Hyperion™ LTK System - P990078

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:	Hyperion™ LTK System
Manufacturer:	Sunrise Technologies, International, Inc.
Address:	3400 West Warren Ave., Fremont, CA 94538
Approval Date:	June 30, 2000
Approval Letter:	http://www.fda.gov/cdrh/pdf/p990078a.pdf

What is it? A new type of surgical laser used for the temporary reduction of hyperopia (farsightedness.)

How does it work? Laser Thermal Keratoplasty (LTK) is a surgical treatment for farsightedness performed using a holmium YAG laser. The laser produces a non visible beam of light. The beam heats the tissue in the cornea (the clear front surface of the eye), causing it to shrink slightly. When the tissue shrinks, the cornea's shape changes and it becomes steeper. This allows incoming light to focus on the light-sensitive retina at the back of the eye, giving clearer images. The goal of LTK is to improve the patient's ability to see objects at a distance.

When is it used? This device may be used to treat patients who have farsightedness (between +0.75 to +2.5 diopters), who are at least 40 years of age, and whose visual acuity has changed very little over time (that is, the patient's glasses prescription has changed no more than 0.50 diopter in the previous six months.)

What will it accomplish? This treatment temporarily improves distance vision in far-sighted people who have difficulty seeing clearly at a distance. Although some patients may retain some or all of the correction achieved during the surgery, for most people the amount of farsightedness correction achieved is temporary and will decrease over time. The amount of correction remaining at 24 months is typically about half of the correction observed at 6 months. How long any significant portion of the correction lasts depends on the amount of correction attempted and age.

When should it not be used? This device should not be used for pregnant or nursing women or for patients who have an abnormal shape or thinning of the cornea, scarring in the center of the cornea, a history of herpetic eye infection, an autoimmune or collagen vascular disease, a clinically significant atopic syndrome, insulin dependent diabetes, or a compromised immune status.

Additional information: Summary of Safety and Effectiveness is available at:
http://www.fda.gov/cdrh/pdf/p990078.html

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