

OCT 28 2004

510(k) K042810

1. SUMMARY OF SAFETY & 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.

510(k) NUMBER: K042810

APPLICANT: Norwood Abbey Limited
63 Wells Road
Chelsea Heights
Victoria 3196
Australia

**OFFICIAL
CORRESPONDENT:** Paul Clark
Manager Quality Assurance and Regulatory Affairs
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TRADE NAME: NORWOOD ABBEY Centurion SES™ Epikeratome

REGULATION No. 21 CFR 886.4370, Keratome

REGULATORY CLASS: Class I

PRODUCT CODE 86 HNO, Keratome, AC – Powered

SUBSTANTIAL EQUIVALENCE:

The new Centurion SES Epikeratome 9.0mm suction ring is substantially equivalent to the CIBA Vision (now Norwood Abbey) Centurion SES Epikeratome 10.0 mm suction ring cleared under K032978. Both the 9.0mm and 10.0mm Suction Ring for the Centurion SES™ Epikeratome has the same intended use and basic scientific technology.

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 new 9.0mm Centurion SES suction ring is functionally equivalent to the predicate Centurion SES 10.0mm suction ring and that any minor differences between the modified device and the predicate device do not affect safety or effectiveness.

DESCRIPTION OF THE DEVICE:

The Norwood Abbey 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.

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The device consists of the following main components and accessories: the drive control unit (DCU), handpiece, separator drive assembly, suction positioning ring assembly (now with 10.0 and 9.0mm sizes), a foot pedal, a tubing set with fluid collection assembly (accessory), and an epithelial separator.

INDICATIONS FOR USE:

The Norwood Abbey 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 Norwood Abbey Centurion SES Epikeratome contains a suction ring (now with both 10.0 and 9.0mm sizes) 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 test results demonstrate that the Centurion SES suction ring and separator assembly 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 new Norwood Abbey Centurion SES Epikeratome 9.0mm Suction Ring is equivalent to the predicate CIBA Vision (now Norwood Abbey) Centurion SES Epikeratome 10.0mm Suction Ring with respect to intended use and technological characteristics.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 28 2004

Norwood Abbey, LTD.
c/o Mr. Paul Clark, Quality & Regulatory Affairs Manager
63 Wells Rd.
Chelsea HGTS., Victoria
Australia, 3196

Re: K042810
Trade/Device Name: Centurion SES™ Epikeratome
Regulation Number: 21 CFR 886.4370
Regulation Name: Keratome
Regulatory Class: Class I
Product Code: HNO
Dated: October 8, 2004
Received: October 12, 2004

Dear Mr. Clark:

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.

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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

9.0MM 510(K) SPECIAL

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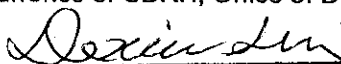
Device Name: **CENTURION SES™ EPIKERATOME**

Indications for Use:

The Norwood Abbey 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

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Prescription Use

OR

Over-The-Counter Use

(Per 21 CFR 801.109)