



MAY - 1 2007

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Paragon Vision Sciences  
William E. Meyers, Ph.D.  
Vice President, Science & Technology  
947 East Impala  
Mesa, AZ 85204-6619

Re: K070637

Trade/Device Name: FluoroPerm® 30 and Paragon Thin™ (paflucocon C);  
FluoroPerm® 60 and Paragon HDS® (paflucocon B);  
FluoroPerm® 92 (paflucocon A); and, FluoroPerm® 151 and  
Paragon HDS® 100 (paflucocon D) RGP Contact Lenses

Regulation Number: 21 CFR 886.5916

Regulation Name: Rigid gas permeable contact lenses

Regulatory Class: Class II

Product Code: HQD

Dated: March 5, 2007

Received: March 7, 2007

Dear Dr. Meyers:

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.

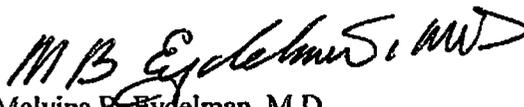
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 – Dr. William Meyers

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address [http://www.fda.gov/earh/industry\\_support/maact.html](http://www.fda.gov/earh/industry_support/maact.html).

Sincerely yours,



Malvina B. Bydelman, M.D.

Director

Division of Ophthalmic and Ear, Nose  
and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications For Use

510(k) Number (if known):

K070637

Device Name:

FluoroPerm<sup>®</sup> 92 (paflucocon A) rigid gas permeable contact lenses  
FluoroPerm<sup>®</sup> 60 (paflucocon B) rigid gas permeable contact lenses  
Paragon HDS<sup>®</sup> (paflucocon B) rigid gas permeable contact lenses  
FluoroPerm<sup>®</sup> 30 (paflucocon C) rigid gas permeable contact lenses  
Paragon Thin<sup>™</sup> (paflucocon C) rigid gas permeable contact lenses  
FluoroPerm<sup>®</sup> 151 (paflucocon D) rigid gas permeable contact lenses  
Paragon HDS<sup>®</sup> 100 (paflucocon D) rigid gas permeable contact lenses

Indications For Use:

### FluoroPerm<sup>®</sup> 92

FluoroPerm<sup>®</sup> 92 rigid gas permeable spherical or aspheric contact lenses are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. FluoroPerm<sup>®</sup> 92 rigid gas permeable bifocal, or toric contact lenses are indicated for daily wear only.

FluoroPerm<sup>®</sup> 92 rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with nondiseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. FluoroPerm<sup>®</sup> 92 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm<sup>®</sup> 92 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

FluoroPerm<sup>®</sup> 92 contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery in otherwise nondiseased eyes.

### FluoroPerm<sup>®</sup> 60

FluoroPerm<sup>®</sup> 60 rigid gas permeable spherical or aspheric contact lenses are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. FluoroPerm<sup>®</sup> 60 rigid gas permeable bifocal, or toric contact lenses are indicated for daily wear only.

FluoroPerm<sup>®</sup> 60 rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with nondiseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. FluoroPerm<sup>®</sup> 60 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm<sup>®</sup> 60 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

FluoroPerm<sup>®</sup> 60 contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery in otherwise nondiseased eyes.

### Paragon HDS<sup>®</sup>

Paragon HDS<sup>®</sup> rigid gas permeable spherical or aspheric contact lenses are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. Paragon HDS<sup>®</sup> rigid gas permeable bifocal, or toric contact lenses are indicated for daily wear only.

Paragon HDS<sup>®</sup> rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with nondiseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. Paragon HDS<sup>®</sup> toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. Paragon HDS<sup>®</sup> bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

Paragon HDS<sup>®</sup> contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery in otherwise nondiseased eyes.

### FluoroPerm<sup>®</sup> 30

FluoroPerm<sup>®</sup> 30 rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner.

FluoroPerm<sup>®</sup> 30 rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with nondiseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. FluoroPerm<sup>®</sup> 30 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm<sup>®</sup> 30 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

FluoroPerm<sup>®</sup> 30 contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery in otherwise nondiseased eyes.

### Paragon Thin<sup>™</sup>

Paragon Thin<sup>™</sup> rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner.

Paragon Thin<sup>™</sup> rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with nondiseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. Paragon Thin<sup>™</sup> toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. Paragon Thin<sup>™</sup> bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

Paragon Thin<sup>™</sup> contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery in otherwise nondiseased eyes.

FluoroPerm<sup>®</sup> 151

FluoroPerm<sup>®</sup> 151 rigid gas permeable spherical or aspheric contact lenses are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. FluoroPerm<sup>®</sup> 151 rigid gas permeable bifocal, or toric contact lenses are indicated for daily wear only.

FluoroPerm<sup>®</sup> 151 rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with nondiseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. FluoroPerm<sup>®</sup> 151 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm<sup>®</sup> 151 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

FluoroPerm<sup>®</sup> 151 contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery in otherwise nondiseased eyes.

Paragon HDS<sup>®</sup> 100

Paragon HDS<sup>®</sup> 100 rigid gas permeable spherical or aspheric contact lenses are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. Paragon HDS<sup>®</sup> 100 rigid gas permeable bifocal, or toric contact lenses are indicated for daily wear only.

Paragon HDS<sup>®</sup> 100 rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with nondiseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. Paragon HDS<sup>®</sup> 100 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. Paragon HDS<sup>®</sup> 100 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

Paragon HDS<sup>®</sup> 100 contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery in otherwise nondiseased eyes.

Prescription Use  (Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use \_\_\_\_\_ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marc Robley  
(Division Sign-Off)  
Division of Ophthalmic Ear,  
Nose and Throat Devices

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510(k) Number K070637

K070637

510(k) Summary of Safety and Effectiveness

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Submitter Information

Paragon Vision Sciences  
947 E. Impala Ave.  
Mesa, AZ 85204

Contact Person: William Meyers PhD  
Vice President, Science & Technology

Email: [wemeyers@MSN.com](mailto:wemeyers@MSN.com)  
Phone: 480 507 7606

Device Name

FluoroPerm<sup>®</sup> 92 (paflucocon A) rigid gas permeable contact lenses  
FluoroPerm<sup>®</sup> 60 (paflucocon B) rigid gas permeable contact lenses  
Paragon HDS<sup>®</sup> (paflucocon B) rigid gas permeable contact lenses  
FluoroPerm<sup>®</sup> 30 (paflucocon C) rigid gas permeable contact lenses  
Paragon Thin<sup>™</sup> (paflucocon C) rigid gas permeable contact lenses  
FluoroPerm<sup>®</sup> 151 (paflucocon D) rigid gas permeable contact lenses  
Paragon HDS<sup>®</sup> 100 (paflucocon D) rigid gas permeable contact lenses

Reason for Submission

Expanded Indication

Predicate Devices

Classification Name: rigid gas permeable (hydrophobic) contact lens

Proprietary Names: Boston<sup>®</sup> XO<sup>®</sup> (hexafocon A),  
Boston EO<sup>®</sup> (enflucocon B)  
Boston ES<sup>®</sup> (enflucocon A)

Description of the device:

FluoroPerm<sup>®</sup> 92, FluoroPerm<sup>®</sup> 60, Paragon HDS<sup>®</sup>, FluoroPerm<sup>®</sup> 30, Paragon Thin<sup>™</sup>, and FluoroPerm<sup>®</sup> 151, and Paragon HDS<sup>®</sup> 100 lenses are available as lath cut rigid gas permeable contact lenses for daily wear only. The lenses are manufactured from these FDA approved contact lens materials; paflucocon A (FluoroPerm<sup>®</sup> 92), paflucocon B (FluoroPerm<sup>®</sup> 60, Paragon HDS<sup>®</sup>), paflucocon C (FluoroPerm<sup>®</sup> 30, Paragon Thin<sup>™</sup>), and paflucocon D (FluoroPerm<sup>®</sup> 151, Paragon HDS<sup>®</sup> 100). These materials are thermoset copolymers derived from fluorosilicone acrylate monomers.

The lenses may be tinted to offer a handling aid for locating the lens. The tinted lenses contain one or more of the following approved color additives: D&C Green No. 6, Peroxide Yellow No. 9, D&C Violet No. 2 and D&C Red No. 17.

The lenses may be available with an ultraviolet absorber (not in all colors and materials). The ultraviolet absorber, Uvinul D-49, has been integrated as an additive within the polymer matrix, blocking up to 97% of light below 380 nm. The UV absorber is 2,2'-dihydroxy-4,4'-dimethoxybenzophenone.

The lens designs have a posterior surface consisting of a base curve and a series of up to four annular spherical or aspherical curves peripheral to the base curve.