

OCT 03 2002



510-528 S. Vermont Avenue Glendora, CA 91741 (626) 914-2891 FAX (626) 914-2285

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 N-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.
514 South Vermont Avenue
Glendora, CA 91741
 - b. **Telephone Number:** (626) 914-2891
Facsimile Number: (626) 914-9372
 - c. **Contact Person:** Yvonne Fernandez - RA/QA Director
 - d. **Date Summary Prepared:** 7/2/02
2. Name of the Device, including trade name, the common or usual name, and the classification:
 - a. **Trade/Proprietary Name:** Disposable N-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 N-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>
Nidek	Nidek MK-2000	K990900

4. Description of the Device:

The OASIS Disposable N-PE Microkeratome Blades are replacement stainless steel blades for the Nidek MK-2000 Microkeratome blade. The Disposable N-PE Microkeratome Blades are made of 400 Series Stainless Steel, packaged and sterilized using the same methods. The OASIS Disposable N-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 0412 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 process, single use, and federal law statements.

5. Intended Use for the Device:

The OASIS N-PE Microkeratome Blades (Catalog #0412) are designed as replacement blades for the Nidek MK-2000 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:

N-PE Blade – Summary of Technological Characteristics of Device Compared to Predicate Device† [Section 807.92(a)(6)] - K981741

Characteristics	PD[†] - Nidek MK-2000 Blade	OASIS 0412 N-PE Blade
Intended Use	As indicated	Same
Target population	As indicated	Same
Performance	Compatibility with Nidek MK-2000 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 N-PE blades (0412) perform as well as the predicate device.
3. Fit into the Nidek MK-2000 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

Oasis Medical, Inc.
Ms. Yvonne Fernandez
RA/QA Director
514 South Vermont Avenue
Glendora, CA 91741

OCT 03 2002

Re: K022205
Trade Name: Oasis Disposable N-PE Microkeratome Blade and Chip
Regulation Number: 21 CFR 886.4370
Regulation Name: Keratome
Regulatory Class: Class I
Product Code: 86 HNO
Dated: July 2, 2002
Received: July 5, 2002

Dear Ms. 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. 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.

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, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health



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

510(k) Number (if known): K022205

Device Name: Disposable N-PE Microkeratome Blades

The OASIS Disposable N-PE (Precision Edge) Microkeratome Blade (Catalog #0412) is designed as a replacement blade for the Nidek MK-2000 Microkeratome for lamellar resection of the cornea.

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



Concurrence of CDRH, Office of Device Evaluation (ODE)

M.B. Nicholas
(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices
510(k) Number K022205

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