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K041206

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Gebauer Medizintechnik GmbH

EpiTome SYSTEM

510(k) PREMARKET NOTIFICATION SUMMARY

Date Summary Prepared: August 23, 2004

Gebauer EpiTome SYSTEM

510(k) PREMARKET NOTIFICATION SUMMARY

- **Device Trade or Proprietary Name:** **EpiTome System**
- **Common/Classification Name:** **Keratome, AC Powered**
- **Class:** **Class I**
- **Classification Panel:** **86**
- **Labeling:**
  Federal (United States) Law restricts this device to sale by or on the order of a physician.
- **Predicate Device for Substantial Equivalence Comparison:**

  The EpiTome System is claimed to be substantially equivalent to the following currently marketed Predicate Device:

Manufacturer	Device Name	510-K Number	Decision Date
CIBA Vision Corporation	CIBA Centurion SES™ Epikeratome	K032978	October 20, 2003

- **Device Description:**

  The EpiTome System is a fully automated, AC powered ophthalmic keratome system designed for the separation of the epithelium from the cornea in preparation for subsequent surgical procedures on the denuded cornea.

  The EpiTome Control Console is comprised of a Vacuum System, Software, and Controls that allow the System User to set the procedure specific cutting parameters. The motorized handpiece contains two motors controlling the oscillation and translation of the cutting blade across the epithelium. The EPI-Head assembly includes a base, an applanation part, and blade unit that fits securely onto the handpiece. The precisely machined EPI-Separator controls the depth of the delamination.

The EpiTome System includes a choice of suction rings to allow the System User to select the appropriate ring on an individual patient basis. The EpiTome system is designed for use with disposable tubing that is readily available/commercially approved within the United States for other approved microkeratome systems.

- **Indications for Use Statement:**

The EpiTome System is indicated for the separation of the epithelium from the cornea in preparation for subsequent surgical procedures on the denuded cornea.

- **Clinical Performance Data**

No clinical performance data has been submitted.

- **Non-Clinical Performance Data**

In-Vitro non-clinical performance data is provided in the submission.

- **Rationale for Substantial Equivalence**

1. The INTENDED USES and the OPERATING and CUTTING PRINCIPLES (ie. Effectiveness) of the Gebauer EpiTome System are the **SAME** as the predicate device.
2. The OPERATIONAL FEATURES of the Gebauer EpiTome System are the **SAME or SIMILAR** to those offered by the predicate device.
3. The SAFETY FEATURES of the Gebauer EpiTome System are the **SAME or very SIMILAR** to those offered by the predicate device.

Therefore, in summary, the EpiTome System is substantially equivalent to the identified predicate device that has previously been allowed for commercial distribution in the United States, in terms of ALL key aspects of the device: device effectiveness/operation, device intended usage, device features/surgical parameters and safety features.

•Safety and Effectiveness

The EpiTome System complies with the electrical standards of the Underwriters Laboratories UL 2601-1 and has passed an inspection to these standards by an independent testing house. Furthermore, the Lasitome, a sister device to the EpiTome System (devices are identical in terms of electrical and EMI issues) underwent independent scrutiny and testing by UL-Germany to assess the overall electrical safety and EMI safety. UL-Germany after extensive evaluation determined that the Lasitome System met all electrical and electromagnetic compatibility (EMI) safety requirements set forth in the International Electro-technical Commissions (IEC) 60601-1:1988 +A1 +A2 (EN 60601-1:1990 + A1 +A2) International Electro-technical Commissions IEC 601-1-1 and IEC 601-1-2 which reasonably assures the device is safe when used as directed for its prescribed intended use.

Additionally several operational safety features are designed into the EpiTome (vacuum level gauge, a low suction LED and "audible tone" indicators, automatic cutting stop if vacuum level drops and forward and reverse foot pedal controls). The effectiveness of the device was confirmed during in-vitro testing which was designed to evaluate the functional ability of the Gebauer EpiTome System to create highly precise epithelial incisions with constant cut thickness.

The Gebauer EpiTome System does not raise any new issues of safety, effectiveness or performance of the device when compared to the existing predicate device.

•Conclusions

The data submitted in this 510(k) Premarket Notification, for the Gebauer EpiTome System demonstrates that this product is substantially equivalent with respect to the indications for use, operating principles, operational features, and safety features to another legally marketed predicate device. With the information provided, the safety and effectiveness of the product can be reasonably assured, and we believe that this device clearly meets the requirement for a "Substantial Equivalence" decision in accordance with the 510(k) guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 5 2004

Gebauer Medizintechnik GmbH
% Kimberly Doney
54 Forest Street
Lexington, MA 02421

Re: K041206
Trade/Device Name: Epitome System
Regulation Number: 21 CFR 886.4370
Regulation Name: Keratome
Regulatory Class: Class I
Product Code: HNO
Dated: April 30, 2004
Received: May 11, 2004

Dear Ms. Doney:

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 : Original Premarket Notification 510(k) K041206
Device Name: Gebauer epiTome System
Indications for Use:

The epiTome System is indicated for the separation of the epithelium from the cornea in preparation for subsequent surgical procedures on the denuded cornea.

Prescription Use ✓
(Per 21 CFR 801.109)

Clay R. Buttemer

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

510(k) Number K041206