K032978

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.

APPLICANT	CIBA Vision Corporation 11460 Johns Creek Parkway Duluth, Georgia 30097, USA
OFFICIAL CORRESPONDENT	Penny Northcutt, RAC Surgical Regulatory Affairs Tel: (678) 415-3214 Fax: (678) 415-4024 e-mail: **penny.northcutt@cibavision.novartis.com**

TRADE NAME:	CIBA Centurion SES™ Epikeratome
CLASSIFICATION NAME:	1. AC Powered Keratome 2. Battery-Powered Corneal Burr
DEVICE CLASSIFICATION AND PRODUCT CODE	1. Class 1 per 21 CFR §886.4370, HNO 2. Class 1 per 21 CFR §886.4070, HOG

SUBSTANTIAL EQUIVALENCE:

The modified Centurion SES Epikeratome is substantially equivalent to the Centurion SES Epikeratome cleared under K031735. The modifications made to the device include a separate dedicated handpiece for the epikeratome function. Minor design modifications were made to the suction ring, separator, separator drive assembly, DCU vacuum pump, and DCU software to accommodate the new. The modified Centurion SES™ Epikeratome has the same intended use and basic scientific technology as the original model.

Both devices have the same indication for use statement, and utilize suction to the cornea and oscillation principles to separate the epithelium from the cornea. Bench testing has demonstrated that the modified Centurion SES device is functionally equivalent to the predicate Centurion SES device and that any minor differences between the modified device and the predicate device do not affect safety or effectiveness.

DESCRIPTION OF THE DEVICE:

The Centurion SES Epikeratome is an AC-powered device that is used for making a separation or flap by incising the epithelium at a predetermined location and diameter using a high-speed oscillating separator made of PMMA.

The device consists of the following main components and accessories: the drive control unit (DCU), handpiece, separator drive assembly, suction positioning ring assembly, a foot pedal, a tubing set with fluid collection assembly (accessory), and an epithelial separator.

INDICATIONS FOR USE:

The CIBA Centurion SES Epikeratome is intended for use in the separation of the epithelium from the cornea in preparation for subsequent surgical procedures on the denuded cornea, and for use in the making of a corneal flap in patients undergoing LASIK or other treatment requiring initial lamellar resection of the cornea.

TECHNICAL CHARACTERISTICS:

The CIBA Centurion SES Epikeratome contains a suction ring that allows the cornea to protrude through the ring. The epithelial separator is suspended from the end of the separator drive assembly housing that is moved by a drive mechanism along a forward path inside the suction ring while oscillating laterally. Drive control and vacuum for the suction ring are provided by user command via the drive control unit and foot pedal.

PERFORMANCE DATA:

All components that come in direct contact with the patient have a long history of use in ophthalmic medical devices and are biocompatible. Functional and electrical safety test results demonstrate that the Centurion SES separator removes epithelium in a consistent and reproducible way and is equivalent to the predicate device.

CONCLUSION:

Based on the performance testing, it can be concluded that the modified CIBA Centurion SES Epikeratome is equivalent to the predicate CIBA Centurion SES Epikeratome with respect to intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2003

CIBA Vision Corporation
c/o Penny Northcutt, RAC
Surgical Regulatory Affairs
11460 Johns Creek Pkwy.
Duluth, GA 30097

Re: K032978

Trade/Device Name: CIBA Vision Centurion SES™ Epikeratome
Regulation Number: 21 CFR 886.4370; 21 CFR 886.4070
Regulation Name: Keratome; AC-Powered corneal burr
Regulatory Class: Class I
Product Code: HNO; HOG
Dated: September 23, 2003
Received: September 24, 2003

Dear Ms. Northcutt:

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

510(k) Number (if known): K032978

Device Name: **CENTURION SES™ EPIKERATOME**

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

10-17-2003

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

510(k) Number K032978

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)