K014000

510(k) SUMMARY
VISITOME 20-10 MICROKERATOME

1. SUBMITTER INFORMATION

A.	Company Name:	Biovision AG
B.	Company Address:	60 Eigerstrasse Bern, Switzerland CH-3007
C.	Company Phone: Company Fax:	031-372-4404 031-372-4412
D.	Contact Person:	Edmond Baumgartner General Manager Biovision AG
E.	Date Summary Prepared:	November 26, 2001

2. DEVICE IDENTIFICATION

A.	Classification Name:	Keratome, AC-Powered
B.	Trade/Proprietary Name:	Visitome 20-10 Microkeratome
C.	Classification:	Class I (886.4370)
D.	Product Code:	86 HNO

3. DEVICE DESCRIPTION

The Visitome 20-10 Microkeratome is an AC-powered device that is used for making a flap by incising the cornea at a predetermined thickness and diameter using a high-speed oscillating blade made of stainless steel. The device consists of the following main components and accessories: the control unit, a surgical unit (handpiece with drive assembly, positioning ring assembly, applanator assembly, and a stainless steel blade holder), a foot pedal, tubing kit (accessory), and a fluid collection container (accessory).

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The Visitome 20-10 Microkeratome contains a positioning ring which allows the cornea to protrude through the ring. The cornea is restrained by an applanation shoe surface, which may be pivoted away. A stainless steel blade is suspended from the end of the positioning ring by a blade support (holder) which is driven by a drive mechanism, so that the blade moves along a forward path between the positioning ring and the applanation shoe while oscillating laterally. Drive control and vacuum for the positioning ring are provided by user command via the control unit and foot pedal.

4. INTENDED USE

The Visitome 20-10 Microkeratome is intended for use in the making of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.

5. SUBSTANTIAL EQUIVALENCE

The Biovision AG. Visitome 20-10 Microkeratome is equivalent to the following predicate device (predicate device information can be found in Section 10):

Predicate Device	**510(K) Owner**	**510(k) No.**	**Date Cleared**
Hansatome Microkeratome	Bausch & Lomb Surgical	K010260	April 27, 2001

6. TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Visitome 20-10 Microkeratome and the predicate device has been performed, and the results are

summarized in the table below. The results of this comparison demonstrate that the Visitome 20-10 Microkeratome has the same basic technological characteristics as the predicate device and is equivalent to the marketed predicate device. The differences between the Visitome 20-10 Microkeratome and the predicate device are insignificant and do not affect the safety or effectiveness of the device.

COMPARISON CHART		
	Biovision AG Visitome 20-10 Microkeratome	**Hansatome Microkeratome Predicate Device – K010260**
Indications For Use	The Visitome 20-10 Microkeratome is indicated for use in the making of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.	The Hansatome Microkeratome is a precision-manufactured instrument indicated for use in the making of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.
Operating Principle	Electrically driven oscillating blade housed in a head which guides the blade across the cornea on a gear rack. A foot pedal with 3 pedal switches is used as the control mechanism.	Electrically driven oscillating blade housed in a head which guides the blade across the cornea on an elevated gear rack. A footswitch (single or dual) is used as the control mechanism.
Type of Hinge or Flap	Nasal and Superior	Nasal and Superior

COMPARISON CHART		
	Biovision AG Visitome 20-10 Microkeratome	**Hansatome Microkeratome Predicate Device – K010260**
Manual or Automatic Blade Advancement	Automatic	Automatic
Blade Advancement Rate	1 to 10 mm/sec	Unknown
Oscillation Rate	0 to 12,000 rpm	Unknown
Flap Diameter Resection	Range of 7.5 to 10.5 mm	8.5 & 9.5 mm; accuracy of each diameter unknown
Thickness of Resection	120, 160 & 180 microns	160 & 180 microns
Eye Fixation Method	Suction Ring (sizes 10.5, 11.5, & 12.0 mm)	Suction Ring (sizes 8.5 & 9.5 mm)
Disposable Blade with Fixed Holder?	Yes	Yes
Blade Angle	32 degrees	25 degrees
Keratome Blade Material	Stainless Steel	Stainless Steel
Handpiece Material	Titanium	Stainless Steel
Components That Contact the Patient	Blade Suction Ring	Blade Keratome Head Suction Ring
Safety Features	1. Internal diagnostics feature ensures system integrity prior to each procedure. 2. Cutting motion will not start until appropriate vacuum level is reached. 3. If vacuum is lost during the	1. Internal diagnostics feature ensures system integrity prior to each procedure. 2. Cutting motion will not start until appropriate vacuum level is reached. 3. Cutting stops if vacuum drops

COMPARISON CHART		
	Biovision AG Visitome 20-10 Microkeratome	**Hansatome Microkeratome Predicate Device – K010260**
	cut, an alarm will sound and the low vacuum light will come on. Cutting will stop automatically.	below threshold.

7. PERFORMANCE DATA

The Visitome 20-10 Microkeratome has been designed and will be tested in accordance with applicable electrical safety standards. The device underwent performance evaluation testing in pig eyes to demonstrate that the device meets all performance specification requirements, and is substantially equivalent to the predicate device.

8. CONCLUSIONS

Biovision AG has demonstrated through its evaluation of the Visitome 20-10 Microkeratome that the device is equivalent to the predicate device with respect to intended use, technological characteristics, and safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2002

Biovision AG
c/o Mr. David S. Fernquist
Regulatory Affairs Consultant
Visitome, Inc.
27 Mauchly, Unit 206
Irvine, CA 92618

Re: K014000
Trade/Device Name: Visitome 20-10 Microkeratome
Regulation Number: 21 CFR 886.4370
Regulation Name: Keratome
Regulatory Class: Class I
Product Code: HNO
Dated: February 20, 2002
Received: February 22, 2002

Dear Mr. Fernquist:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

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

INDICATIONS FOR USE

510(k) Number: K014000 (To Be Assigned By FDA)

Device Trade Name: VISITOME 20-10 MICROKERATOME

Indications For Use: The Visitome 20-10 Microkeratome is indicated for use in the making of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K014000

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)