OCT 24 1997

K972808

SECTION 15

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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

   a. Hansa Research and Development, Inc.
   7790 N. W. 55th Street
   Miami, FL 33166

   b. Contact Person: Brigitta Hellenkamp
   Vice President

   Brigitta Hellenkamp

   c. Date Summary Prepared: July 25, 1997

2. **Name of device, including trade name and classification name:**

   a. Trade/Proprietary Name: Hansatome™ microkeratome

   b. Classification Name: Keratome

3. **Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:**

   Company: Hansa Research & Development, Inc.

   Device: Automatic Corneal Shaper

   510(k) : K913697

Date Cleared: November 5, 1991

4. **A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):**

The Hansatome™ microkeratome is a precision-manufactured instrument designed for cutting a precise corneal disc of preselected thickness and diameter. The device is intended for use in performing lamellar corneal resections. The Hansatome™ Microkeratome materials are similar to those used in the predicate device.

5. **Statement of intended use:**

The Hansatome™ microkeratome is a precision-manufactured instrument intended for use in performing initial lamellar corneal resections.

6. **Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.**

Comparative Technological Characteristics

CHARACTERISTICS	AUTOMATIC CORNEAL SHAPER (PREDICATE)	Hansatome™
Intended Use	Intended for use in performing initial lamellar resections of the cornea.	Same
Operating Principle	Electrically driven oscillating blade housed in head which guides blade across the cornea within controlled parameters	Same
Patient contact portion of device*	• Suction Ring • Microkeratome Head • Blade	• Same • Same • Same
Materials • Suction Ring • Microkeratome Head • Blade	 • Stainless Steel • Stainless Steel • Low Carbon Stainless Steel	 • Same • Same • Same
Sterilization method (blade)	Radiation (GAMMA)	EO
Keratome Mechanism • Suction Ring w/ Gear Track • Microkeratome	 • Dual linear guideways with single linear gear tracks • 1 head with interchangeable	 • Single arcuate gear rack with temporal pivot pin • 2 interchangeable heads with fixed

Head/Thickness Plate • Electric motor • Control Mechanism • Cutting Principle • Footswitch	thickness plates • DC Powered, 12 volt • Footswitch • Blade Oscillation • Electric	thickness plates • DC Powered, 6-9 volt • Same • Same • Same

7. Brief summary of nonclinical tests and results:

The Hansatome™ microkeratome has been designed and will be tested to applicable safety standards. In addition, the Hansatome™ microkeratome was found to perform equivalently to the predicate device, Automatic Corneal Shaper (ACS) with respect to the creation of corneal resections. Thus, the technological changes in the Hansatome™ microkeratome 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

OCT 24 1997

Judy F. Gordon, D.V.M.
Vice President, Scientific Affairs
Chiron Vision Corporation
9342 Jeronimo Road
Irvine, CA 92618-1903

Re: K972808
Trade Name: Hansatome™ Microkeratome
Regulatory Class: I
Product Code: 86 HNO
Dated: July 25, 1997
Received: July 28, 1997

Dear Dr. Gordon:

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

SECTION 6

INDICATIONS FOR USE

The Hansatome™ microkeratome is a precision-manufactured instrument indicated for use in patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea.

Prescription Use ✓ EXB
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K972808