K973294/A1

510(K) Summary
INNOVATOME™ MICROKERATOME

OCT - 3 1997

This 510(K) summary of safety and effectiveness for the INNOVATOME™ Microkeratome is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(K) summary.

Applicant:	Innovative Optics, Inc
Address:	4307 Cedarwood Drive Lilburn, GA 30247
Contact Person:	Mr. Larry Hicks President
Telephone:	770-717-0707 770-717-9386 – Fax
Preparation date: (of the summary)	August 1997
Device Trade Name:	INNOVATOME™ Microkeratome
Common Name	Microkeratome
Classification Name:	Keratome Surgical Instrument Ophthalmology (21 CFR 886.4370)
Class of Device:	Class I (AC powered or Battery powered)
Legally marketed predicate device:	Chiron Microkeratome: Plancon Microlamellar Keratome
Description of the Device:	The INNOVATOME™ is a microkeratome that rotates at 14,000 rpm and is capable of creating lamella with diameters ranging from 8-10 mm.
Intended use:	The INNOVATOME™ microkeratome is indicted for the resection of a circular anterior lamellar flap. This intended uses is the same or similar to that for the claimed predicate device.

Comparison of the INNOVATOME™ and legally marketed predicate devices:	The rotational speed, the depth of cut to create a lamella, and the diameters of the resulting lamellae are essentially the same for these devices. There are no significant differences between these devices under conditions of intended use.
INDICATIONS:	The INNOVATOME™ and its claimed predicates have the same indication; i.e., used to create corneal lamellae, i.e., corneal resection.
Performance Data:	None. The specifications and intended uses of the INNOVATOME™ Microkeratome are the same as or very similar to those of the claimed predicate devices, e.g., the Chiron Microkeratome and the Plancon Microlamellar Keratome. Because of this, performance data were not required.
CONCLUSION:	Based on the foregoing, Innovative Optics, Inc. believes that the INNOVATOME™ microkeratome is substantially equivalent to the claimed legally marketed predicate devices, i.e., the Chiron Microkeratome and the Plancon Microlamellar Keratome.

ATTACHMENT C

COMPARISON TO PREDICATE DEVICES

Comparison of specifications of INNOVATOME™ Microkeratome and claimed predicate devices:

Specification	INNOVATOME™ Microkeratome	Chiron Microkeratome*	Plancon Microlamellar Microkeratome**
Keratome Material Blade	Stainless Steel Sapphire	Stainless Steel Steel	Stainless Steel Stainless Steel
Keratome	adjustable	adjustable	adjustable
Rotational Speed Usual or recommend.	12,000 rpm; 24,000 cuts per minute	14,000 rpm	0 - 20,000 rpm 14,000 rpm
Diameter of lamella	8-10 mm	9.5-10.0 mm	not stated*
Thickness of lamella	175 microns	130-180 microns	not stated*
Indications	see below	see below	see below

** a brochure covering the Chiron Microkeratome is attached for reference

* copy of Safety and Effectiveness Summary for K960395 is attached for reference - this document cites unnamed predicate devices

INDICATIONS

INNOVATOME™ Microkeratome: The INNOVATOME™ microkeratome is indicated for anterior lamellar circular resection.

Chiron Microkeratome: Lamellar circular resection
Plancon Microlamellar Kerat.: Microlamellar keratoplasty

Performance Data: None. The specifications and intended uses of the INNOVATOME™ microkeratome are the same or very similar to those of the claimed predicate devices, e.g., the Chiron microkeratome, the Plancon microlamellar keratome, and an unnamed device cited in K960395 (see attached document).

There are no significant differences in specifications of the cited devices or of intended use.

Because of this, performance data were not required.

CONCLUSION: Based on the foregoing, Innovative Optics, Inc. believes that the INNOVATOME™ microkeratome is substantially equivalent to the claimed legally marketed predicate devices such as the Chiron microkeratome (K941550), the Plancon Microlamellar keratome (as described in K960395 and K970377), or the unnamed microkeratome cited in K960395.

Attachment 1 - Chiron Brochure (page 6 in this application)
Attachment 2 - Public summary for K960395 (pages 7-8 in this application

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 1997

Mr. Larry Hicks
President
Innovative Optics, Inc.
4307 Cedarwood Drive
Lilburn, GA 30247

Re: K973294
Trade Name: Innovatome™ Microkeratome
Regulatory Class: I
Product Codes: 86 HNO and 86 HMY
Dated: September 2, 1997
Received: September 2, 1997

Dear Mr. Hicks:

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

If you desire specific advice for your devices 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 devices, 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

ATTACHMENT D

INDICATIONS FOR USE STATEMENT

510(K) Number (if known):_____

Device Name: INNOVATOME™ MICROKERATOME

Indications For Use:

The INNOVATOME™ microkeratome system is indicated for the resection of a circulal anterior lamellar flap.

Note: The device is labeled as a restricted device (21 CFR 801.109) - see Operator's Manual

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use____
(Per 21 CFR 810.109)

Denis L. McCarthy
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K973294