K990900

SEP 24 1999

APPENDIX III

510(k) SUMMARY

[As required by 21 CFR 807.93]

I GENERAL INFORMATION

Applicant's Name & Address:	Nidek Incorporated 47651 Westinghouse Drive Fremont, California 94539-7474
Contact:	Mr. Jerry Tsutsumi Regulatory/Quality Manager
Date Summary Prepared:	16 March 1999

II DEVICE NAME

Trade or Proprietary Name:	Nidek Keratome, MK-2000
Model Number:	MK-2000
Common/Classification Name:	Keratome
Class:	Class I
Classification Panel:	86
Regulation Number:	886.4370

III PREDICATE DEVICES

The Nidek MK-2000 Keratome is claimed to be substantially equivalent to the following currently Marketed Predicate Devices:

Submitter	Model	510(k) Number	Date
Hansa R&D*	AUTOMATED CORNEAL SHAPER	**K912697**	05-Nov-91
Hansa R&D	HANSATOME	**K972808**	24-Oct-97
Innovative Optics	INNOVATOME	**K973294**	03-Oct-97
MORIA	CARRAZIO BARRAQUER	**K981141**	24-Jul-98
Hawken Industries	FLAPMAKER	**K981155**	14-Aug-98
LaserSight Tech.	ADK	**K974004**	08-Jan-98

* The 510(k) for the AUTOMATED CORNEAL SHAPER was submitted by Hansa Research and Development, Inc., but his product is currently being sold by CHIRON INTRAOPTICS as identified in **APPENDIX VII**.

IV PRODUCT DESCRIPTION

This DEVICE is an AC powered device consisting of three main parts:

1. **CONTROL BOX:** The FRONT PANEL consists of:
   - LED for Power Indicator, Suction Indicator, Confirmation Indicator.
   - Pressure Gauge with a pointer for suction pressure.
   - Self Test button to perform a pre-test.
   - Hand Piece Connector
   - Connector for suction and suction pressure monitoring

   The REAR PANEL consists of a AC Power Inlet, Power Switch and a Foot Pedal Connector. The MOTOR CONTROL is Bi-directional control (forward/reverse), one way control for oscillation.

2. **HAND PIECE:** The Handpiece contains the blade running and reversing mechanism, the oscillation mechanism, an attachment slot for the Suction Ring, the Blade Holder, and a connector for the Control Box. The Handpiece is made of aluminum.
   - Blade Holder: is made of Stainless Steel
   - Applanation Plate: that determines the thickness of the incised cornea (flap) and is fixed to the top of the blade holder. Three Applanation Plates are available dependent on the desired flap thickness (130, 160 & 180 µm).
   - Blade: the keratome blade is pre-sterilized and made of "Stainless Steel" and is a one-time-use disposable blade.
   - Single Suction Ring: fixes the hollow part of the suction ring to the eyeball under suction. 2 suction ports, one to monitor suction pressure and a second to provide suction. Three suction ring sizes are available, dependent on the desired flap diameter (8.5 mm, 9.5 mm or 10.5 mm). There are NO gear mechanism or sliding guide around the suction ring.

2. **FOOT PEDAL:** Consists of:
   - "SUCTION SWITCH" to control the applying and stopping of the suction pressure to the suction ring.
   - "FORWARD SWITCH" to control the running and oscillation of the blade.
   - "REVERSE SWITCH" control the reverse motion of the blade.
   - "CABLE" allow connection to the Control Box.

V INDICATIONS FOR USE

Intended Use: The Nidek MK-2000, Keratome is intended to make a flap by incising the cornea at a pre-selected thickness and diameter.

VI CLINICAL PERFORMANCE DATA

No clinical performance data has been provided.

VII NON-CLINICAL PERFORMANCE DATA

None provide.

VIII RATIONAL FOR SUBSTANTIAL EQUIVALENCE

Our claim of Substantial Equivalence is based on the following;

- The INTENDED USES and the OPERATING & CUTTING PRINCIPLES of the Nidek MK-2000 Keratome is the same as the SIX predicate devices.
- The OPERATIONAL FEATURES of the Nidek MK-2000 Keratome are the same or similar to those offered on one or more of the predicate devices.
- The SAFETY FEATURES of the Nidek MK-2000 Keratome are the same or very similar to those offered on one or more of the predicate devices.

IX SAFETY AND EFFECTIVENESS

This device is designed to comply with the electrical standards of the Underwriters Laboratories UL2601-1, International Electro-technical Commissions IEC601-1-1 and IEC601-1-2 which reasonably assures the device to be Safe when used as directed for its prescribed intended use. Additionally several operational safety features are designed into this device (Vacuum Level Gauge, a low suction LED and "audible tone" indicators, automatic cutting stop if vacuum level drops, and forward & reverse foot pedal controls). The effectiveness of the device was confirmed by use of QWF050B, Nidek MK-2000 Keratome Validation Test Procedure.

X CONCLUSION

The data submitted in this 510(k) Premarket Notification, for the Nidek MK-2000 Keratome demonstrates that this product is substantially equivalent with respect to the indications for use, operating principles, operational features, and safety features, to other legally market predicate devices. With the information provided, the safety and effectiveness of this product can be reasonably assured, and thus we believe that this device clearly meets the requirement for a "Substantial Equivalence" decision in accordance with the 510(k) guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 4 1999

Mr. Jerry Tsutsumi
Regulatory/Quality Manager
Nidek Incorporated
47651 Westinghouse Drive
Fremont, California 94539-7474

Re: K990900
Trade Name: Nidek Keratome, MK 2000
Regulatory Class: I
Product Code: 86 HNO
Dated: August 26, 1999
Received: August 27, 1999

Dear Mr. Tsutsumi:

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 legally marketed predicate devices 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 at (301) 443-6597.

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX II

Trade or Proprietary Name:	Nidek MK-2000 Keratome
Common or Classification Name:	Keratome
Model Number:	MK-2000
Class:	Class I
Classification Panel:	86
Product Code:	
Regulation Number:	886.4370

INDICATIONS FOR USE:

The Nidek MK-2000, Keratome is intended to make a flap by incising the cornea at a predetermined thickness and diameter using a high speed oscillation blade of stainless steel.

Prescription Use YES
(Per 21 CFR 801.109)

Denis L. McCarthy
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K990900