MICROspecialties, Inc.
264 Quarry Road, Milford, CT 06460 Tel: 203-874-1832 Fax: 203-877-3762

DEC 1 6 2002

K020482

510(k) Summary (ref. 807.87h)

This summary of the 510(k) safety and effectiveness information is being submitted for two styles of microkeratome blades for use on Moria microkeratome systems. The MICROspecialties 200200 Blade is designed for use on the Moria, Model LSK microkeratome and the MICROspecialties 600600 Blade for use on the Moria, Model CB microkeratome.

The blades are manufactured using the same materials and packaging. The method of sterilization is commonly used in these devices and their packaging.

Content and Format of a 510(k) Summary (807.92a)

1. Submitter: Gaston Levesque, President
   MICROspecialties, Inc.
   264 QUARRY Road
   Milford, CT 06460
   Phone: 203/874/1832
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2. Keratome Blade

3. 200200 Keartome Blade
   600600 Keratome Blade

4. The disposable 200200 microkeratome blade is designed to be used with the Moria LSK microkeratome system. The disposable 600600 microkeratome blade is designed to be used with the Moria CB microkeratome system. Both of these blades are designed to produce a corneal flap. The blades are packaged in plastic cases to protect the cutting edge and the placed in a Tyvek/poly pouch. They are sold as ten blades per box or in larger quantities of thirty (three ten-packs). Labeling identifies each quantity per box. The blades are then gamma radiation sterilized.

   The blades are made from medical grade stainless steel with a single cutting edge. They are assembled with their compatible head and driver systems.

5. The 200200 and 600600 keratome blades are designed to produce a corneal flap. This is part of a surgical procedure to correct vision in the adult population.

510(k) Summary – cont. (ref. 807.87h)

5. The MICROspecialties 200200 and 600600 keratome blades are designed for use with Moria Microkeratome systems. The 200200 blade is for use with the Moria, Model LSK Microkeratome and the 600600 for use with the Moria, Model CB Microkeratome.

   A risk analysis was performed to provide a systematic approach to the evaluation of hazards associated with the keratome blades.

   Independent physicians and clinics were used to evaluate the performance of the 200200 and 600600 microkeratome blades as part of a nonclinical evaluation. The evaluation included package handling, ease of use, performance on the respective Moria microkeratomes.

   Engineering, manufacturing and inspection specifications were finalized based on this evaluation. A design validation was conducted to validate the appearance, compatibility with the Moria microkeratomes and performance within these systems. The blades go through 100% inspection to insure that they meet the product specification and follow design controls of MICROspecialties.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2002

MICROspecialties, Inc.
c/o Ms. Leigh Ayres, Director
Quality Assurance and Regulatory Affairs
264 Quarry Road
Milford, CT 06460

Re: K020482
Trade/Device Name: MICROspecialties 200200 Blade for the Moria LSK Microkeratome
MICROspecialties 600600 Blade for the Moria CB Microkeratome
Regulation Number: 21 CFR 886.4370
Regulation Name: Keratome
Regulatory Class: Class I
Product Code: HNO
Dated: November 20, 2002
Received: November 21, 2002

Dear Ms. Ayres:

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) 594-4692. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

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

Indications for Use

MICROspecialties.Inc.
Disposable Keratome Blades

510(k) Number (if known): K020482

Device Name: Disposable Keratome Blades for use on Moria Microkeratomes

The MICROspecialties, keratome blades are designed to produce a corneal flap when used with the following Moria microkeratomes:

- MICROspecialties 200200 Blade for use on Moria LSK Microkeratome
- MICROspecialties 600600 Blade for use on Moria CB Microkeratome

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jan C Callaway

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

510(k) Number K020482

(Optional Format 3-10-98)

Prescription Use ✓
(Per 21 CFR 801.109)