4/28/99

K984540

510(k) Summary for KeraVision, Inc.'s KeraVision® Intacs™ Vacuum System

Submitter's Name, Address, Telephone Number and Contact Person:

KeraVision, Inc.
48630 Milmont Drive
Fremont, California, 94538

Contact: Darlene Crockett-Billig
KeraVision, Inc.
Phone: (510) 353-3000
Facsimile: (510) 353-3030

Date Prepared: March 24, 1999

Name of the Device:

KeraVision® Intacs™ Vacuum System

Common or Usual Name:

Keratome

Classification Name

AC Powered Keratome

Product Code

HNO

Predicate Devices

(1) Chiron Vision Corp.'s Hansatome Microkeratome

(2) Laser Light Technology, Inc.'s Automated Disposable Keratome ("ADK")

Intended Use

The KeraVision® Intacs™ Vacuum System ("the Vacuum System") is intended to be used to fixate the eye in patients undergoing ophthalmic surgery requiring a lamellar dissection of the cornea.

Principles of Operation

The vacuum pump is used to provide controlled vacuum to the Vacuum Centering Guide ("VCG"). The sterile tubing delivers vacuum from the vacuum pump to the VCG. The VCG holds the eye in position while the clockwise and counterclockwise dissectors dissect the lamellae and create an intrastromal tunnel for placement of the KeraVision® Intacs™ corneal ring segments.

Technical Characteristics

The Vacuum System primarily consists of the VCG, a vacuum pump, a tubing set with filtration, and dissectors (clockwise and counterclockwise).

Performance Data

A biocompatibility certification regarding the contact components of the device is included in the 510(k) notice. In addition, the 510(k) notice includes cytotoxicity test reports regarding the VCG and the dissectors. The 510(k) notice also summarizes the data regarding the use of the Vacuum System during the clinical trials of the KeraVision Intacs.

Summary of the Basis for the Finding of Substantial Equivalence

The KeraVision® Intacs™ Vacuum System ("the Vacuum System") and all of the predicate devices have the same intended use, *i.e.*, fixate the eye in patients undergoing ophthalmic surgery requiring a lamellar dissection of the cornea. The Vacuum System and the predicate devices have similar indications. The Vacuum System is indicated to fixate the eye and dissect the lamellae to create tunnels for placement of corneal ring segments to treat myopia, while the predicate devices are indicated to fixate the eye and cut the lamellae for other refractive surgery procedures to treat myopia. The Vacuum System and all of the predicate devices have similar principles of operation in that vacuum pressure is supplied by a vacuum pump that secures a ring to the cornea to fixate the eye and to dissect or cut the cornea to perform refractive surgery procedures.

The Vacuum System and all of the predicate devices also have similar technological characteristics in that each of these devices has a ring, a

vacuum pump, a tubing set, and a surgical blade. The minor technological differences between the Vacuum System and the predicate devices are that the Vacuum System's maximum vacuum pressure is lower than the predicate devices' maximum vacuum pressure, it does not contain an oscillating blade, and it dissects and separates instead of cutting the lamellae. However, these minor technological differences do not raise any new questions of safety or effectiveness.

FDA has granted 510(k) premarket clearance to each of the predicate devices. Thus, the KeraVision® Intacs™ Vacuum System is substantially equivalent to legally marketed keratomes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 1999

KeraVision, Inc.
Mr. Howard H. Holstein
c/o Hogan & Hartson, LLP
555 13th Street, N.W.
Washington, DC 20004-1109

Re: K984540
Trade Name: Keravision® Intacs™ Vacuum System
Regulatory Class: I
Product Code: 86 HNO
Dated: March 24, 1999
Received: March 24, 1999

Dear Mr. Holstein:

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): K984540

Device Name: Intacs™ Vacuum System

Indications for Use:

The KeraVision Intacs™ Vacuum System is indicated to fixate the eye and dissect the lamellae to create tunnels for placement of corneal ring segments to treat myopia.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dwight Hoering, Scientific Reviewer

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K984540

Prescription Use X OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)