VISX Excimer Laser System and Custom Contoured Ablation Pattern (C-CAP) Method™ - H000002

FDA approved this device under the Humanitarian Device Exemption (HDE) program http://www.fda.gov/cdrh/ode/hdeinfo.html. See the links below to the Summary of Safety and Probable Benefit (SSPB) and other sites for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name:	VISX Excimer Laser System and Custom Contoured Ablation Pattern (C-CAP) Method™
Manufacturer:	VISX, Inc.
Address:	3400 Central Expressway, Santa Clara, California 95051-0703
Approval Date:	December 19, 2001
Approval Letter:	http://www.fda.gov/cdrh/pdf/h000002a.pdf

What is it? The C-CAP Method™ is a treatment system used to remove microscopic amounts of tissue from the cornea (the clear, front surface of the eye) in order to correct a problem called "off-center ablation," produced during prior laser surgery to correct vision. The treatment restores the cornea's normal shape. Off-center ablations can result in vision that is worse than it was before the original laser surgery. It can also lead to glare, double vision in one eye, and a halo effect. This treatment system uses the VISX Star 3 Excimer Laser System with the Humphrey Systems Ablation Planner Topography Unit.

How does it work? The C-CAP Method™ uses the Humphrey System to identify appropriate treatment sites by analyzing where off-centered corneal irregularities exist. That information is then programmed into the laser software. http://www.fda.gov/cdrh/LASIK/glossary.htm

When is it used? The C-CAP Method™ is a more precise treatment to correct off-center ablation patterns than manual treatments, which have been used up until now. Candidates for this treatment should have both an irregular ablation and debilitating visual symptoms.

What will it accomplish? This treatment may correct off-center ablations resulting from prior laser surgery to correct vision.

When should it not be used? Patients should not be treated with this device if:

- They have not had prior laser surgery to correct vision,
- They have an abnormally thin cornea,
- The treatment might remove too much corneal tissue,
- They exhibit signs of keratoconus (cone shaped cornea),
- They are taking either of the drugs isoretinoin (Accutane) or amiodarone hydrochloride (Cordarone)

Additional information: The Summary of Safety and Probable Benefit and Labeling will be available at: http://www.fda.gov/cdrh/ode/H000002sum.html

Other:

Center for Devices and Radiological Health:

Extensive information on Lasik procedure: http://www.fda.gov/cdrh/lasik/

National Institutes of Health:

Information on refractive errors and links to eye organizations: http://medlineplus.nlm.nih.gov/medlineplus/refractiveerrors.html

(Updated 2/13/2002)