New Device Approvals

ViewPoint™ CK System P010018

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name:	ViewPoint™ CK System
Manufacturer:	Refractec, Inc
Address:	5 Jenner, Suite 150, Irvine, CA 92618
Approval Date:	April 11, 2002
Approval Letter:	http://www.fda.gov/cdrh/pdf/p010018a.pdf

What is it? An electrically-powered surgical device that performs a procedure called "conductive keratoplasty" to temporarily reduce hyperopia (farsightedness).

How does it work? Using a metal probe, radiofrequency energy is applied to the surface of the cornea (the clear front surface of the eye) in a circular pattern. The energy from the probe heats the tissue in the cornea, causing it to shrink slightly. This changes the cornea's shape, giving it a steeper angle. This allows light to better focus on the retina at the back of the eye and gives clearer images of objects at a distance. For a picture of the normal eye, see http://www.nlm.nih.gov/medlineplus/ency/imagepage/9925.htm

When is it used? The device may be used to treat patients who are farsighted, who are at least 40 years of age, and whose eyesight has changed very little over the previous 12 months.

What will it accomplish? The treatment temporarily improves distance vision in far-sighted people. Although some patients may retain some or all of the correction achieved during surgery, for most people

the amount of farsightedness correction is temporary and will decrease over time. Vision without glasses is improved after CK[SM], but some people still need glasses or contact lenses. Since it corrects only farsightedness, CK[SM] does not eliminate the need for reading glasses.

When should it not be used? This device should not be used for patients who:

- are pregnant or nursing,
- have an abnormally shaped cornea,
- have thinning of the cornea,
- have a history of herpes infection in the eye,
- have an untreatable dry eye,
- have an autoimmune disease
- have a collagen vascular disease (e.g. rheumatic fever),
- have clinically significant allergies,
- are insulin dependent diabetics,
- have a compromised immune status (lack the ability to fight diseases), or
- have an implantable electrical device such as a pacemaker, defibrillator, or cochlear implant.

Additional information: Summary of Safety and Effectiveness and labeling will be available at: http://www.fda.gov/cdrh/pdf/p010018.html

Other: National Institutes of Health: "Information on Farsightedness": http://www.nlm.nih.gov/medlineplus/ency/article/001020.htm#visualFile

(Updated 04-17-2002)