FEB 1 5 2002

K011833

Section 16

Summary of Safety and Effectiveness

Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

1. **Submitter's name, address, telephone number, contact person, and data summary prepared:**

   a. Millennium Biomedical Inc.
   360 East Bonita Avenue
   Pomona, California 91767
   Phone: (909)-621-7646
   Fax: (909)-621-7556

   b. Contact Person: Jerry Kaeni
   President

   c. Date Summary Prepared: May 22, 2001

2. **Name of device, including trade name and classification name:**

   a. Trade/Proprietary Name: MB 103 Millennium Blades

   b. Classification Name: Keratome, AC-Powered, and/or Blades

3. **Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:**

Company	Device	510(k) No.	Date Cleared
Moria (Plancon Instruments)	Moria CB Blade	K980924	04-15-1998
Surgical Specialties Corp.	Precision Edge Microkeratome Blade	K002849	10-18-2000

4. **A description of the device that is the subject of the 510(k), including explanation of how device function, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):**

The MB 103 Millennium Blade is a replacement blade designed to be used with the Moria CB Microkeratome. The MB 103 Millennium Blade is a single-use only, disposable device. The Blade material is similar to that used in predicate devices (stainless steel).

5. **A statement of intended use:**

The MB 103 Millennium blade is intended to be used as a replacement blade for the Moria CB Microkeratome.

6. **A statement of how the technological characteristics of the device compare to those of the predicate or legally marketed devices:**

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE

CHARACTERISTICS	MORIA CB BLADE (PREDICATE DEVICE)	MBI MB 103 MILLENNIUM BLADE
Intended Use	Indicated for use with the Moria CB Microkeratome by surgeons to cut cornea in the form of a hinged flap in LASIK refractive surgery procedures.	Indicated for use as a replacement blade for t he Moria CB Microkeratome.
Operating Principle	The blade is held in the keratome head and oscillates by means of the turbine. The keratome head adapts to the turbine by means of a threaded part. The turbine motor is gas powered.	The blade is held in the keratome head and oscillates by means of the turbine. The keratome head adapts to the turbine by means of a threaded part. The turbine motor is gas powered.
Blade Design	Single edge blade with the plastic blade holder	Single edge blade with the plastic blade holder
Blade Hardness	52 Rockwell C	52 Rockwell C
Sterilization Method	Cobalt 60 radiation	Cobalt 60 radiation
Blade Material	Stainless steel	Stainless steel
Blade Holder Material	Delrin	Delrin
Patient Contact Portion of Device	Blade cutting edge	Blade cutting edge

DIMENSIONAL EQUIVALENCY CHART

ATTRIBUTE	MORIA CB BLADE (PREDICATE DEVICE) MEASURED	MB 103 MILLENNIUM BLADE
Length	0.45975	0.4600" ± 0.002"
Width	0.31570	0.316" ± 0.001"
Thickness	0.1015	0.010" ± 0.0003"
Bevel	13°	13°
Mounting hole length	0.2810	0.2800" ± 0.0010"
Mounting hole width	0.0861	0.0860" ± 0.0010"
Sharpness verification	-	• Clinically tested and verified in Korea and China

7. Brief summary of clinical tests and results

The performance of the MB 103 Millennium Blades was found to be acceptable by positive feedback from the market field study conducted in Korea and China. The blades met the intended use and there were no adverse events reported when used according to the Moria CB microkeratome manufacturers' instructions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Jerry Kaeni
President
Millennium Biomedical Inc.
360 East Bonita Avenue
Pomona, CA 91767

Re: K011833
Trade/Device Name: MB 103 Millennium Blade
Regulation Number: 21 CFR 886.4370
Regulation Name: Keratome
Regulatory Class: I
Product Code: HNO
Dated: December 1, 2001
Received: December 7, 2001

Dear Mr. Kaeni:

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 and additionally 21 CFR Part 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" (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

510(k) Number (if known): K011833

Device Name: MB 103 Millennium Blade

Indications for Use:

The MB 103 Millennium blade is intended to be used as a replacement blade for the Moria CB Microkeratome.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean L. McCarthy
(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K011833

Prescription Use X **OR Over-The-Counter Use** _____

(Per 21 CFR 801.109)