

DEC 22 1999

K993487

510(k) Summary

Submitter

Company Name: **Paragon Vision Sciences**
Address: **945 East Impala Ave., Mesa, AZ 85204**
Phone: **480-892-7602** Fax: **480-892-3226**
Registration: **Owner Operator # 9024618**

Manufacturer

Company Name: **Paragon Vision Sciences**
Address: **945 East Impala Ave., Mesa, AZ 85204**
Phone: **480-892-7602** Fax: **480-892-3226**
Registration: **Site Registration #2020433**

Official Correspondent

William E. Meyers, Ph.D.

Company Name: **Paragon Vision Sciences**
Address: **945 East Impala Ave., Mesa, AZ 85204**
Phone: **480-507-7606** Fax: **480-892-322**

Reason for 510(k)

New Device

Date of submission

October 12, 1999

Device Identification

Trade Name: **Paragon Lens Vial**
Common Name: **Contact Lens Case**
Classification Name: **Soft (hydrophilic) contact lens solution, contact lens case**
Reference: **Soft (hydrophilic) contact lens solution (21CFR 886.5928)**
Also see "GUIDANCE FOR INDUSTRY- PREMARKET NOTIFICATION (510(k)) GUIDANCE DOCUMENT FOR CONTACT LENS CARE PRODUCTS, May 1, 1997.

Indication for use

The **Paragon Lens Vial** is indicated for the chemical disinfection and storage of Rigid Gas Permeable and Hard contact lenses.

Equivalence

The **Paragon Lens Vial** is substantially equivalent to the Paragon Contact Lens Case marketed by Paragon Vision Sciences which is presently approved and marketed under 510k # K974635.

Toxicology Testing

In support of the premarket notification information the following is submitted.

1. Eye Irritation Test
2. Cytotoxicity Test
3. Systemic Injection Test



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 22 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

William E. Meyers, Ph.D.
Vice President, Science and Technology
Paragon Vision Sciences
945 East Impala Ave.
Mesa, AZ 85204

Re: K993487
Trade Name: Paragon ® Lens Vial
Regulatory Class: Unclassified
Product Code: 86 LRX
Dated: October 12, 1999
Received: October 15, 1999

Dear Dr. Meyers:

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 (Premarket 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.

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 handwritten signature in cursive script, reading "A. Ralph Rosenthal".

A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications Statement

510(k) Number (if known): **K 993487**

Device Name: **Paragon Lens Vial**

Indications For Use: **The Paragon Lens Vial is indicated for storage of rigid gas permeable and hard contact lenses during chemical disinfection.**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____ ✓

(Optional Format 1-2-96)



Radiological Health

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