

5174004
JAN - 8 1998

Summary of Safety and Effectiveness for 510(k) K974004

1. Submitter of Information

LaserSight Technologies, Inc.
12249 Science Drive, Suite 160
Orlando, Florida 32826

Contact Person:

Charles W. Stewart, O.D.
Executive Vice President
Business Development
Tel (407) 382-2700
Fax (407) 382-2701
e-mail: cstewart@lasetech.com

2. Name of Device:

Trade / Proprietary Name: Automated Disposable Keratome (ADK)

Classification / Usual Name: Keratome

Device Classification: Class I, 86 HNO
(21 CFR, Section 886.4370)

3. Predicate Devices:

The Automated Disposable Keratome for which marketing clearance is requested is substantially equivalent to the following predicate devices:

- Automatic Corneal Shaper, manufactured and distributed by Chiron Vision Corporation, 9342 Jeronimo Road, Irvine, CA [cleared under K941550].
- Steinway-Barraquer In-Situ Microkeratome Set, manufactured and distributed by Steinway Instrument Company, Inc., San Diego, CA. This device is identical to the Allergan Medical Optics Barraquer-Krumeich Refractive Set [cleared under K860001].
- Micro Refractive System Model 1000, manufactured and distributed by Micro Precision Instrument Company, 2323 N. Central Avenue, Suite 2105, Phoenix, AZ [cleared under K903912].

4. Descriptions of Subject Device:

Device Description: The Automated Disposable Keratome consists of two components: (a) disposable keratome, (b) power / suction supply and DC motor with foot actuated switch.

The ADK is a keratome designed to perform anterior lamellar circular corneal resections of a predetermined diameter and thickness based upon the principle of a carpenter's plane. A cutting blade emerges from the center of the keratome plane. The stainless steel blade oscillates by a small DC motor controlled by foot switch. The keratome, which is fabricated from high density engineering plastic (except the blade and motor), has a one piece head that is pre-assembled with a fixed foot plate, and is available in two standard head sizes, 130 or 160 microns, depending upon the thickness of corneal section desired.

The keratome head has dovetail guides, which correspond to guides on the suction ring that is placed upon the ocular globe. Tandem gears on both sides of the keratome head and corresponding gears on the suction ring automatically move the cutting blade along the dovetail guides. Whereas gears on competitive keratomes are exposed, the gears on the ADK are covered to minimize entrapment of lashes and lids. A DC motor controls the gears and blade movement via the foot switch control. The cutting principle is the same as with manual keratomes and other automated keratomes. The automatic movement of the keratome allows for a more uniform translation across the suction ring and thusly across the cornea.

The power supply provides the power to both the keratome motor and the suction supply for holding the suction ring in place on the cornea. The ADK has three settings for vacuum control: "off", "low", "high"; whereas predicate devices have only two vacuum settings, "on" and "off". The vacuum suction of predicate devices in the "on" position is the same as the suction of the "high" setting of the ADK. The "low" suction setting of the ADK provides the option of using the suction ring to aid in globe fixation after the resection. Predicate devices require the surgeon to use the "off" position for globe fixation after resection, where residual suction declines variably back to 0 mmHg. The keratome is provided sterile in a sealed blister/Tyvek® tray and is discarded after single use.

5. Intended Use of the Subject Device:

The Automated Disposable Keratome is an AC-powered device that is intended to shave a partial lamellar section of the cornea.

6. Comparison of Technological Characteristics with Predicate Devices:

The Automated Disposable Keratome (ADK) operates on the same principles and has the same technological characteristics as other legally marketed keratomes. However, the ADK is most similar to the Chiron Automated Corneal Shaper (ACS). The ADK shares the same primary drive mechanism as the Chiron ACS. Historically this DC-powered gear drive design, which automatically draws the blade across dovetail guides, has proven itself safe and effective in producing precise sections of corneal tissue. The ADK has an additional

gear and track which creates a dual parallel drive action across the cornea. Torque induced by single sided drives, such as the Chiron ACS, may allow inadvertent jamming of the drive mechanism. Refer to TABLE 1 for a comparison of features for substantially equivalent devices.

3. The primary drawbacks of the presently marketed keratomes are: (1) human error during cleaning, re-assembly and final intra-operative assembly of the keratome, (2) wearing out of keratome parts as a function of re-use, and (3) the potential for residual tissue to jam or disrupt the gears during the resection procedure. The ADK eliminates these drawbacks by providing the keratome pre-assembled and pre-sterilized in a copolyester tray sealed with a Tyvek® lid, where the keratome is disposed of after single use. The sterilization of the ADK is performed under a validated gamma irradiation cycle, with a sterility assurance level (SAL) of 10^{-6} , and dosimetric release. Certain parts of the keratome, except the stainless steel blade, have been replaced with high density plastic materials which have been tested according to FDA Tripartite Guidelines and the ISO 10993-1 Standard and are deemed biocompatible. The ADK power supply conforms to the IEC-601-1 electrical safety standard.

Together with the proven reliability of the DC-powered gear drive mechanism and the elimination of the problems associated with cleaning, tedious assembly and component wear, the ADK offers an improvement over currently available keratomes. These differences between the ADK and currently marketed devices do not affect the safety and effectiveness of the device since they do not alter the energy source, cutting parts or principle of operation.

7. Discussion of Clinical Tests:

The techniques and instrumentation for lamellar keratoplasty were introduced 45 years ago. Keratomes have been in use for nearly 30 years, beginning with the introduction into commercial distribution of the Steinway/Barraquer In Situ Microkeratome Set in 1965. A review of the published literature on keratomes indicates that these devices are associated with acceptable clinical results in terms of postoperative refraction and visual acuity, and minimal postoperative complications.

TABLE 1
INFORMATION ON SUBSTANTIALLY EQUIVALENT PRODUCTS
COMPARISON OF FEATURES

<i>Parameter</i>	<i>Company</i>			
	<i>LaserSight</i>	<i>Chiron Vision</i>	<i>Allergan Medical</i>	<i>Micro Precision</i>
<i>Major Components</i>	Console	Console	Console	Console
	1 Fixed Height Suction Ring	1 Adjustable Height Suction Ring	25 Suction Rings	25 Suction Rings
	Fixed Depth Keratome Head (130 μ or 160 μ)	Adjustable Keratome Head	Keratome Head with Thickness Plates	Adjustable Keratome Head
	Electric Motor 12 v DC	Electric Motor 12 v DC	Electric Motor 12 v DC	Turbine Motor
	Blade Oscillation 10,000 RPM	Blade Oscillation 7,500 RPM	Blade Oscillation Not known	Blade Oscillation 0-20,000 RPM
<i>Console Details</i>				
Electrical	110/120 AC	110/120 AC	110/120 AC	None
Motor RPM	10,000 RPM	10,000 RPM	10,000 RPM	0-20,000 RPM
Vacuum Pump	AC Powered	AC Powered	AC Powered	Nitrogen Gas Venturi Type Pump
Blade Height Verification	At Factory with Micron Optical Comparator	Clinic Measured with Micron-Scope	None	Clinic measured with Digital Indicator
Foot Controls	DC Powered	DC Powered	DC Powered	Pneumatic



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 8 1998

Charles W. Stewart, O.D.
LaserSight Technologies, Inc.
12249 Science Drive, Suite 160
Orlando, Florida 32826

Re: K974004
Trade Name: Automated Disposable Keratome (ADK)
Regulatory Class: I
Product Code: 86 HNO
Dated: December 19, 1997
Received: December 22, 1997

Dear Dr. Stewart:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Charles W. Stewart, O.D.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

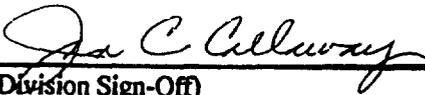
510(k) Number: K974004

Device Name: Automated Disposable Keratome (ADK)

Indications for Use: ADK (Automated Disposable Keratome) is intended to perform anterior, lamellar, circular corneal resections of a predetermined diameter and thickness.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K974004

Prescription Use
(Per 21 CRR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)