NOV 16 2004

# 510(k) SUMMARY
# VISITOME 20-10 MICROKERATOME

## 1. APPLICANT

| | |
|---|---|
| Company Name: | Biovision AG<br>27 Erlenstrasse<br>2555 Brugg, Switzerland |
| Official Correspondent: | Dale Sadlik<br>Product Director<br>Visitome, Inc.<br>27 Mauchly, Unit 206<br>Irvine, CA 92618<br>Tel: 949-450-0770<br>Fax: 949-450-0990 |
| Date Summary Prepared: | November 3, 2004 |

## 2. DEVICE IDENTIFICATION

| | | |
|---|---|---|
| A. | Classification Name: | Keratome, AC-Powered |
| B. | Trade/Proprietary Name: | Visitome 20-10 Microkeratome |
| C. | Classification: | Class I per 886.4370 |
| D. | Product Code: | 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, and tubing kit with filter and fluid collection container (accessory).

## 4. INTENDED USE

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

## 5. SUBSTANTIAL EQUIVALENCE

The Biovision AG Visitome 20-10 Microkeratome is equivalent to the predicate devices listed below. Each of these devices has a similar indication for use and utilizes suction to the cornea. With respect to corneal resections, the Visitome and device uses a stainless steel blade to cut a corneal flap, while the IntraLase device uses a femtosecond laser for cutting/resection created by micro-photodisruption of the corneal tissue. Bench testing demonstrates that the Visitome 20-10 Microkeratome is equivalent to the predicate devices, and that any differences do not affect safety or effectiveness.

| **Predicate Device** | **Applicant** | **510(k) No.** | **Date Cleared** |
|---|---|---|---|
| Visitome 20-10 Microkeratome | Biovision AG | K014000 | March 11, 2002 |
| FS Laser Keratome | Intralase Corporation | K031960 | September 29, 2003 |

## 6. TECHNOLOGICAL CHARACTERISTICS

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.

## 7. PERFORMANCE DATA

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

## 8. CONCLUSIONS

Biovision AG has demonstrated through its evaluation of the Visitome 20-10 Microkeratome that the device is equivalent to the predicate devices 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

NOV 16 2004

Biovision AG
c/o Mr. Dale Sadlik
Visitome, Inc
27 Mauchly, Unit 206
Irvine, CA 92618

Re: K042083
Trade/Device Name: Visitome 20-10 Microkeratome
Regulation Number: 21 CFR 886.4370
Regulation Name: Keratome
Regulatory Class: Class I
Product Code: HNO
Dated: July 19, 2004
Received: August 3, 2004

Dear Mr. Sadlik:

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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# INDICATIONS FOR USE

510(k) Number: K042083 (To Be Assigned By FDA)

Device Trade Name: VISITOME 20-10 MICROKERATOME

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

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daxadin 11-8-2004

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

510(k) Number K042083