OCT 1 3 2004

K 041110

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: April 22, 2004

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

   a. Trade/Proprietary Name: Millennium Blades, Model MB 105

   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 S.A	Moria M2 Non-Disposable Microkeratome	K002191 (blade)	10-12-2000
Med-Logics, Inc	Med-Logics Microkeratome Blade, Model 7050clb	K022982	11-15-2002
Oasis Medical, Inc	Disposable M2-Pe Microkeratome Blades	K030401	06-19-2003

Surgin Surgical Instrumentation, Inc	Prizm Keratome Blade, Model Mk8512m2	K033236	03-26-2004

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 105 Millennium Blade is a replacement blade designed to be used with the Moria M2 Non Disposable Microkeratome. The MB 105 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 105 Millennium blade is intended to be used as a replacement blade for the Moria M2 Non-Disposable Microkeratome.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 3 2004

Millennium Biomedical, Inc.
c/o Mr. Jerry Kaeni
President
306 East Bonita Avenue
Pomona, CA 91767

Re: K041110
Trade/Device Name: MB 105 Millennium Blade
Regulation Number: 21 CFR 886.4370
Regulation Name: Kertatome
Regulatory Class: Class I
Product Code: HNO
Dated: September 24, 2004
Received: September 28, 2004

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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

510(k) Number (if known): K041110

Device Name: MB 105 Millennium Blade

Indications for Use:

The MB 105 Millennium blade is intended to be used as a replacement blade for the Moria M2 Non-Disposable Microkeratome.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

M L B Nicholas

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

510(k) Number K041110

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

(Per 21 CFR 801.109)