May 11, 2021

Valley Contax, Inc.
% Bret Andre
Principal Consultant
EyeReg Consulting, Inc.
6119 Canter Lane
West Linn, OR 97068

Re: K202860
Trade/Device Name: Valley Contax Single Vision (SV) Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A), Valley Contax Goldeneye Aspheric Front Multifocal (AFM) Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A), Valley Contax V Kone (VK) Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Permeable Contact Lens
Regulatory Class: Class II
Product Code: HQD
Dated: April 1, 2021
Received: April 7, 2021

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

J. Angelo Green, Ph.D.
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202860

Device Name
Valley Contax Single Vision (SV) Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)

Indications for Use *(Describe)*
The Valley Contax SV Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A) is indicated for daily wear for the correction of refractive error in aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10.00 diopters.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

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.

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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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202860

Device Name
Valley Contax Goldeneye Aspheric Front Multifocal (AFM) Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)

Indications for Use *(Describe)*
The Valley Contax AFM Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A) is indicated for daily wear for the correction of refractive error in aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10.00 diopters and are presbyopic requiring add power of up to +4.00 diopters.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202860

Device Name
Valley Contax V Kone (VK) Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)

Indications for Use *(Describe)*
The Valley Contax VK Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A) is indicated for daily wear for the correction of refractive error in aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10.00 diopters and are presbyopic requiring add power of up to +4.00 diopters. The lens may also be prescribed in otherwise non-diseased eyes that require a gas permeable lens for the management of irregular corneal conditions such as; keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

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)

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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: K202860

I. SUBMITTER

Date Prepared: May 6th, 2021

Name: **Valley Contax, Inc.**
Address: 200 South Mill St.
Springfield, Oregon 97477

Contact Person: Josh Adams
Vice President
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Consultant: Bret Andre
EyeReg Consulting, Inc.
6119 Canter Ln.
West Linn, OR 97068
Phone number: (503) 372-5226

II. DEVICE

Trade Name: **Valley Contax Single Vision (SV) Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A);**
Valley Contax Goldeneye Aspheric Front Multifocal (AFM) Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A);
Valley Contax V Kone (VK) Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)

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

III. PREDICATE DEVICE

Valley Contax SV, AFM, and VK Gas Permeable Contact Lenses (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A) for daily wear are substantially equivalent to the following predicate devices:

- "Optimum Gp With Hpt (Roflufocon A, B, C, D, & E) Daily Wear Contact Lenses" (Primary Predicate)
  By Contamac Ltd.
  510(k) number; **K161100**
- "Hyper Gp (Tisilfocon A) Daily Wear Contact Lens" (Predicate)
  By Contamac Ltd.
  510(k) number; **K182304**
- "Hexa100 (Hexafocon A) Daily Wear Contact Lenses" (Predicate)
  By Contamac Ltd.
  510(k) number; **K171077**
- "Enflu 18 (Enflufocon A) Daily Wear Contact Lens" (Predicate)
  By Contamac Ltd.
  510(k) number; **K171575**
- "Custom Stable Rigid Gas Permeable Scleral Contact Lens" (Reference Predicate)
  By Valley Contax, Inc.
  510(k) number: **K170335**

IV. DEVICE DESCRIPTION

Valley Contax Single Vision (SV) Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)

The **Valley Contax SV Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)** for daily wear is made-to-order with spherical or aspheric front surfaces, or a prism-ballasted toric front surface. The **Valley Contax SV Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)** is available in the following lens parameters:

Parameter	Range	Tolerance
Base Curve	6.00mm to 10.0mm	± 0.05 mm
Center Thickness	0.08mm to 0.75mm	± 0.02 mm
Diameter	6.0mm to 12.5mm	± 0.10mm
Spherical Power	-30.00D to +30.00D	± 0.12 (0 to </= 5D) ± 0.18 (5 to </= 10.0D) ± 0.25 (10 to </= 15D) ± 0.37 (15 to </= 20D) ± 0.50 (over 20D)
Cylindrical Power	Up to 10.00D	± 0.25 (0 to </= 2D) ± 0.37 (2 to </= 4D) ± 0.50 (over 4D)
Surface Appearance	-	Lenses should be clear with no surface defect

Valley Contax Goldeneye Aspheric Front Multifocal (AFM) Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)

The **Valley Contax AFM Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)** for daily wear is made-to-order in a range of multifocal strengths and options. The **Valley Contax AFM Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)** is available in the following lens parameters:

Parameter	Range	Tolerance
Base Curve	6.00mm to 10.00mm	± 0.05 mm
Center Thickness	0.08mm to 0.75mm	± 0.02 mm
Diameter	6.0mm to 12.5mm	± 0.10mm
Spherical Power	-30.00D to +30.00D	± 0.12 (0 to </= 5D) ± 0.18 (5 to </= 10.0D) ± 0.25 (10 to </= 15D) ± 0.37 (15 to </= 20D) ± 0.50 (over 20D)
Cylindrical Power	Up to 10.00D	± 0.25 (0 to </= 2D) ± 0.37 (2 to </= 4D) ± 0.50 (over 4D)
Multifocal Power	+0.75D to 4.00D	± 0.25D
Surface Appearance	-	Lenses should be clear with no surface defect

Valley Contax V Kone (VK) Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)

The **Valley Contax VK Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)** for daily wear is indented for the management of irregular cornea conditions and is made-to-order in spherical, aspheric, prism-ballasted toric, and multifocal front surface options. The **Valley Contax VK Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)** is available in the following lens parameters:

Parameter	Range	Tolerance
Base Curve	6.00mm to 10.00 mm	± 0.05 mm
Center Thickness	0.08mm to 0.75mm	± 0.02 mm
Diameter	6.0mm to 12.5mm	± 0.10mm
Spherical Power	-30.00D to +30.00D	± 0.12 (0 to </= 5D) ± 0.18 (5 to </= 10.0D) ± 0.25 (10 to </= 15D) ± 0.37 (15 to </= 20D) ± 0.50 (over 20D)
Cylindrical Power	Up to 10.00D	± 0.25 (0 to </= 2D) ± 0.37 (2 to </= 4D) ± 0.50 (over 4D)
Multifocal Power	+0.75D to 4.00D	± 0.25D
Surface Appearance	-	Lenses should be clear with no surface defect

The **Valley Contax SV, AFM, and VK Gas Permeable Contact Lenses (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)** are lathe cut from one of the following hydrophobic, fluorosilicone acrylate materials:

- roflufocon D
- roflufocon E
- tisilfocon A
- hexafocon A
- enflufocon A

The physical properties of the **Valley Contax SV, AFM, and VK Gas Permeable Contact Lenses (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)** are as follows (reported from predicate devices):

	roflufocon D	**roflufocon E**	**tisilfocon A**	**hexafocon A**	**enflufocon A**
Refractive Index	1.4333	1.4332	1.4378	1.4136	1.4436
Light Transmission (tinted)	>90%	>90%	>91%	>91%	>90%
Specific Gravity	1.166	1.155	1.200	1.266	1.221
Oxygen Permeability (Dk) ISO/FATT Method	100×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)	125×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)	180×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)	113×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)	21×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)
Color Additives	D & C Green No. 6, FD & C Red No. 17, CI Solvent Yellow 18	D & C Green No. 6, FD & C Red No. 17, CI Solvent Yellow 18	D&C Green No. 6, C.I. Solvent Yellow No. 18, D&C Violet No. 2 and D&C Red No. 17	D&C Green No. 6, C.I. Solvent Yellow No. 18, D&C Violet No. 2 and D&C Red No. 17	D&C Green No. 6, C.I. Solvent Yellow No. 18, D&C Violet No. 2 and D&C red No. 17
UV Light Blocking (UVB – 280nm – 315nm; UVA 316nm – 380nm)	>98% UVB >95% UVA	>98% UVB >95% UVA	>98% UVB >86% UVA	>98% UVB >84% UVA	>98% UVB >83% UVA

The **Valley Contax SV, AFM, and VK Gas Permeable Contact Lenses (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)** for daily wear are shipped "dry" in a polypropylene contact lens case. The primary container for shipping the **Valley Contax SV, AFM, and VK Gas Permeable Contact Lenses (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)** is the Amcon CL-5001—with 510(k) clearance under K052809.

V. INDICATIONS FOR USE

Valley Contax Single Vision (SV) Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)

The **Valley Contax SV Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)** is indicated for daily wear for the correction of refractive error in aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10.00 diopters.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

Valley Contax Goldeneye Aspheric Front Multifocal (AFM) Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)

The **Valley Contax AFM Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)** is indicated for daily wear for the correction of refractive error in aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10.00 diopters and are presbyopic requiring add power of up to +4.00 diopters.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

Valley Contax V Kone (VK) Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)

The **Valley Contax VK Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)** is indicated for daily wear for the correction of refractive error in aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10.00 diopters and are presbyopic requiring add power of up to +4.00 diopters. The lens may also be prescribed in otherwise non-diseased eyes that require a gas permeable lens for the management of irregular corneal conditions such as; keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The **Valley Contax SV, AFM, and VK Gas Permeable Contact Lenses (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)** are substantially equivalent to the predicate devices (cleared under K161100, K182304, K171077, and K171575) in terms of the following:

- Intended use – daily wear contact lenses
- Indications for use
- Actions
- Classification – Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)
- FDA material group – group # 3 fluoro silicone acrylate
- USAN materials (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)
- Production method – lathe cut
- Final packaging and shipping

The following matrix illustrates the production method, lens function and material characteristics of the **Valley Contax SV, AFM, and VK Gas Permeable Contact Lenses**, as well as the predicate device.

	Valley Contax SV, AFM, VK GP Contact Lenses	**Optimum GP (roflufocon D & E) RGP Contact Lenses**	**Hyper Gp (Tisilfocon A) Daily Wear Contact Lens**	**Hexa100 (Hexafocon A) Daily Wear Contact Lenses**	**Enflu 18 (Enflufocon A) Daily Wear Contact Lens**	**Custom Stable Scleral Contact Lens**
	Subject Device	**Predicate Device (K161100)**	**Predicate Device (K182304)**	**Predicate Device (K171077)**	**Predicate Device (K171575)**	**Predicate Device (K170335)**
Classification	Same as predicate	Class II Lenses, Rigid Gas Permeable, Daily Wear 21 CFR 886.5916	Class II Lenses, Rigid Gas Permeable, Daily Wear 21 CFR 886.5916	Class II Lenses, Rigid Gas Permeable, Daily Wear 21 CFR 886.5916	Class II Lenses, Rigid Gas Permeable, Daily Wear 21 CFR 886.5916	Class II Lenses, Rigid Gas Permeable, Daily Wear 21 CFR 886.5916
Product Code	Same as predicate	HQD	HQD	HQD	HQD	HQD
FDA Group #	Same as predicate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate
Material (USAN)	roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A,	roflufocon D, roflufocon E	tisilfocon A,	hexafocon A	enflufocon A	roflufocon D, roflufocon E
Production Method	Same as predicate	Lathe-Cut	Lathe-Cut	Lathe-Cut	Lathe-Cut	Lathe-Cut
Intended Use	Same as predicate	Daily Wear	Daily Wear	Daily Wear	Daily Wear	Daily Wear
Water Content (%)	<1%	<1%	<1%	<1%	<1%	<1%
UV Absorber Available	Yes	Yes	Yes	Yes	Yes	Yes

	Indications for Use
Valley Contax SV, AFM, VK GP Contact Lenses (Subject Device)	**Valley Contax Single Vision (SV) Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)** The **Valley Contax SV Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)** is indicated for daily wear for the correction of refractive error in aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10.00 diopters. Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system. **Valley Contax Goldeneye Aspheric Front Multifocal (AFM) Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)** The **Valley Contax AFM Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)** is indicated for daily wear for the correction of refractive error in aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10.00 diopters and are presbyopic requiring add power of up to +4.00 diopters. Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system. **Valley Contax V Kone (VK) Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)** The **Valley Contax VK Gas Permeable Contact Lens (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)** is indicated for daily wear for the correction of refractive error in aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10.00 diopters and are presbyopic requiring add power of up to +4.00 diopters. The lens may also be prescribed in otherwise non-diseased eyes that require a gas permeable lens for the management of irregular corneal conditions such as; keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery. Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.
Optimum GP (roflufocon D & E) RGP Contact Lenses (K161100)	The **Optimum GP with HPT** (roflufocon C, D, and E) **Spherical** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be disinfected with a chemical disinfection system only. The **Optimum GP with HPT** (roflufocon C, D, and E) **Toric** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10.00 diopters. The lens may be disinfected with a chemical disinfection system only. The **Optimum GP with HPT** (roflufocon C, D, and E) **Multifocal/Bifocal** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 4 diopters and are presbyopic requiring add power of up to +4.00 diopters. The lens may be disinfected with a chemical disinfection system only The **Optimum GP with HPT** (roflufocon C, D, and E) **Irregular Cornea** Daily Wear Contact Lens may be prescribed in otherwise non-diseased eyes that require a rigid gas permeable lens for the management of irregular corneal conditions such as; keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.

	Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.
Hyper Gp (Tisilfocon A) Daily Wear Contact Lens (K182304)	The **Hyper GP (tisilfocon A) SPHERICAL** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The **Hyper GP (tisilfocon A) TORIC** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10.00 diopters. The **Hyper GP (tisilfocon A) MULTIFOCAL/BIFOCAL** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 4 diopters and are presbyopic requiring add power of up to +4.00 diopters. The **Hyper GP (tisilfocon A) IRREGULAR CORNEA** Daily Wear Contact Lens may be prescribed in otherwise non-diseased eyes that require a rigid gas permeable lens for the management of irregular corneal conditions such as; keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery. The **Hyper GP (tisilfocon A) ORTHOKERATOLOGY** contact lenses are indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 5.00 diopters in non-diseased eyes. To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule. Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.
Hexa100 (Hexafocon A) Daily Wear Contact Lenses (K171077)	The **HEXA100 (hexafocon A) SPHERICAL** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The **HEXA100 (hexafocon A) TORIC** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10.00 diopters. The **HEXA100 (hexafocon A) MULTIFOCAL/BIFOCAL** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 4 diopters and are presbyopic requiring add power of up to +4.00 diopters. The **HEXA100 (hexafocon A) IRREGULAR CORNEA** Daily Wear Contact Lens may be prescribed in otherwise non-diseased eyes that require a rigid gas permeable lens for the management of irregular corneal conditions such as; keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery. The **HEXA100 (hexafocon A) ORTHOKERATOLOGY** contact lenses are indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 5.00 diopters in non-diseased eyes. To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule. Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

Enflu 18 (Enflufocon A) Daily Wear Contact Lens (K171575)	The **ENFLU 18 (enflufocon A) SPHERICAL** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The **ENFLU 18 (enflufocon A) TORIC** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10.00 diopters. The **ENFLU 18 (enflufocon A) MULTIFOCAL/BIFOCAL** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 4 diopters and are presbyopic requiring add power of up to +4.00 diopters. The **ENFLU 18 (enflufocon A) IRREGULAR CORNEA** Daily Wear Contact Lens may be prescribed in otherwise non-diseased eyes that require a rigid gas permeable lens for the management of irregular corneal conditions such as; keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery. Eye care practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.
Custom Stable Rigid Gas Permeable Scleral Contact Lens (K170335)	The Custom Stable Rigid Gas Permeable Scleral Contact Lenses for daily wear are indicated for use for the management of multiple ocular conditions, such as, degenerations that lead to an irregular corneal shape (e.g. keratoconus, keratoglobus, pellucid marginal degeneration, Salzmann's Nodular Degeneration), dystrophies (e.g. Cogan's dystrophy, granular corneal dystrophy, Lattice Corneal Dystrophy), post-surgery (e.g. corneal transplant, LASIK, radial keratotomy), and corneal scarring. The lens may also be prescribed for the management of ocular surface diseases (e.g. dry eye syndrome, Keratoconjunctivitis Sicca (Graft vs Host Disease, Sjogren's syndrome, Filamentary Keratitis), limbal stem cell deficiency, epidermal ocular disorders, neurotrophic keratitis, and corneal exposure/lagophthalmos). When prescribed for therapeutic use, the Custom Stable RGP Scleral Lenses is also indicated for correction of refractive error in persons with myopia, hyperopia or presbyopia. Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

VII. PERFORMANCE DATA

~ Non-Clinical Studies ~

Non-clinical testing to validate safety and effectiveness for finished contact lenses manufactured from roflufocon D, roflufocon E, tisilfocon A, hexafocon A, and enflufocon A blanks has been addressed by reference to previously cleared 510(k) premarket notifications. Additional non-clinical testing was conducted to support the claim that the **Valley Contax SV, AFM, and VK Gas Permeable Contact Lenses (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)** are substantially equivalent to the currently marketed predicate devices. A summary of the results from the non-clinical studies is presented below.

Bioburden:

Bioburden testing conducted on gas permeable lenses manufactured at Valley Contax, Inc. demonstrated that the colony forming units (CFU) per lens was within the established acceptance criteria of less than 100 CFU per lens.

Lens Design/Manufacturing Verification:

Bench testing was performed to verify the ability of Valley Contax, Inc. to manufacture the **Valley Contax SV, AFM, and VK Gas Permeable Contact Lenses (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)** to a variety of prescribed parameters within manufacturing tolerances.

~ *Clinical Studies* ~

Clinical performance data to validate the safety and effectiveness of contact lenses manufactured from roflufocon D, roflufocon E, tisilfocon A, hexafocon A, and enflufocon A has been addressed by reference to previously cleared 510(k) premarket notificaitons.

VIII. CONCLUSIONS

Substantial Equivalence

Information presented in this premarket notification establishes that **Valley Contax SV, AFM, and VK Gas Permeable Contact Lenses (roflufocon D, roflufocon E, tisilfocon A, hexafocon A, enflufocon A)** for daily wear are as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the proposed indications.

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.