K990227

JAN 31 2000

Summary of Safety and Effectiveness for 510(k)

1. Submitter of Information:

LaserSight Technologies, Inc.
3300 University Boulevard, Suite 140
Winter Park, Florida 32792
Contact Person: Michael P. Dayton, MS, RAC
Senior Vice President
Chief Technical Officer
Tel (407) 678-9900
Fax (407) 671-0180

2. Device Name:

Trade / Proprietary Name: UltraShaper™ System

Classification / Usual Name: Keratome

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

Performance Standards: N/A

3. Predicate Devices:

The UltraShaper™ 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. Description of Device:

Device Description: The UltraShaper™ System consists of the following components: (a) cutting head, (b) suction rings / handles, (c) motor handpiece, (d) handpiece-to-console cable, (e) suction tubing set, (g) blade assembly, and (h) console power / suction supply with foot actuated switches.

The cutting head and suction rings / handles are constructed entirely from stainless steel. The UltraShaper™ System is 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 (in the motor handpiece) controlled by foot switch. The cutting head slides on dovetail guides on a circular suction ring. The cutting head contains a gear drive train that engages a gear rack on one side of the suction ring to drive the keratome head across the suction ring and cornea. The suction ring provides an annular vacuum chamber for temporary attachment to the ocular globe. The cutting head has a fixed foot plate and is available in three standard head sizes, 130, 160 and 180 microns, depending on the thickness of the corneal section desired. There are also three different suction ring / handle sizes available to accommodate the variations in corneal curvature from patient to patient. A (motor handpiece-to-console) cable is also supplied with each UltraShaper™ keratome.

The UltraShaper™ Console Power Supply provides the power to both the keratome motor and the suction supply for holding the ring in place on the cornea. This is the same console which drives the company's ADK disposable keratome. The console has three vacuum suction settings, HIGH, LOW, OFF. The console will only permit the keratome to operate (transverse the cutting plane) while in the HIGH setting. While in the HIGH mode, the console, with its internal barometer, reacts to vacuum suctions values which are below the optimum by signaling the operator with audible and visual warnings. The UltraShaper™ Console Power Supply conforms to IEC-601-1 electrical safety standard.

A sterile suction tubing set, which is generic to several keratome systems, is used to connect the suction ring / handle of the UltraShaper™ to the suction port on the console. Suction tubing sets are supplied sterile and are intended for single use. Likewise, keratome blades are supplied sterile and are intended for single use.

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

The motor handpiece for the UltraShaper™ device uses the same DC motor in the Chiron ACS™. The connect point between the UltraShaper™ motor handpiece is similar to the ACS™ system. The UltraShaper™ motor handpiece, like the ACS™ motor handpiece, is disinfected by cleaning with alcohol. Refer to TABLE 1 for a comparison of features for substantially equivalent devices.

The differences between the UltraShaper™ and currently marketed devices, particularly the Chiron ACS device, are insignificant and do not affect the safety and effectiveness of the device since they do not alter the energy source, materials 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

	Company			
Parameter	***LaserSight*** UltraShaper™ System	***Chiron Vision*** ***Automated Corneal Shaper™***	***Allergan Medical*** ***Barraquer-Krumeich Refractive Set™***	***Micro Precision*** ***Micro Refractive™ System Model 1000***
Major Components	Console	Console	Console	Console
	1 Suction Rings	1 Adjustable Height Suction Ring	25 Suction Rings	25 Suction Rings
	Fixed Depth Keratome Head (130, 160, 180 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 7,500 RPM	Blade Oscillation 7,500 RPM	Blade Oscillation Not known	Blade Oscillation 0-20,000 RPM
Console Details				
Electrical	110/120 AC	110/120 AC	110/120 AC	None
Vacuum Pump	DC Powered	DC Powered	AC Powered	Nitrogen Gas Venturi Type Pump
Blade Height Verification	Measured in Clinic with Micron-Scope	Measured in Clinic with Micron-Scope	None	Measured in Clinic with Digital Indicator
Foot Controls	DC Powered	DC Powered	DC Powered	Pneumatic

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2000

Mr. Sam A. Mirza
Manager, Regulatory Affairs
LaserSight Technologies, Inc.
3300 University Boulevard, Suite 140
Winter Park, Florida 32792

Re: K990227
Trade Name: UltraShaper™ System
Regulatory Class: I
Product Code: 86 HNO
Regulation: 886.4370 (Keratome)
Dated: January 12, 2000
Received: January 13, 2000

Dear Mr. Mirza:

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.

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 (IF KNOWN) : K990227

DEVICE NAME : UltraShaper™ System

INDICATIONS FOR USE :

The UltraShaper™ System is an AC-powered device that is intended to shave a partial lamella section of the cornea.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bruce Drum

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K990227

Prescription Use X OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)