K 983317

DEC 2 1998

Barron Precision Instruments, L.L.C.	**Section:** 11
Document: FDA 510(k) Application	**Revision:** 1.1
Subject: Barron Microkeratome System	**Effective Date:** 9/14/98
Issued by: M.B. Barron	**Page:** 1 of 4

SECTION 11 - 510(k) SUMMARY

This 510(k) summary of safety and effectiveness for the Barron Microkeratome System is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92, and follows the Office of Device Evaluation guidance concerning the presentation and content of a 510(k) summary.

1. Submitter's name, address, telephone number, contact person, and date the summary was prepared:

a. Applicant	Barron Precision Instruments, L.L.C. PO Box 973 8170 Embury Road Grand Blanc, MI 48439
b. Telephone Number Faxsimile Number	(810) 695-2080 (810) 695-0948
c. Contact Person	Mark Barron General Manager
d. Date Summary Prepared	September 14, 1998

2. Name of the Device, including trade name, the common or usual name, and the classification

a. Device Trade Name	Barron Microkeratome System Model B2000
b. Common name	Keratome
c. Classification Name	Keratome, AC-Powered Ophthalmology (21 CFR 886.4370)
d. Class of Device	Class I
e. Product Code	86HNO

3. Identification of legally marketed predicate devices to which equivalence is being claimed

Company	Device	510(k)
~~LaserSight Technologies~~	Automated Disposable Keratome	K974004
Hansa Research & Development	Automated Corneal Shaper	K913697
Innovative Optics, Inc.	INNOVATOME	K973294
Micro Precision Instrument Co	Micro Refractive System Model 1000	K903912

4. Description of the Device

The Barron Microkeratome System consists of two components: a single-use Microkeratome and a Control Console that provides 9V DC and vacuum to the Microkeratome.

The Barron Microkeratome is designed to perform a lamellar section of the cornea to yield a flap of predetermined diameter, thickness, and flap hinge width. The product will be offered in various sizes to provide flap diameters from 7.5 mm to 10.5 mm, and flap thickness of 130 μm, 160 μm, and 180 μm. The lamellar section is obtained by an oscillating stainless steel blade that is driven by a small motor in the Microkeratome. The Microkeratome is fixated on the eye by use of vacuum which is applied to a Vacuum Ring that seats on the eye. The vacuum exhaust from the Microkeratome is isolated from the ambient atmosphere by a 0.45-μm hydrophobic filter.

The Microkeratome is supplied in a sterile package, and includes all components that are necessary to perform the section. The package contains the fully assembled and inspected Microkeratome including Vacuum Ring, Luer Lok connector with filter, Vacuum Tubing, Blade, Electrical wire, and Electrical connector. There are no reusable components to be sterilized, and there are no reusable motor and drive mechanisms that are subject to long term wear. The entire Microkeratome, including the motor and the blade drive mechanism, are disposable. The only reusable portion of the Barron Microkeratome is the electronic Control Console, which is outside the operative sterile field.

5. Intended use of the device

The Barron Microkeratome is intended to be used for creating a lamellar section from the cornea to create a flap with predetermined diameter, thickness, and flap hinge width.

6. Summary of the technological characteristics of the submitted device compared to predicate devices

Comparative Technological Characteristics

		Predicate #1 510(k): K974004	Predicate #2 510(k): K913697	Predicate #3 510(k): K973294	Predicate #4 510(k): K903912
Parameter	***Barron Precision***	***Lasersight***	***Chiron Vision***	***Innovative Optics***	***Micro Precision***
Indications for use	Partial Anterior Circular Lamellar Resection of the Cornea	Shaving a Partial Lamellar Section of the Cornea	Initial Lamellar Corneal Resections	Resection of a Circular Anterior Lamellar Flap	Lamellar Sectioning of the Cornea
Suction Ring	1 Fixed Height Suction Ring (Disposable - Stainless Steel)	1 Fixed Height Suction Ring (Disposable - Plastic)	1 Adjustable Height Suction Ring (Reusable Stainless Steel)	1 Fixed Height Suction Ring (Reusable Stainless Steel)	20 Suction Rings (Reusable Stainless Steel)
Thickness Control	Fixed Depth Keratome Head (130u, 160u, or 180u)	Fixed Depth Keratome Head (130u or 160u)	Adjustable Keatome Head to 180u	Fixed at 175u	1-500u Variable
Blade Drive Source	Electric Motor 9V DC (Disposable)	Electric Motor 12V DC (Reusable)	Electric Motor 12V DC (Reusable)	Electric Motor in Console (Reusable)	Turbine Motor (Reusable)
Blade Speed	Blade Oscillation 20,000 RPM	Blade Oscillation 10,000 RPM	Blade Oscillation 7,500 RPM	12,000 RPM	0-20,000 RPM
Blade Angle	25°	25°	25°	Not Stated	9°
Blade Movement	Reciprocating Sideways	Reciprocating Sideways	Reciprocating Sideways	Reciprocating Sideways	Reciprocating Sideways
Blade Material	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel
Flap Diameter	Fixed at 8 or 9.5mm	Fixed at 9.5mm	Variable to 9mm	Variable 8 to 10mm	Variable 7.5-8.5mm
Keratome Head Movement	Manual	Automatic	Automatic	Automatic	Manual
Console Details					
Electrical	Universal AC - 85V to 260V	110/120 AC	110/120 AC	AC Powered	None
Vacuum Pump	DC Powered	AC Powered	AC Powered	AC Powered	Nitrogen Gas Venturi
Blade Height Verification	At Factory with Optical Comparator	At Factory with Optical Comparator	Clinic Measured with Microscope	At Factory	Clinic Measured with Digital Indicator
Foot Controls	DC Powered	DC Powered	DC Powered		Pneumatic

7. Brief discussion of non-clinical tests and results

The Barron Microkeratome System has been designed and tested to applicable safety standards such as IEC60601-1, Medical Electrical Equipment - Part 1:General Requirements for Safety . The specifications and intended use of the Barron Microkeratome are the same or very similar to predicate devices. Non-clinical testing on porcine eyes and cadaver eyes was found to result in corneal lamellar sections equivalent to predicate devices. Therefore, the technological differences between the Barron Microkeratome System and predicate devices do not raise any new issues of safety, effectiveness, or performance of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 1998

Mr. Mark Barron
General Manager
Barron Precision Instruments, L.L.C.
PO Box 973 8170 Embury Road
Grand Blanc, Michigan 48439-0973

Re: K983317
Trade Name: Barron Microkeratome System Model B2000
Regulatory Class: I
Product Code: 86 HNO
Dated: November 16, 1998
Received: November 20, 1998

Dear Mr. Barron:

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

INDICATIONS FOR USE

510(k) NUMBER: K983317

DEVICE NAME: Barron Microkeratome System, Model 2000

INDICATIONS FOR USE:

The Barron Microkeratome System is indicated for performing lamellar sectioning of the cornea.

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

_____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Dennis L. McCarthy

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K983317