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Summary of Safety and Effectiveness Information <small>Pre-market Notification, Section 510(k)</small>	Summit Krumeich-Barraquer Microkeratome <small>Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92</small>
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1. **Device Name:** Summit Krumeich-Barraquer Microkeratome
Trade Name: Electronic Microkeratome
Common Name: Keratome
Classification Name: KERATOME, AC-POWERED

2. **Establishment Name & Registration Number:**

Name: Summit Technology, Inc.
Number: 1287364

3. **Classification:**

§ 886.4370 Keratome.

§ 886.4370 Keratome. (a) Identification. A keratome is an AC-powered or battery-powered device intended to shave tissue from sections of the cornea for a lamellar (partial thickness) transplant. (b) Classification. Class I. [55 FR 48443, Nov. 20, 1990]

Device Class: Class I
Classification Panel: Ophthalmic devices panel
Product Code: 86HNO

4. **Special Controls:**

Not applicable to this device.

5. **Labeling:**

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

The warnings, cautions for the device are presented here. The balance of the product labeling is found in Appendix I.



Danger

During installation or removal of the cutting blade as well as in the cutting area there is danger of cutting oneself and thereby sustaining an injury.



Do not remove the cover of the electronic part of the instrument. There is an energy reserve in it which, despite disconnection from the main voltage, remains live. Servicing works should only be undertaken by qualified personnel.



This instrument conforms with the requirements of the safety regulations for Class I medical instruments. This instrument is specially constructed so that it remains safe even in the event of electrical loss.



Caution

The microkeratome is a precision instrument. The cutting head is constructed from hardened materials and should always be laid on a soft underlay. Should the instrument suffer any damage (e.g. if it falls to the ground or if it is laid on hard material) it must be sent to our service department to be reinterchecked before further use.

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6. Equivalent / Predicate Device:

- Eyetech – Barraquer-Krumeich-Swinger Refractive Set, K954058

7. Device Description:

The Summit Krumeich-Barraquer Microkeratome is an automated version of the Eyetech-Barraquer-Krumeich Swinger Refractive Set found substantially equivalent under K954058. Other than the automated cutting action option of the electronic model, both microkeratomes share the following basic description.

The Microkeratome is a medical “instrument” exclusively designed for use in ophthalmic surgery. This instrument should only be installed, used and serviced by suitably qualified personnel. The speed of forward movement during cutting and the frequency of oscillation of the blade can be individually set and controlled by the operator. The instrument will remain programmed until the data is overwritten by new data. For safety reasons the instrument is equipped with an electrical energy and vacuum reserve which is maintenance free. There is enough reserve energy and vacuum stored that in the event of an electrical failure or loss of main voltage at an inconvenient point in the procedure, the procedure can still be completed.

The primary function of this instrument is to make a thin anterior corneal lamellar section leaving the cornea attached nasally by means of a hinge or to remove or harvest the cornea completely. The suction ring is responsible for positioning the microkeratome over the eye. The microkeratome has an oscillating blade, which, with a defined advancing speed (0.1 to 3.0mm/sec.) is guided over the cornea of the patient. The frequency of oscillation and the advancing speed of the blade greatly influence the quality of the cut surface.

Indications.

- Keratoplasty & corneal harvesting
- Microlamellar keratoplasty

The instrument consists of 4 components:

- Service Terminal, Microcomputer and Vacuum-Pump
- Motor for oscillating blade and Step Motor for Forward Movement
- Microkeratome
- Suction Ring with Vacuum Connection

Elements of the Instrument:

1. LCD Display
2. Service keys and LED
3. Vacuum tubing to suction ring
4. Manometer, pressure indicator of vacuum container
5. Water separator
6. Button for forward movement of microkeratome drive steel leaf
7. Stepper motor for microkeratome advancement
8. Foot pedal for vacuum
9. Foot pedal for cutting, start, stop function
10. Button to position microkeratome drive steel leaf
11. Microkeratome drive steel leaf of stepper motor for forward movement
12. Pin guide for forward movement of microkeratome drive steel leaf
13. Coupling clip for microkeratome drive steel leaf
14. Suction ring

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- 15. Suction ring handle
- 16. Microkeratome
- 17. Motor for blade oscillation

8. Modified Device Data:

The Summit Krumeich-Barraquer Microkeratome is an improved model of a previously reviewed substantially equivalent device, the Eyetech-Barraquer-Krumeich-Swinger Refractive Set, covered by K954058.

9. Applicant Name & Address:

Summit Technology, Inc.
21 Hickory Drive
Waltham, MA 02451

10. Submission Correspondent:

Eric P. Ankerud
Vice President, Quality, Regulatory and Clinical Affairs
Summit Technology, Inc.
21 Hickory Drive
Waltham, MA 02451
Ph: 781-672-0570 Fax: 781-890-6316

11. Manufacturing Facility:

At the present time, the Summit Krumeich-Barraquer Microkeratome is manufactured by GEBAUER GMBH., MONBACHSTR. 7/1, 75242 NEUHAUSEN – ENZKREIS. GEBAUER GMBH, is a registered medical device manufacturing facility located in Germany.

12. Feature Comparison Table:

FEATURE	Summit K-B Microkeratome	Eyetech Refractive Set K954058	SE?
Indications for Use(s):	Keratoplasty & corneal harvesting; Microlamellar keratoplasty	Same	Yes
Method of cut	Automatic – Step motor controlled 0.1 to 3.0mm/sec.	Manual advance – micrometer-type dial	Yes
Sterilization Method:	Autoclave	Same	Yes
Blade Oscillation	Adjustable, with preset default	Fixed	Yes
Materials:	Stainless Steel, Plastic, Glass, Natural Diamond	Same	Yes
Manufacturer:	Gebauer GMBH	Same	Yes



DEC 22 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Eric Ankerud, J.D.
Vice President, Quality, Regulatory and Clinical Affairs
Summit Technology, Inc.
21 Hickory Drive
Waltham, Massachusetts 02451

Re: K980675
Trade Name: Summit Krumeich - Barraquer Microkeratome
Regulatory Class: I
Product Code: 86 HNO
Dated: December 15, 1998
Received: December 16, 1998

Dear Mr. Ankerud:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K980675

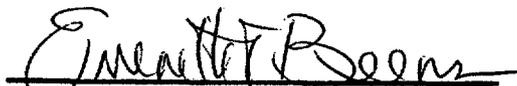
Device Name: Summit Krumeich-Barraquer Microkeratome

Indications For Use:

- Keratoplasty & corneal harvesting
- Microlamellar keratoplasty

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K980675

Prescription Use

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional format 1-2-96)