

MAY 15 1998

A 980697

510(k) Summary

SUBMITTER:

Submitted on behalf of:

Company Name: Eye-Deal Ocular Safety, Inc.
Address: 3620 Lake Mendota Drive
Madison, WI 53705
Telephone: 608-238-9004

by: Elaine Duncan **Official Correspondent**
Paladin Medical[®], Inc.
PO Box 560
Stillwater, MN 55082
715-549-6035

CONTACT PERSON: Elaine Duncan

DATE SUMMARY PREPARED: February 13, 1998: Revised 5-11-98

TRADE NAME: Eye Irrigator, Ocular Irrigator
COMMON NAME: Eye irrigator

SUBSTANTIALLY EQUIVALENT TO: The Eye Irrigator is substantially equivalent to the Morgan Lens, by Mortan, Inc., K821897

DESCRIPTION of the DEVICE: The Eye-Deal Eye Irrigator, an ocular irrigator, consists of a plastic irrigation tube that works like a shower-head to irrigate continuously from under the upper eye-lid. The device is held in place with the lower speculum wire resting within the lower lid. The frame of the irrigator can be applied using adhesive tape provided, to the cheek of the patient, to stabilize the irrigator during the procedure. The device is designed to provide approximately 20 minutes of irrigation using a standard saline bag.

INDICATIONS FOR USE: The Eye Irrigator, Ocular Irrigating System, is indicated for use as an eye irrigating device. It is designed especially for post-traumatic injury; chemical exposure and burns, permitting irrigation of the eye and under the upper eyelid, with sterile saline.

CLINICAL INFORMATION and SAFETY and EFFECTIVENESS: A preliminary study was conducted to compare the efficacy of the irrigation of the Eye Irrigator to the Morgan lens, to evaluate the tolerance of the patient to the device and the ease of insertion of the device by the emergency care provider. Six patients and 12 total eyes were compared, and although the study size was too small for statistically significant results, the trend was clear that the Eye Irrigator was well tolerated by the patient and easy to use by the technician. The Eye Irrigator was efficient in clearance of fluorescein, an indicator dye commonly used as an indicating dye. A complete summary of the study is provided in the submission. In addition to the clinical testing, the materials used in the Eye Irrigator were pre-qualified by selecting materials with medical or food grade toxicity testing. In addition, the complete assembly (after sterilization) was tested for biocompatibility as indicated for surface devices/mucosal membrane/short-term ocular membrane contact by the Blue Book Memorandum for adoption of the ISO 10993-1 Part 1. Testing results indicated that the materials passed the required assays. Validation of the sterilization process that was conducted according to the procedures of ANSI/AAMI/ISO 11135-1994 showed that the ethylene oxide gas cycle will reproducibly provide a sterility assurance level of 10^{-6} for processes meeting the specified cycle parameters.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 1998

Eye-Deal Ocular Safety Products, Inc.
c/o Ms. Elaine Duncan
Paladin Medical Inc.
P.O. Box 560
Stillwater, MN 55082-0560

Re: K980647
Trade Name: Eye-Deal Eye Irrigator
Regulatory Class: I
Product Code: 86 KYG
Dated: February 13, 1998
Received: February 13, 1998

Dear Ms. Duncan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K980647

Device Name **Eye-Deal EYE IRRIGATOR, Ocular Irrigator**

Indications for Use:

The Eye Irrigator, Ocular Irrigating System, is indicated for use as an eye-irrigating device. It is designed especially for post-traumatic injury, chemical exposure and burns, permitting irrigation of the eye and under the upper eyelid, with sterile saline.

(Please Do Not Write Below This Line-Continue On Another Page If Needed)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

Myra Smith
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K980647