



March 16, 2018

Paragon Vision Sciences
% Bret Andre
Principal Consultant
EyeReg Consulting, Inc.
6119 Canter Lane
West Linn, OR 97068

Re: K180172

Trade/Device Name: FluoroPerm 30 & Paragon Thin (paflucocon C) RGP contact lenses with Tangible Hydra-PEG; FluoroPerm 60 & Paragon HDS (paflucocon B) RGP contact lenses with Tangible Hydra-PEG; FluoroPerm 92 (paflucocon A) RGP contact lenses with Tangible Hydra-PEG; FluoroPerm 151 & Paragon HDS 100 (paflucocon D) RGP contact lenses with Tangible Hydra-PEG

Regulation Number: 21 CFR 886.5916

Regulation Name: Rigid Gas Permeable Contact Lens

Regulatory Class: Class II

Product Code: HQD

Dated: January 22, 2018

Received: January 26, 2018

Dear Bret Andre:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Denise L. Hampton -S

for Malvina B. Eydelman, 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)

K180172

Device Name

FluoroPerm® 92 (pafluocon A) RGP contact lenses with Tangible Hydra-PEG

Indications for Use (Describe)

FluoroPerm® 92 rigid gas permeable spherical or aspheric contact lenses with Tangible Hydra-PEG are indicated for daily wear as recommended by the eye care practitioner.

FluoroPerm® 92 rigid gas permeable spherical, aspheric and bifocal contact lenses with Tangible Hydra-PEG are indicated for the correction of visual acuity in not-aphakic persons with non-diseased 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 toric contact lenses with Tangible Hydra-PEG are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm® 92 bifocal lenses with Tangible Hydra-PEG are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, FluoroPerm® 92 contact lenses with Tangible Hydra-PEG 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 non-diseased eyes.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Indications for Use

510(k) Number (if known)

K180172

Device Name

FluoroPerm® 60 (pafluocon B) RGP contact lenses with Tangible Hydra-PEG

Indications for Use (Describe)

FluoroPerm® 60 rigid gas permeable spherical or aspheric contact lenses with Tangible Hydra-PEG are indicated for daily wear as recommended by the eye care practitioner.

FluoroPerm® 60 rigid gas permeable spherical, aspheric and bifocal contact lenses with Tangible Hydra-PEG are indicated for the correction of visual acuity in not-aphakic persons with non-diseased 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 toric contact lenses with Tangible Hydra-PEG are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm® 60 bifocal lenses with Tangible Hydra-PEG are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, FluoroPerm® 60 contact lenses with Tangible Hydra-PEG 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 non-diseased eyes.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Indications for Use

510(k) Number (if known)

K180172

Device Name

Paragon HDS® (paflucofen B) RGP contact lenses with Tangible Hydra-PEG

Indications for Use (Describe)

Paragon HDS® rigid gas permeable spherical or aspheric contact lenses with Tangible Hydra-PEG are indicated for daily wear as recommended by the eye care practitioner.

Paragon HDS® rigid gas permeable spherical, aspheric and bifocal contact lenses with Tangible Hydra-PEG are indicated for the correction of visual acuity in not-aphakic persons with non-diseased 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® toric contact lenses with Tangible Hydra-PEG are indicated to correct astigmatism of up to 6.00 diopters. Paragon HDS® bifocal lenses with Tangible Hydra-PEG are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, Paragon HDS® contact lenses with Tangible Hydra-PEG 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 non-diseased eyes.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Indications for Use

510(k) Number (if known)

K180172

Device Name

FluoroPerm® 30 (pafluocon C) RGP contact lenses with Tangible Hydra-PEG

Indications for Use (Describe)

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

FluoroPerm® 30 rigid gas permeable spherical, aspheric and bifocal contact lenses with Tangible Hydra-PEG are indicated for the correction of visual acuity in not-aphakic persons with non-diseased 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 toric contact lenses with Tangible Hydra-PEG are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm® 30 bifocal lenses with Tangible Hydra-PEG are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, FluoroPerm® 30 contact lenses with Tangible Hydra-PEG 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 non-diseased eyes.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Indications for Use

510(k) Number (if known)

K180172

Device Name

Paragon Thin (pafluocon C) RGP contact lenses with Tangible Hydra-PEG

Indications for Use (Describe)

Paragon Thin rigid gas permeable contact lenses with Tangible Hydra-PEG are indicated for daily wear as recommended by the eye care practitioner.

Paragon Thin rigid gas permeable spherical, aspheric and bifocal contact lenses with Tangible Hydra-PEG are indicated for the correction of visual acuity in not-aphakic persons with non-diseased 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 toric contact lenses with Tangible Hydra-PEG are indicated to correct astigmatism of up to 6.00 diopters. Paragon Thin bifocal lenses with Tangible Hydra-PEG are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, Paragon Thin contact lenses with Tangible Hydra-PEG 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 non-diseased eyes.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Indications for Use

510(k) Number (if known)

K180172

Device Name

FluoroPerm® 151 (paflucocon D) RGP contact lenses with Tangible Hydra-PEG

Indications for Use (Describe)

FluoroPerm® 151 rigid gas permeable spherical or aspheric contact lenses with Tangible Hydra-PEG are indicated for daily wear as recommended by the eye care practitioner.

FluoroPerm® 151 rigid gas permeable spherical, aspheric and bifocal contact lenses with Tangible Hydra-PEG are indicated for the correction of visual acuity in not-aphakic persons with non-diseased 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 toric contact lenses with Tangible Hydra-PEG are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm® 151 bifocal lenses with Tangible Hydra-PEG are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, FluoroPerm® 151 contact lenses with Tangible Hydra-PEG 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 non-diseased eyes.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Indications for Use

510(k) Number (if known)

K180172

Device Name

Paragon HDS® 100 (paflucocon D) RGP contact lenses with Tangible Hydra-PEG

Indications for Use (Describe)

Paragon HDS® 100 rigid gas permeable spherical or aspheric contact lenses with Tangible Hydra-PEG are indicated for daily wear as recommended by the eye care practitioner.

Paragon HDS® 100 rigid gas permeable spherical, aspheric and bifocal contact lenses with Tangible Hydra-PEG are indicated for the correction of visual acuity in not-aphakic persons with non-diseased 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 toric contact lenses with Tangible Hydra-PEG are indicated to correct astigmatism of up to 6.00 diopters. Paragon HDS® 100 bifocal lenses with Tangible Hydra-PEG are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, Paragon HDS® 100 contact lenses with Tangible Hydra-PEG 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 non-diseased eyes.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K180172**

I. SUBMITTER

Date Prepared: January 17th, 2018

Name: **Paragon Vision Sciences**
Address: 947 E Impala Ave
Mesa, AZ 85204
United States

Contact Person: Rich Jefferies
President

Phone number: (480) 892-7602

Consultant: Bret Andre
EyeReg Consulting, Inc.
6119 Canter Ln.
West Linn, OR 97068

Phone number: (503) 372-5226

II. DEVICE

Trade Name: FluoroPerm® 30 & Paragon Thin™ (paflucocon C) RGP contact lenses with Tangible™ Hydra-PEG; FluoroPerm® 60 & Paragon HDS® (paflucocon B) RGP contact lenses with Tangible™ Hydra-PEG; FluoroPerm® 92 (paflucocon A) RGP contact lenses with Tangible™ Hydra-PEG; FluoroPerm® 151 & Paragon HDS® 100 (paflucocon D) RGP contact lenses with Tangible™ Hydra-PEG

Common Name: Daily wear rigid gas permeable contact lens

Classification Name: Rigid gas permeable contact lens. (21 CFR 886.5916)

Regulatory Class: Class II

Product Code: HQD

Purpose of 510(k) Submission:

~ New Technology ~

The FluoroPerm® 30, Paragon Thin™, FluoroPerm® 60, Paragon HDS®, FluoroPerm® 92, FluoroPerm® 151 & Paragon HDS® 100 Daily Wear Rigid Gas Permeable Contact Lenses—cleared under 510(k) K120996—are modified to include the Tangible™ Hydra-PEG surface coating—which is a thin, polyethylene glycol (PEG)-based polymer designed to improve the wettability of the contact lenses. Specifically, Tangible Hydra-PEG treated contact lenses demonstrate a measurable improvement in the contact angle compared to untreated lenses.

III. PREDICATE DEVICE

The FluoroPerm® 30, Paragon Thin™, FluoroPerm® 60, Paragon HDS®, FluoroPerm® 92, FluoroPerm® 151 & Paragon HDS® 100 Daily Wear Rigid Gas Permeable Contact Lenses with Tangible™ Hydra-PEG are substantially equivalent to the following predicate devices:

- “FluoroPerm® 30 & Paragon Thin™ (paflucocon C) RGP contact lenses”
“FluoroPerm® 60 & Paragon HDS® (paflucocon B) RGP contact lenses”
“FluoroPerm® 92 (paflucocon A) RGP contact lenses”
“FluoroPerm® 151 & Paragon HDS® 100 (paflucocon D) RGP contact lenses”
By Paragon Vision Sciences
510(k) number; **K120996**
-primary predicate
- “Optimum GP with HPT (roflucocon C, D, and E) Daily Wear Contact Lenses”
By Contamac Ltd.
510(k) number; **K161100**
-reference predicate

IV. DEVICE DESCRIPTION

FluoroPerm® 30, Paragon Thin™, FluoroPerm® 60, Paragon HDS®, FluoroPerm® 92, FluoroPerm® 151 & Paragon HDS® 100 lenses with Tangible™ Hydra-PEG are available as lathe cut rigid gas permeable contact lenses for daily wear only. The lenses are manufactured from the following currently marketed contact lens materials:

- paflucocon A (FluoroPerm® 92)
- paflucocon B (FluoroPerm® 60, Paragon HDS®)
- paflucocon C (FluoroPerm® 30, Paragon Thin™)
- paflucocon D (FluoroPerm® 151, Paragon HDS® 100)

Non-proprietary names paflucocon A, B, C, and D were assigned by the United States Adopted Names Council (USAN). 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 lenses may be available with an ultraviolet absorber (not in all colors and materials). The lens designs have a posterior surface consisting of a base curve and a series of up to four annular spherical or aspheric curves peripheral to the base curve.

The FluoroPerm® 92, FluoroPerm® 60, Paragon HDS®, FluoroPerm® 30, Paragon Thin™, FluoroPerm®151, and Paragon HDS® 100 lenses are treated to incorporate Tangible™ Hydra-PEG—which is a thin polyethylene glycol (PEG)-based polymer that is covalently bonded to the surface of the contact lens and is designed to enhance the surface properties of the contact lens while retaining the mechanical properties of the underlying material. When treated with Tangible™ Hydra-PEG, the underlying material is encapsulated in a thin layer of polymer that results in measurable improvement of wettability (sessile drop contact angle) compared to untreated lenses.

The surface properties of paflucocon A, paflucocon B, paflucocon C, and paflucocon D materials uncoated and coated with Tangible Hydra-PEG are depicted in the following table:

	Paflucocon A	Paflucocon B	Paflucocon C	Paflucocon D
Sessile Drop Contact Angle ± Standard Deviation	Coated: 10.5°±2.3° Uncoated: 56.4°±6.8°	Coated: 10.3°±1.7° Uncoated: 59.4°±5.8°	Coated: 10.2°±0.8° Uncoated: 53.6°±4.7°	Coated: 11.3°±3.8° Uncoated: 58.8°±4.9°

The FluoroPerm® 30, Paragon Thin™, FluoroPerm® 60, Paragon HDS®, FluoroPerm® 92, FluoroPerm® 151 & Paragon HDS® 100 lenses with Tangible™ Hydra-PEG are available in the same design configurations and available parameters as the predicate device, cleared under K120996.

V. INDICATIONS FOR USE

FluoroPerm® 92

FluoroPerm® 92 rigid gas permeable spherical or aspheric contact lenses with Tangible™ Hydra-PEG are indicated for daily wear as recommended by the eye care practitioner.

FluoroPerm® 92 rigid gas permeable spherical, aspheric and bifocal contact lenses with Tangible™ Hydra-PEG are indicated for the correction of visual acuity in not-aphakic persons with non-diseased 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 toric contact lenses with Tangible™ Hydra-PEG are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm® 92 bifocal lenses with Tangible™ Hydra-PEG are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, FluoroPerm® 92 contact lenses with Tangible™ Hydra-PEG 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 non-diseased eyes.

FluoroPerm® 60

FluoroPerm® 60 rigid gas permeable spherical or aspheric contact lenses with Tangible™ Hydra-PEG are indicated for daily wear as recommended by the eye care practitioner.

FluoroPerm® 60 rigid gas permeable spherical, aspheric and bifocal contact lenses with Tangible™ Hydra-PEG are indicated for the correction of visual acuity in not-aphakic persons with non-diseased 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 toric contact lenses with Tangible™ Hydra-PEG are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm® 60 bifocal lenses with Tangible™ Hydra-PEG are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, FluoroPerm® 60 contact lenses with Tangible™ Hydra-PEG 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 non-diseased eyes.

Paragon HDS®

Paragon HDS® rigid gas permeable spherical or aspheric contact lenses with Tangible™ Hydra-PEG are indicated for daily wear as recommended by the eye care practitioner.

Paragon HDS® rigid gas permeable spherical, aspheric and bifocal contact lenses with Tangible™ Hydra-PEG are indicated for the correction of visual acuity in not-aphakic persons with non-diseased 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® toric contact lenses with Tangible™ Hydra-PEG are indicated to correct astigmatism of up to 6.00 diopters. Paragon HDS® bifocal lenses with Tangible™ Hydra-PEG are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, Paragon HDS® contact lenses with Tangible™ Hydra-PEG 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 non-diseased eyes.

FluoroPerm® 30

FluoroPerm® 30 rigid gas permeable contact lenses with Tangible™ Hydra-PEG are indicated for daily wear as recommended by the eye care practitioner.

FluoroPerm® 30 rigid gas permeable spherical, aspheric and bifocal contact lenses with Tangible™ Hydra-PEG are indicated for the correction of visual acuity in not-aphakic persons with non-diseased 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 toric contact lenses with Tangible™ Hydra-PEG are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm® 30 bifocal lenses with Tangible™ Hydra-PEG are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, FluoroPerm® 30 contact lenses with Tangible™ Hydra-PEG 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 non-diseased eyes.

Paragon Thin™

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

Paragon Thin™ rigid gas permeable spherical, aspheric and bifocal contact lenses with Tangible™ Hydra-PEG are indicated for the correction of visual acuity in not-aphakic persons with non-diseased 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™ toric contact lenses with Tangible™ Hydra-PEG are indicated to correct astigmatism of up to 6.00 diopters. Paragon Thin™ bifocal lenses with Tangible™ Hydra-PEG are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, Paragon Thin™ contact lenses with Tangible™ Hydra-PEG 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 non-diseased eyes.

FluoroPerm® 151

FluoroPerm® 151 rigid gas permeable spherical or aspheric contact lenses with Tangible™ Hydra-PEG are indicated for daily wear as recommended by the eye care practitioner.

FluoroPerm® 151 rigid gas permeable spherical, aspheric and bifocal contact lenses with Tangible™ Hydra-PEG are indicated for the correction of visual acuity in not-aphakic persons with non-diseased 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 toric contact lenses with Tangible™ Hydra-PEG are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm® 151 bifocal lenses with Tangible™ Hydra-PEG are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, FluoroPerm® 151 contact lenses with Tangible™ Hydra-PEG 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 non-diseased eyes.

Paragon HDS® 100

Paragon HDS® 100 rigid gas permeable spherical or aspheric contact lenses with Tangible™ Hydra-PEG are indicated for daily wear as recommended by the eye care practitioner.

Paragon HDS® 100 rigid gas permeable spherical, aspheric and bifocal contact lenses with Tangible™ Hydra-PEG are indicated for the correction of visual acuity in not-aphakic persons with non-diseased 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 toric contact lenses with Tangible™ Hydra-PEG are indicated to correct astigmatism of up to 6.00 diopters. Paragon HDS® 100 bifocal lenses with Tangible™ Hydra-PEG are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, Paragon HDS® 100 contact lenses with Tangible™ Hydra-PEG 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 non-diseased eyes.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The FluoroPerm® 92, FluoroPerm® 60, Paragon HDS®, FluoroPerm® 30, Paragon Thin™, FluoroPerm® 151, and Paragon HDS® 100 lenses with Tangible™ Hydra-PEG surface technology are substantially equivalent to the FluoroPerm® 92, FluoroPerm® 60, Paragon HDS®, FluoroPerm® 30, Paragon Thin™, FluoroPerm® 151, and Paragon HDS® 100 rigid gas permeable contact lenses (cleared under K120996) in terms of the following:

- Proprietary contact lens material formulation and USAN
- Intended use – daily wear contact lenses
- Indications for use
- Lens designs and available parameters

The FluoroPerm® 92, FluoroPerm® 60, Paragon HDS®, FluoroPerm® 30, Paragon Thin™, FluoroPerm® 151, and Paragon HDS® 100 lenses with Tangible™ Hydra-PEG surface technology are substantially equivalent to the Optimum GP with HPT (rofluocon C, D, and E) Daily Wear Contact Lenses (cleared under K161100) in terms of the following:

- Thermoset copolymers derived from fluorosilicone acrylate monomers
- Tangible™ Hydra-PEG surface coating

The following matrix illustrates the production method, lens function and material characteristics of the FluoroPerm® 92, FluoroPerm® 60, Paragon HDS®, FluoroPerm® 30, Paragon Thin™,

FluoroPerm® 151, and Paragon HDS® 100 lenses with Tangible™ Hydra-PEG surface technology, as well as the predicate devices.

Substantial Equivalence Matrix

	FluoroPerm® 92, FluoroPerm® 60, Paragon HDS®, FluoroPerm® 30, Paragon Thin™, FluoroPerm® 151, and Paragon HDS® 100 lenses with Tangible™ Hydra-PEG	FluoroPerm® 92, FluoroPerm® 60, Paragon HDS®, FluoroPerm® 30, Paragon Thin™, FluoroPerm® 151, and Paragon HDS® 100 lenses	Optimum GP with Tangible™ Hydra-PEG (roflufocon C, D, E)
	New Device	Predicate Device	Predicate Device
Functionality	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina
Intended Use	Daily Wear	Daily Wear	Daily Wear
Indication for Use	Indicated for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. The contact lenses are indicated to correct astigmatism of up to 6.00 diopters, and bifocal lenses are indicated to treat presbyopia up to +4.00 D add power. The lenses are also indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery in otherwise non-diseased eyes.	Indicated for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. The contact lenses are indicated to correct astigmatism of up to 6.00 diopters, and bifocal lenses are indicated to treat presbyopia up to +4.00 D add power. The lenses are also indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery in otherwise non-diseased eyes.	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or presbyopia. The lens may also be prescribed for management of irregular corneal conditions such as keratoconus and post graft fitting.
Production Method	Lathe-Cut, custom manufactured	Lathe-Cut, custom manufactured	Lathe-Cut, custom manufactured
USAN name	paflufocon A, B, C, D	paflufocon A, B, C, D	roflufocon C, D, E
Water Content (%)	<1%	<1%	<1%
Wettability (sessile drop advancing contact angle)	Paflufocon A: 10.5° Paflufocon B: 10.3° Paflufocon C: 10.2° Paflufocon D: 11.3°	Paflufocon A: 56.4° Paflufocon B: 59.4° Paflufocon C: 53.6° Paflufocon D: 58.8°	-
Includes Hydra-PEG	Yes	No	Yes

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Non-clinical Testing

A series of in vitro and in vivo preclinical toxicology and biocompatibility tests were performed to assess the safety and effectiveness of FluoroPerm® 30, Paragon Thin™, FluoroPerm® 60, Paragon HDS®, FluoroPerm® 92, FluoroPerm® 151 & Paragon HDS® 100 rigid gas permeable contact lenses with Tangible™ Hydra-PEG packaged in vials. All non-clinical toxicology tests were conducted in accordance with the GLP regulation. All other testing was conducted according to valid scientific protocols. Test results of the non-clinical testing on the device demonstrate that:

- The finished lenses are not toxic and not irritating,
- Bioburden levels are below the acceptance criteria (<100 cfu/lens) initially and following 30 days of storage in solution (Boston Simplus) at ambient temperatures,
- The physical properties of the lenses are stable following 30 disinfection cycles in Clear Care & Boston Simplus at ambient temperatures, and
- The surface properties of the lens are stable following 30 days of accelerated aging.
- The physicochemical and mechanical properties are unchanged after the addition of Tangible™ Hydra-PEG, with the exception of wettability (contact angle).

Clinical Testing

The clinical safety and effectiveness of finished rigid gas permeable contact lenses manufactured from FluoroPerm® 30, Paragon Thin™, FluoroPerm® 60, Paragon HDS®, FluoroPerm® 92, FluoroPerm® 151 & Paragon HDS® 100 materials have been demonstrated in PMA P870024 and several of its supplements. The clinical safety and effectiveness for contact lenses treated with Hydra-PEG has been previously demonstrated.

VIII. CONCLUSIONS

Validity of Scientific Data

Laboratories under Good Laboratory Practice regulations conducted toxicology, microbiology, and shelf-life stability studies following scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7.

Substantial Equivalence

Information presented in this Premarket Notification establishes that the FluoroPerm® 30, Paragon Thin™, FluoroPerm® 60, Paragon HDS®, FluoroPerm® 92, FluoroPerm® 151 & Paragon HDS® 100 rigid gas permeable contact lenses with Tangible™ Hydra-PEG are as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the proposed indication.

Risks and Benefits

The risks of the subject device are the same as those normally attributed to the wearing of rigid gas permeable (RGP) daily wear contact lenses. The benefits to the patient are the same as those for other RGP contact lenses.