

JUN 19 2003



510-528 S. Vermont Avenue Glendora, CA 91741 (626) 914-2891 FAX (626) 914-2885

**Ref:** 510(k) Premarket Notification Summary

**To:** Document Control Clerk:

This is to notify you of the intention of OASIS Medical, Inc. to manufacture and market the following device:

**Disposable M2-PE Microkeratome Blades**

**Establishment Registration Number:** 2083373

This 510(k) summary of safety and effectiveness for the OASIS Microkeratome Blades is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92, and follows the Office of Device Evaluation guidance concerning the presentation and content of a 510(k) summary.

1. Submitter's name, address, telephone number, contact person, and date the summary was prepared:
  - a. **Applicant:** OASIS Medical, Inc.  
512 South Vermont Avenue  
Glendora, CA 91741
  - b. **Telephone Number:** (626) 852-5170  
**Facsimile Number:** (626) 914-9372
  - c. **Contact Person:** Yvonne Fernandez- RA/QA Director
  - d. **Date Summary Prepared:** 01/27/03
2. Name of the Device, including trade name, the common or usual name, and the classification:
  - a. **Trade/Proprietary Name:** Disposable M2-PE Microkeratome Blades
  - b. **Common/Usual Name:** Keratome Blade
  - c. **Classification Name:** Keratome (Blade Only) - 21CFR §886.4370
  - d. **Classification:** Class I
  - e. **Product Code:** 86 HNO
  - f. **Classification Panel:** Ophthalmic



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**3. Identification of legally marketed devices to which equivalence is being claimed:**

The OASIS Medical, Inc. Disposable M2-PE Microkeratome Blades are substantially equivalent in design, material and function to the devices as marketed by:

<u>Company</u>	<u>Device</u>	<u>510(k) Number</u>
Moria	Moria M2 Microkeratome	K002191

**4. Description of the Device:**

The OASIS Disposable M2-PE Microkeratome Blades are replacement stainless steel blades for the Moria M2 Microkeratome Blade. The Disposable M2-PE Microkeratome Blades are made of 400 Series Stainless Steel, packaged and sterilized using the same methods. The OASIS Disposable M2-PE Microkeratome Blades are single-use, disposable blades.

**Certification of Safety and Effectiveness:**

When used according to the keratome manufacturer's instructions, there are no adverse safety indications the 0415 blade.

**Sterilization Methodology:**

All blades are sterilized by exposure to ethylene oxide to a Sterilization Assurance Level (SAL) of  $10^{-6}$  according a validated process in compliance with EN 550.

**Labeling:**

The pouch will indicate OASIS name, address, product identification, lot number, sterilization notes, single use, and federal law statements.

**5. Intended Use for the Device:**

The OASIS M2-PE Microkeratome Blades (Catalog #0415) are designed as replacement blades for the Moria M2 Microkeratome for lamellar resection of the cornea.



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**6. Summary of the technological characteristics of the submitted device compared to predicate devices:**

M2-PE Blade – Summary of Technological Characteristics of Device Compared to Predicate Device† [Section 807.92(a)(6)] - K002191

Characteristics	PD* - Moria M2 Blade	OASIS 0415 M2-PE Blade
Intended Use	As indicated	Same
Target population	As indicated	Same
Performance	Compatibility with Moria M2 Microkeratome	Same
Blade Material	Low carbon stainless steel	Same
Biocompatibility	For Stainless Steel Blades	Same
Mechanical Safety	Assured	Same

**Performance Tests and Conclusions:**

1. Dimensional Equivalency Test – Physical measurements of the predicate device are substantially equivalent to the measurements of blades manufactured by OASIS Medical, Inc.
2. Sharpness Tests – Sharpness tests show that the OASIS M2-PE blades (0415) perform as well as the predicate device.
3. Fit into the Moria M2 Microkeratome has been tested and shown to be acceptable.
4. Non-clinical testing on porcine eyes resulted in corneal lamellar sections equivalent to the predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 19 2003

Oasis Medical, Inc.  
c/o Yvonne Fernandez  
RA/QA Director  
512 S. Vermont Avenue  
Glendora, CA 91740

Re: K030401  
Trade/Device Name: Disposable M2-PE (Precision Edge) Microkeratome Blade  
Regulation Number: 21 CFR 886.4370  
Regulation Name: Keratome  
Regulatory Class: Class I  
Product Code: HNO  
Dated: February 05, 2003  
Received: February 06, 2003

Dear Ms. Yvonne Fernandez:

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.

Page 2 – Ms. Yvonne Fernandez

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 handwritten signature in cursive script that reads "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

Enclosure



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**OASIS Medical, Inc.**  
**Disposable M2-PE (Precision Edge) Microkeratome Blades**  
**Indications For Use**

510(k) Number (if known):              K030401          

Device Name:    Disposable M2-PE Microkeratome Blades

The OASIS Disposable M2-PE (Precision Edge) Microkeratome Blade (Catalog #0415) is designed as a replacement blade for the Moria M2 Microkeratome for lamellar resection of the cornea.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*MKB Nicholas*  
\_\_\_\_\_  
Division Sign-Off)  
Division of Ophthalmic Ear,  
Nose and Throat Devices  
510(k) Number           K030401          

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