K072102

Gebauer EpiVision™ SL SYSTEM

JAN 16 2009

510(k) PREMARKET NOTIFICATION SUMMARY

- **Device Trade or Proprietary Name:** **EpiVision™ SL System**
- ***Common/Classification Name:*** ***Keratome, AC Powered***
- **Class:** **Class I**
- **Classification Panel:** **86**
- **Product Code** **HNO**
- **Labeling:**

Federal (United States) Law restricts this device to sale by or on the order of a physician

- **Predicate Devices for Substantial Equivalence Comparison:**

The EpiVision™ SL System is claimed to be substantially equivalent to the following currently marketed Predicate Devices

Manufacturer	***Device Name***	**510-K number**	**Decision Date**
Gebauer Medizintechnik GmbH	EpiTome System and Lasitome System Keratome AC powered *Now EpiVision System	K041206	09/15/2004
BioVision	Visitome 20-10 Microkeratome	K014000 & K042083	3/11/2002 & 11/16/2004

*The name was changed from EpiTome to EpiVision System and LasiTome System on 06/10/2005

•Device Description:

The EpiVision™ SL System is a fully automated, AC powered ophthalmic keratome system. The EpiVision™ SL System is used to produce a lamellar corneal flap in an Epithelial Separation or LASIK procedure.

With these methods, the refraction of the cornea is changed using a laser beam. Prior to laser treatment, a corneal flap is created. However, this flap is not completely separated (except when an epithelial free flap is desired), but remains connected by a small segment of the flap to the eyeball. This segment is called the hinge.

The hinge size, the advancing speed during cutting, and the oscillation frequency of the cutter are fixed parameters. The user cannot change these parameters.

The EpiVision™ SL System's function is to remove an eye's upper corneal layer (epithelium) using an Epithelial Separation method or to create a cut in the epithelium of the cornea for using a LASIK operation method, after which the contour of the cornea is treated with a vision-correcting laser system. The laser is not manufactured by Gebauer Medizintechik GmbH.

The oscillating Separator/Blade, with fixed parameters creates a separation between the epithelium and Bowman's layers, or a cut in the epithelium.

The EpiVision™ SL System is a motor driven Microkeratome which is composed of a Console with power-cable, a Handpiece with a removable Handpiece-cable, a Footswitch, with different colored Foot-pedals, a Single-Use-Set/Single-Use LASIK Set for EpiVision™ SL and a Disposable Tubing System for EpiVision™ SL System. The Single-Use Set/Single-Use LASIK Set for EpiVision™ SL consists of a Head, a Suction-Ring and a Separator.

The components should be assembled per the assembly description in Section 7 of the Users Manual. The EpiVision™ SL System is operated exclusively

by the Footswitch. On top of the Console are LEDs which provide optical signals for "on" and "off" of the console, activated vacuum, vacuum level and run cycle. In addition to LEDs there are acoustical signals which sound when 0.75 bar vacuum is achieved, when the vacuum is deactivated, when the vacuum level drops below 0.6 bar during a run cycle, and when the Handpiece has reached the forward stop and the reverse stop. The EpiVision™ SL Control Console is comprised of a Vacuum.

The EpiVision™ SL System includes a choice of sterile Single-Use Sets/Single-Use LASIK Sets to allow the System User to select the appropriate ring size and head on an individual patient basis. The EpiVision™ SL 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 EpiVision™ SL System is indicated for the following uses:

> The EpiVision™ SL System is indicated for 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 treatment.

•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 EpiVision™ SL System are the **SAME** as the predicate devices

2 The OPERATIONAL FEATURES of the Gebauer EpiVision™ SL System are the same/comparable to those offered to the predicate devices

3 The SAFETY FEATURES of the EpiVision™ SL System are the same, very similar or better to those offered on one or more of the predicate devices

Therefore, in summary, the EpiVision™ SL System is substantially equivalent to the two identified predicate devices that have 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 EpiVision™ SL System is designed to comply 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 EpiVision, a sister device to the EpiVision™ SL 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 EpiVision 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 EpiVision™ SL (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 bench testing which was designed to evaluate the functional ability of the Gebauer EpiVision™ SL System to create highly precise epithelial incisions with constant cut thickness

The Gebauer EpiVision™ SL System does not raise any new issues of safety, effectiveness or performance of the device when compared to the existing predicate devices

- **Conclusions**

The data submitted in this 510(k) Premarket Notification, for the Gebauer EpiVision™ SL 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

Gebauer Medizintechnik GMBH
c/o Kimberley Doney
54 Forest Street
Lexington, Massachusetts 02421

JAN 16 2009

Re K072102
Trade/Device Name EpiVision™ SL System
Regulation Number 21 CFR 886 4370
Regulation Name AC Powered Keratome
Regulatory Class I
Product Code HNO
Dated January 12, 2009
Received January 13, 2009

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464 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 (240) 276-3150 or at its Internet address
http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Malvina B. Eydelman, 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 (if known): Original Premarket Notification

Device Name: EpiVision™ SL System

Indications for Use:

The EpiVision™ SL System is indicated for 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 treatment.

Prescription Use __X____
(Part 21 CFR 801 Subpart D)

Daryl L. Kenfman
(Division Sign-Off)
Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices
510(k) Number K072102