K051486

JUL 6 - 2005

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.

Applicant	Norwood Abbey Limited 63 Wells Road Chelsea Heights Victoria 3196 Australia
Official Correspondent	Paul Clark Manager Quality Assurance and Regulatory Affairs Tel: +613 9782 7308 Fax: +613 9782 7335 e-mail: **pclark@norwoodabbey.com.au**
Trade Name:	Centurion SES™ Epikeratome
Classification Name:	AC Powered Keratome Battery-Powered Corneal Burr
Device Classification and Product Code	Class 1 per 21 CFR §886.4370, HNO

SUBSTANTIAL EQUIVALENCE:

The new Centurion SES Epikeratome with modified console is substantially equivalent to the currently marked Centurion SES Epikeratome. Both designs have the same intended use and basic scientific technology.

Bench testing has demonstrated that the new console is functionally equivalent to the predicate console 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.

The device consists of the following main components and accessories: console, handpiece, separator drive assembly, suction ring assembly (with 10.0 and 9.0mm suction ring sizes), foot pedal, vacuum tubing set with fluid collection assembly (accessory), forceps 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.

TECHNICAL CHARACTERISTICS:

The Norwood Abbey Centurion SES Epikeratome contains a Head Unit Assembly (with 9.0mm and 10.0mm suction ring 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 console and foot pedal.

PERFORMANCE DATA:

Functional test results demonstrate that the Centurion SES system with new console performs as the predicate device console does to drive the separator assembly to remove epithelium in a consistent and reproducible way.

CONCLUSION:

Based on the qualification testing, it can be concluded that the new Norwood Abbey Centurion SES Epikeratome with modified console is equivalent to the predicate 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

JUL 6 - 2005

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

Re: K051486
Trade/Device Name: Centurion SES™ Epikeratome
Regulation Number: 21 CFR 886.4370
Regulation Name: Keratome
Regulatory Class: Class I
Product Code: HNO
Dated: June 2, 2005
Received: June 6, 2005

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.

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) 827-8910. 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/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CHANGE TO CENTURION SES EPIKERATOME CONSOLE

510(k) Number (if known): K051486

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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

7/5/2005

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

510(k) Number K051486

Prescription Use ✓ OR Over-The-Counter Use ___

(Per 21 CFR 801.109)