January 07, 2022

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

Re: K213880
Trade/Device Name: Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) Scleral Contact Lens
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Permeable Contact Lens
Regulatory Class: Class II
Product Code: HQD
Dated: December 10, 2021
Received: December 13, 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)*
K213880

Device Name
Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) Scleral Contact Lens

Indications for Use *(Describe)*
The Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) 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.

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.

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Special 510 (k) Summary

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: K213880

I. SUBMITTER

Date Prepared: December 10th, 2021

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

Contact Person: Josh Adams
Vice President
Phone number: (541) 744-9393

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

II. DEVICE

Trade Name: **Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) Scleral Contact Lens**

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

Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) Scleral Contact Lens for daily wear is substantially equivalent to the following predicate device:

- "Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) Scleral Contact Lens" (Primary Predicate)
  By Valley Contax, Inc.
  510(k) number; **K170335**

IV. DEVICE DESCRIPTION

The **Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) Scleral Contact Lens** for daily wear is a large diameter rigid gas permeable contact lens design that vaults over the cornea and rests on the conjunctiva overlying the sclera. The **Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) Scleral Contact Lens** is lathe cut from one of the following hydrophobic, fluoro-silicone acrylate materials:

- roflufocon D (supplied by Contamac Ltd.)
- roflufocon E (supplied by Contamac Ltd.)

The physical properties of the **Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) Scleral Contact Lens** are as follows:

	ROFLUFOCON D	**ROFLUFOCON E**
Refractive Index	1.430	1.4332
Light Transmission (clear)	>97%	>97%
Light Transmission (tinted)	>90%	>90%
Water Content	<1%	<1%
Dynamic Contact Angle (Receding)	3°	6°
Specific Gravity	1.166	1.155
Modulus	697 MPa	77 MPa
Shore D Hardness	75	77
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)
contain one or more of the following color additives conforming to: 21 CFR Part 73 & 74, Subpart D	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
UV Light Blocking (UVB – 280nm – 315nm; UVA 316nm – 380nm)	>98% UVB >95% UVA	>98% UVB >95% UVA

The parameters for the **Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) Scleral Contact Lens** are as follows:

Parameter	Range	Tolerance
Base Curve	6.6 mm to 11.0 mm	± 0.05 mm
Center Thickness	0.20 mm to 1.20 mm (0.01mm increments)	± 0.02 mm
Diameter	13.8 mm to 19.0 mm	± 0.10mm
Spherical Power	-30.00 D to +30.00 D (0.125 D steps)	± 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	-0.25D to -6.50D	± 0.25 (0 to </= 2D) ± 0.37 (2 to </= 4D) ± 0.50 (over 4D)
Surface Appearance	-	Lenses should be clear with no surface defect

The **Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) Scleral Contact Lens** may be shipped "dry" or "wet". The containers for shipping the **Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) Scleral Contact Lens** are as follows:

- Bonasse SC 106 (510(k) K991206)
- Bonasse SC-107 (510(k) K991206)
- Amcon CL-5001 (510(k) K923458)
- Amcon JC-4013 (510(k) K923458)

When shipped "wet", The **Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) Scleral Contact Lens** is packaged and shipped in the Menicon Unique pH multipurpose solution.

V. INDICATIONS FOR USE

The **Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The **Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) Scleral Contact Lenses** are substantially equivalent to the predicate device (cleared under K170335) 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)
- Lens design (Custom Stable)
- Production method – lathe cut
- Final packaging and shipping

The following matrix illustrates the production method, lens function and material characteristics of the **Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) Scleral Contact Lenses**, as well as the predicate device.

	Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) Scleral Contact Lenses	**Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) Scleral Contact Lenses**
	Subject Device	**Predicate Device (K170335)**
Classification	Same as predicate	Class II Lenses, Rigid Gas Permeable, Daily Wear 21 CFR 886.5916
Product Code	Same as predicate	HQD
FDA Group #	Same as predicate	Group # 3 Fluoro Silicone Acrylate
Material (USAN)	Same as predicate	roflufocon D, roflufocon E
Production Method	Same as predicate	Lathe-Cut
Intended Use	Same as predicate	Daily Wear
Water Content (%)	Same as predicate	<1%
UV Absorber Available	Same as predicate	Yes

	Indications for Use
Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) Scleral Contact Lenses (Subject Device)	The **Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) 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.
Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) Scleral Contact Lenses (Predicate Device: K170335)	The **Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) 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 and roflufocon E blanks has been addressed by reference to previously cleared 510(k) premarket notifications. To evaluate the changes presented in this 510(k), Valley Contax conducted the following tests:

Lens Design/Manufacturing Verification:

Bench testing was performed to verify the ability of Valley Contax, Inc. to manufacture the **Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) Scleral Contact Lenses** to a variety of prescribed parameters within manufacturing tolerances. Testing was conducted in accordance with ISO 18369-3.

Refractive Index Testing:

Bench testing was performed to verify the refractive index of the **Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) Scleral Contact Lenses**. Testing was conducted in accordance with ISO 18369-4.

~ Clinical Studies ~

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

VIII. CONCLUSIONS

Substantial Equivalence

Information presented in this premarket notification establishes that **Custom Stable™ Rigid Gas Permeable (roflufocon D, roflufocon E) Scleral Contact Lenses** 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.