MAY 1 1998

510K Summary
MICROspecialties.Inc.
Disposable Keratome Blades

Ref. K980508

MICROspecialties,Inc.
16 Higgins Drive
Milford, CT 06460
Tel: 203-874-1832
Fax: 203-877-3762

Submitters Name: Charles Vassallo — 9 Mar 98 (Date)

Ref: 510K Premarket Notification

To: Document Control Clerk:

This summary of 510K safety and effectiveness information is being submitted for the MICROspecialties disposable keratome blades, which an equivalence determination could be based. There are two blade styles as part of this submission, which have very slight differences in width dimension. The catalog number 500500 blade is designed to fit Chiron Keratomes, the 400400 blade will fit S.C.M.D. Keratomes. Both blades are manufactured out of the same materials, packaged and sterilized using the same methods.

Trade/Proprietary Name: Disposable Keratome Blade

Common/Usual Name: Keratome Blade

Classification Name: Keratome

Establishment Registration Number: In process at FDA

K980508

Performance Standard:

The MICROspecialties disposable keratome blade is similar in design construction, and function to the devices as marketed by:

- Howard Instruments, Inc.
  Tuscaloosa, AL 35405
  Cbalk-1000 LASIK Blade
  Reference 510k: K972727

- Med-Logics, Inc.
  Temple City, CA 91780
  ML Microkeratome Blade
  Reference 510k: K962661

Descriptive Comparison:

The 500500 blade is equivalent to the Med-Logics ML Lasik Blade and the Howard Instruments CBALK-1000 Blade. The 400400 blade is designed for use in the S.C.M.D. Keratomes of Arizonia.

Characteristics:

The 500500 and the 400400, keratome blades are single-use, disposable. The 500500 blade is for use in the Chiron keratome while the 400400 blade is used in the S.C.M.D. unit.

Both blades are packages in a plastic "clamshell" for protection and then double pouched. Each blade will be sold in single units.

Certification of Safety and Effectiveness:

When used according to the keratome manufacturers' instructions, there are no adverse safety indications for the either the 500500 or 400400 blade.

Components that come in direct contact with tissue are made of surgical stainless steels commonly used in other surgical blades. The blades will be presterilized by ethylene oxide gas.

Labeling:

The outer pouch will indicate MICROspecialties name, address, product identification, lot number, sterilization notes, single use, and federal law statements. The inner pouch will bear the catalog number and lot number.

The blades could be relabeled for sale for other companies. These include Oasis Medical, Howard Instruments, Eye-Med, Insight Technologies Instruments, and S.C.M.D.

There will be no advertising using the word "Lasik" in any sales literature, manuals, etc.

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Sterilization Methodology:

Presterilized by ethylene oxide gas in accordance with ANSI/AAMI/ISO 11135-1994, Medical Device-Validation and Routine Control, Ethylene Oxide Sterilization.

Materials:

The material used in the blade is a 400 Series Stainless Steel.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 1998

Mr. Charles Vassallo
MICROspecialties, Inc.
16 Higgins Drive
Milford, CT 06460

Re: K980508
Trade Name: Keratome Blade
Regulatory Class: I
Product Code: 86 HNO
Dated: February 6, 1998
Received: February 10, 1998

Dear Mr. Vassallo:

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 (Premarket 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 809.1Q 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

Indications for Use

MICROspecialties.Inc.

Disposable Keratome Blades

510(k) Number (if known): K980508

Device Name: Disposable Keratome Blades

The Microspecialties, Inc., 500500 and 400400 keratome blades are designed for use with other manufacturer's keratome. The 500500 blade is for use in the Chiron Keratome while the 400400 blade is used in the S.C.M.D. Keratome.

Daryl Kaufman
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K980508

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over The Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)