510(k) SUMMARY K032297

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:** (909) 305-5400

   Facsimile Number: (626) 914-9372

   c. **Contact Person:** Yvonne Fernandez - RA/QA Director

   d. **Date Summary Prepared:** 7/22/03

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

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:

Company	Device	510(k) Number
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 low carbon 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 microkeratome manufacturer's instructions, there are no adverse safety indications the OASIS N-PE 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 are designed as replacement blades for the Nidek MK-2000 Microkeratome for lamellar resection of the cornea.

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

Summary of Technological Characteristics of Device Compared to Predicate Device

Characteristics	Nidek MK-2000 Blade	OASIS 0412 N-PE
Intended Use	As indicated	Same
Target population	As indicated	Same
Performance	Comparable to Nidek MK-2000 Microkeratome	Same
Blade Material	Low carbon stainless steel	Same
Biocompatibility	For Stainless Steel Blades	Same
Mechanical Safety	Assured	Same
Sterilization	Ethylene Oxide	Same
Flap Diameter	Measured	Equivalent
Flap Thickness	Measured	Equivalent
Dimensions	Measured	Equivalent

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 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 6 2003

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

Re: K032297
Trade/Device Name: Disposable N-PE Microkeratome Blades
Regulation Number: 21CFR 886.4370
Regulatory Name: Keratome
Regulatory Class: Class I
Product Code: HNO
Dated: July 23, 2003
Received: July 30, 2003

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.

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

Indications For Use Statement

510(k) Number (if known): K032297

Device Name: Disposable N-PE Microkeratome Blades

The OASIS Disposable N-PE Microkeratome Blade 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)

8-21-2003

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

510(k) Number K032297

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