Summary of Clinical Studies

There have been a total of only three reported cases of de-centered ablations using the C-CAP Method™. To date while only three cases are directly related to the use of C-CAP for decentration, there have been a number of other cases in different indications where C-CAP has been used. A total of 88 cases inclusive of the three cases of known de-centered ablations treated with the C-CAP Method™ have been recorded internationally. The early results from C-CAP for all indications indicate that vision improved in all cases, two patients achieved 20/20 and many others were 20/25 to 20/40. There was a general topographical improvement in corneal symmetry with no loss of best-corrected spectacle visual acuity or uncorrected visual acuity. Most cases were keratoconus, and penetrating keratoplasty, and a few (3) post LASIK.

Summary of Three Patients:

1. Patient JR

   Patient JR is a 26 year old female who suffered irregular astigmatism in the right eye after LASIK surgery. The patient complained of double vision and glare. UVCA was 20/200. With +2.25 -1.25 X 90 the BSCVA was 20/40. Surgery in January 1999 was for a de-centered LASIK. Last examination of March 1999 the patient had no complaints of double vision and UCVA of 20/30. With +0.50 -1.25 X 60 the BSCVA was 20/20.

   In this patient a de-centered single ablation of -1.00 diopter that was placed + 1.2mm from the X axis ordinate of the patient defined visual axis and -1.3mm from the Y axis ordinate of the patient defined visual axis. The original flap was lifted and the procedure was performed without incident. The treatment plan is based on the elevation data and not on the provided axial power data. Power of the ablation was based on the projected required depth garnered from the above elevation maps. A diameter of 5.5 mm and a standard myopic sphere was selected to perform this repositioned ablation. Postoperative data from six months later is provided.

2. Patient AS

   Patient AS is a 39 year old female who suffered from irregular astigmatism after a LASIK procedure in her left eye. Pre-operatively she complained of double vision, glare and ghosting. Multiple treatments were used to move the optical center of the procedure towards the visual axis. UCVA was 20/100. With +3.50 -3.25 X 70 she was BSCVA 20/40. In January 1998 UCVA was 20/50 and BSCVA was 20/25 with +0.50-1.75 X 75. Most importantly the patient had no complaints of double vision, glare or ghosting. Elevation data was used to calculate three separate small (-1.25 diopter and 4.5mm) off axis treatments. All were displaced along the X axis positively. The first was placed at + 1.2mm along the X axis and +l.7mm along the Y axis. The second was placed +l.5mm along the X axis and non-displaced in reference to the Y axis. The final, third ablation was placed + 1.5mm along the X axis and -2.00mm along the Y axis. Please note that these three ablations overlapped substantially.

3. Patient FO

   One patient, FO is a 53 year old male with irregular astigmatism following an improperly centered LASIK procedure. UCVA was 20/60 and with a +3.00 -1.50 X 050 his BSCVA was 20/30. The patient complained of double vision, glare and ghost images. The patient had a de-centered LASIK superiorly. On last examination of 2/15/99 the patient had no complaints of double vision, no glare and only faint ghosting. UCVA was 20/40 while with a + 1.50 - 1.50 X 035 the patient achieved BSCVA of 20/30.

   In this patient, the flap was lifted and a 6 mm superior myopic spherical ablation was performed of power 2.25 diopters. This treatment was displaced + 1. 1 mm superiorly along the Y axis and -0.3mm along the X axis. Power of the ablation was based on the projected required depth garnered from the above elevation maps. The post-op map is from 2 months postoperatively.

C-CAP procedures (with software) were performed internationally on 85 patients although data could be retrieved for only 11 patients. None of the 85 cases were treated with the S3 model because the eye-tracking device was not yet available. The clinical data obtained for the 11 patients treated with this procedure produced refractive outcomes much improved from their pretreatment visual acuity: post-op uncorrected visual acuity (UCVA) ranged from 20/20 to 20/200 (this patient had a pre-treatment acuity of "count fingers"); post-op best spectacle corrected vision (BSCVA) ranged from 20/20 to 20/40.

X. Conclusion Drawn From Studies

The data presented of clinical experience with the device using the C-CAP Method™ to treat decentered ablations has demonstrated with the limited available evidence that this usage provides a means of eliminating irregular cornea topography through the use of a special algorithm developed to place the locus of the laser beam at pre-determined positions on the cornea and utilize specific shape elements from the approved laser shapes already evaluated and validated in prior applications of the laser. This proprietary software program which uses information provided by the Humphrey Systems Ablation Planner Topography Unit establishes sufficient information upon which to treat these corneal contour irregularities. The three cases presented in this submission illustrate the before conditions and after outcomes of such uses of the device. Specifically, the anticipated benefits of this treatment are:

1. an improvement in the BSCVA
2. an improvement in the overall corneal contour
3. a reduction in patient symptoms

Corneal contour maps of before and after further illustrate the capability of the C-CAP Method™ in alleviating decentered ablations and re-shaping the cornea into a normal centered aspheric contour that allows for the restoration of normal vision and visual acuity.

Theoretically, as with any laser ablation of the cornea the risks specific to the lasering of that cornea reside in poor centration and additional thinning. As the same patient skills are necessary for obtaining a topography map on the Humphrey topography system (self fixation used to define the visual axis) as is required for laser surgery using the STAR Excimer Laser System, there should be no safety issue. Regarding the thinning, there are specific warnings to avoid violation of posterior stromal 250 microns. In any event, as one known alternative is corneal transplant to symptomatic decentration, the risk of the planned ablation is relatively small.

XI. Panel Recommendation

The Ophthalmic Devices Panel has previously provided reviews and comments on other refractive lasers. The VISX Star S2 Excimer Laser System was evaluated by the Ophthalmic Devices Panel for +1.00D to +6.00D hyperopia (PRK) on July 23, 1998, and 0.00D to –14.00SD spherical myopia with or without –0.5 to –5.0 cyl (LASIK) on June 22, 1999. The addition of the eyetracker for the S3 laser did not require panel review. This HDE did not raise any unanticipated safety issues; therefore, it was determined that this application did not need to be submitted to the advisory panel.

XII. FDA Decision

CDRH determined that, based on the data submitted in the HDE, the VISX Star S3™ Excimer Laser System with Eye Tracker and C-CAP software will not expose patients with decentered ablations suffering from visually related symptoms to an unreasonable or significant risk of illness or injury, and the probable benefit to health from using the device outweighs the risk of illness or injury, or less precise outcomes from manual treatments. Approval was issued on December 19, 2001.

XII. Approval Specifications

Directions for Use: See the Labeling (Attachment I)

Indications for Use: See section II above.

Hazards to health from the use of the device: See the Warnings, Precautions, and Adverse Effects Section in the Labeling (Attachment I)

Publications and other Outside Information