

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. These products may be plasma treated.

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 four spherical or aspherical curves progressively flatter than the base curve.

Properties of the Contact Lenses

Property	FluoroPerm				Paragon		
	30	60	92	151	Thin	HDS	HDS 100
Specific Gravity	1.14	1.15	1.10	1.10	1.145	1.16	1.10
Refractive Index	1.466	1.453	1.453	1.442	1.463	1.449	1.442
% Light Transmittance*	94	95	93	93	94	95	93
% Water Content	< 1	< 1	< 1	< 1	< 1	< 1	< 1
Oxygen Permeability(Dk)**	30	60	92	151	29	58	>145

*Blue tinted material

**Revised Method of I. Fatt

Safety and Efficacy

The safety and efficacy of paflucocon A (FluoroPerm[®] 92), paflucocon B (FluoroPerm[®] 60 and Paragon HDS[®]), paflucocon C (FluoroPerm[®] 30 and Paragon Thin[™]) and paflucocon D (FluoroPerm[®] 151 and Paragon HDS[®] 100) materials as rigid gas permeable contact lenses have been demonstrated in PMA P870024 and various of its supplements.

Intended Use

Device Name: FluoroPerm[®] 30 (paflucocon C) rigid gas permeable contact lenses

FluoroPerm[®] 30 rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner.

FluoroPerm[®] 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[®] 30 contact lenses are indicated for persons requiring keratoconus management with otherwise non-diseased eyes. FluoroPerm[®] 30 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm[®] 30 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

Device Name: Paragon Thin[™] (paflucocon C) rigid gas permeable contact lenses

Paragon Thin[™] rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner.

Paragon Thin[™] 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™ contact lenses are indicated for persons requiring keratoconus management with otherwise non-diseased eyes. Paragon Thin™ toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. Paragon Thin™ bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

Device Name: FluoroPerm® 60 (paflucocon B) rigid gas permeable contact lenses

FluoroPerm® 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® 60 rigid gas permeable bifocal, or toric contact lenses are indicated for daily wear only.

FluoroPerm® 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® 60 contact lenses are indicated for persons requiring keratoconus management with otherwise non-diseased eyes, daily wear application only. FluoroPerm® 60 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm® 60 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

Device Name: Paragon HDS® (paflucocon B) rigid gas permeable contact lenses

Paragon HDS® 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® rigid gas permeable bifocal, or toric contact lenses are indicated for daily wear only.

Paragon HDS® 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® contact lenses are indicated for persons requiring keratoconus management with otherwise non-diseased eyes, daily wear application only. Paragon HDS® toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. Paragon HDS® bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

Device Name: FluoroPerm® 92 (paflucocon A) rigid gas permeable contact lenses

FluoroPerm® 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® 92 rigid gas permeable bifocal, or toric contact lenses are indicated for daily wear only.

FluoroPerm® 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® 92 contact lenses are indicated for persons requiring keratoconus management with otherwise non-diseased eyes, daily wear application only. FluoroPerm® 92 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm® 92 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

Device Name: FluoroPerm® 151 (paflucocon D) rigid gas permeable contact lenses

FluoroPerm® 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[®] 151 rigid gas permeable bifocal, or toric contact lenses are indicated for daily wear only.

FluoroPerm[®] 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[®] 151 contact lenses are indicated for persons requiring keratoconus management with otherwise non-diseased eyes, daily wear application only. FluoroPerm[®] 151 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm[®] 151 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

Device Name: Paragon HDS[®] 100 (paflucocon D) rigid gas permeable contact lenses

Paragon HDS[®] 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[®] 100 rigid gas permeable bifocal, or toric contact lenses are indicated for daily wear only.

Paragon HDS[®] 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[®] 100 contact lenses are indicated for persons requiring keratoconus management with otherwise non-diseased eyes, daily wear application only. Paragon HDS[®] 100 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. Paragon HDS[®] 100 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

Substantial Equivalence

The 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) Rigid Gas Permeable Contact Lenses are similar to the currently marketed Boston[®] II (itafocon A) Rigid Gas Permeable Contact Lens, in that all fall into the same FDA contact lens classification (Class II) and all are manufactured by the same manufacturing process. The following Substantial Equivalence Summary Table lists the similarities and differences among the devices.

Substantial Equivalence Summary Table

Similarities								
	Boston [®] II	FluoroPerm [®]				Paragon Thin [™]	Paragon HDS [®]	Paragon HDS [®] 100
		30	60	92	151			
Indications for Use	Daily Wear	Daily Wear	Daily Wear	Daily Wear	Daily Wear	Daily Wear	Daily Wear	Daily Wear
Differences								
Material	itafocon	paflucocon						
		C	B	A	D	C	B	D
Indication for Keratoconus	YES	NO	NO	NO	NO	NO	NO	NO

As the comparison table shows there are virtually no differences between the products offered by Paragon Vision Sciences and the Boston[®] II product, except material and the indication for keratoconus.



FEB 10 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Paragon Vision Sciences
c/o William E. Meyers, PhD
Vice President, Science and Technology
947 East Impala Ave.
Mesa, AZ 85204-6619

Re: K052983

Trade/Device Name: FluoroPerm® 92 (paflucocon A) Rigid Gas Permeable Contact Lenses
FluoroPerm® 60 (paflucocon B) Rigid Gas Permeable Contact Lenses
Paragon HDS® (paflucocon B) Rigid Gas Permeable Contact Lenses
FluoroPerm® 30 (paflucocon C) Rigid Gas Permeable Contact Lenses
Paragon Thin™ (paflucocon C) Rigid Gas Permeable Contact Lenses
FluoroPerm® 151 (paflucocon D) Rigid Gas Permeable Contact Lenses
Paragon HDS® 100 (paflucocon D) Rigid Gas Permeable Contact Lenses

Regulation Number: 21 CFR 886.5916

Regulation Name: Rigid Gas Permeable Contact Lens

Regulatory Class: Class II

Product Code: HQD

Dated: January 13, 2006

Received: January 17, 2006

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.

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) 827-8910. 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/industry/support/index.html>.

Sincerely yours,



Malvina B. Eydelman, M.D.
Acting Division 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): K052983

Device Name: FluoroPerm[®] 92 (paflucocon A) rigid gas permeable contact lenses
FluoroPerm[®] 60 (paflucocon B) rigid gas permeable contact lenses
Paragon HDS[®] (paflucocon B) rigid gas permeable contact lenses
FluoroPerm[®] 30 (paflucocon C) rigid gas permeable contact lenses
Paragon Thin[™] (paflucocon C) rigid gas permeable contact lenses
FluoroPerm[®] 151 (paflucocon D) rigid gas permeable contact lenses
Paragon HDS[®] 100 (paflucocon D) rigid gas permeable contact lenses

Indications For Use:

FluoroPerm[®] 92

FluoroPerm[®] 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[®] 92 rigid gas permeable bifocal, or toric contact lenses are indicated for daily wear only.

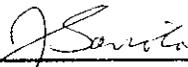
FluoroPerm[®] 92 rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with nondiseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. FluoroPerm[®] 92 contact lenses are indicated for persons requiring keratoconus management with otherwise non-diseased eyes, daily wear application only. FluoroPerm[®] 92 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm[®] 92 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

FluoroPerm[®] 60

FluoroPerm[®] 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[®] 60 rigid gas permeable bifocal, or toric contact lenses are indicated for daily wear only.

FluoroPerm[®] 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[®] 60 contact lenses are indicated for persons requiring keratoconus management with otherwise non-diseased eyes, daily wear application only. FluoroPerm[®] 60 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm[®] 60 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

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

510(k) Number K052983



Paragon HDS®

Paragon HDS® 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® rigid gas permeable bifocal, or toric contact lenses are indicated for daily wear only.

Paragon HDS® 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® contact lenses are indicated for persons requiring keratoconus management with otherwise non-diseased eyes, daily wear application only. Paragon HDS® toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. Paragon HDS® bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

FluoroPerm® 30

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

FluoroPerm® 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® 30 contact lenses are indicated for persons requiring keratoconus management with otherwise non-diseased eyes. FluoroPerm® 30 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm® 30 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

Paragon Thin™

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

Paragon Thin™ 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™ contact lenses are indicated for persons requiring keratoconus management with otherwise non-diseased eyes. Paragon Thin™ toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. Paragon Thin™ bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

FluoroPerm® 151

FluoroPerm® 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® 151 rigid gas permeable bifocal, or toric contact lenses are indicated for daily wear only.



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

510(k) Number K052983



FluoroPerm® 151 (continued)

FluoroPerm® 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® 151 contact lenses are indicated for persons requiring keratoconus management with otherwise non-diseased eyes, daily wear application only. FluoroPerm® 151 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm® 151 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

Paragon HDS® 100

Paragon HDS® 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® 100 rigid gas permeable bifocal, or toric contact lenses are indicated for daily wear only.

Paragon HDS® 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® 100 contact lenses are indicated for persons requiring keratoconus management with otherwise non-diseased eyes, daily wear application only. Paragon HDS® 100 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. Paragon HDS® 100 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

Prescription Use *js*
(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)

Myra Smith

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

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