DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 24, 2017

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

Re: K170335
Trade/Device Name: Custom Stable ™ Rigid Gas Permeable Scleral Contact Lens
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Permeable Contact Lens
Regulatory Class: Class II
Product Code: HQD
Dated: January 30, 2017
Received: February 2, 2017

Dear Mr. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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 of 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170335

Device Name
Custom Stable(TM) Rigid Gas Permeable Scleral Contact Lenses

Indications for Use *(Describe)*

The Custom Stable(TM) 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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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: K170335

Applicant information:

Date Prepared:	January 30th, 2017
Name:	**Valley Contax, Inc.**
Address	200 South Mill St. Springfield, Oregon 97477
Contact Person:	Josh Adams Vice President
Phone number:	(541) 744-9393
Consultant/Correspondent:	EyeReg Consulting, Inc. Bret Andre
Phone number	(503) 372-5226
Fax number	(503) 419-4475

Device Information:

Device Classification:	Class II
Classification Number:	HQD
Classification Name:	Lenses, Rigid Gas Permeable, Daily Wear
Trade Name:	**Custom Stable™ Rigid Gas Permeable Scleral Contact Lens**

Predicate Devices:

The **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens** is substantially equivalent to the following predicate device(s)

- "**BostonSight PD Prosthetic Device**"
  – Primary Predicate
  Manufactured by Boston Foundation for Sight
  510(k) number; K161461
- "**Optimum GP (roflufocon A,B,C,D&E) Daily Wear Contact Lens**"
  – Reference Predicate
  Manufactured by Contamac Ltd.
  510(k) number; K033594

Device Description:

The **Custom Stable™ Rigid Gas Permeable 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 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 Scleral Contact Lens** are as follows:

	ROFLUFOCON D	**ROFLUFOCON E**
Refractive Index	1.4333	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 Scleral Contact Lens** are as follows:

*	Chord Diameter:	14.8 mm to 17.8 mm
*	Center Thickness:	0.20 mm to 0.40 mm
*	Base Curve:	6.6 mm to 11.0 mm
*	Spherical Powers:	-30.00 Diopters to +30.00 Diopters (0.125 Diopter steps)

The **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens** may be shipped "dry" or "wet". The primary container for shipping the **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens** is the Bonasse Flat Bed Soaking Case, Model SC 106—with 510(k) clearance under K991206. When shipped "wet", The **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens** is packaged and shipped in the Menicon Unique pH multipurpose solution.

Indication for Use:

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.

Description of Testing:

~ Non-Clinical Studies ~

Non-clinical testing to demonstrate the safety and effectiveness of contact lenses manufactured from roflufocon D and roflufocon E has been addressed by reference to 510(k) K033594—Optimum GP (roflufocon A,B,C,D&E) Daily Wear Contact Lens (the predicate device).

Additionally, the following testing was performed on the finished **Custom Stable™ Rigid Gas Permeable Scleral Contact Lenses**:

Bench Testing—manufacturing verification testing was conducted to demonstrate the ability of Valley Contac, Inc. to manufacture lenses, on a repeatable basis, from supplied lens blanks to a variety of prescribed parameters. All lenses were manufactured to established finished product specifications within the ANSI Z80.20 tolerance.

Bioburden Testing—bioburden testing conducted on rigid gas permeable lenses manufactured at Valley Contax, Inc. demonstrated that the colony forming units (CFU) per lens was less than 1, which is within the established acceptance criteria of less than 100 CFU per lens.

~ Clinical Studies ~

Clinical testing to demonstrate the safety and effectiveness of contact lenses manufactured from roflufocon D and roflufocon E has been addressed by reference to 510(k) K033594—Optimum GP (roflufocon A,B,C,D&E) Daily Wear Contact Lens (the predicate device).

Additionally, a series of clinical case reports demonstrate the performance of the **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens** when prescribed for the proposed indications for use.

~ Conclusions Drawn from Testing ~

Testing presented in this submission for the **Custom Stable™ Rigid Gas Permeable Scleral Contact Lenses** demonstrate no significant differences from the predicate devices—supporting the substantial equivalence claim.

Substantial Equivalence:

The **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens** is substantially equivalent to the predicate device(s), and *does not raise* different questions of safety and effectiveness.

The **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens** is substantially equivalent to the BostonSight PD Prosthetic Device (predicate device) in the following key areas:

- Components/Materials/Formulation (roflufocon D & E contact lens materials)
- FDA classification and group number (Class 2, Group #3 Fluoro Silicone Acrylate)
- Lathe cut manufacturing process
- Large diameter (scleral) design
- Actions and intended use
- Therapeutic indications for use

The following table depicts the characteristics of the **Custom Stable™ Rigid Gas Permeable Scleral Contact Lens**, as well as the predicate device(s).

	Custom Stable™ Rigid Gas Permeable Scleral Contact Lens	**BostonSight PD Prosthetic Device K161461**	**Optimum GP (roflufocon A,B,C,D&E) Daily Wear Contact Lens K033594**
	Subject Device	***Predicate Device***	***Predicate Device***
Indication for Use	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.	Indicated for therapeutic use in eyes with ocular surface disease from dry eye (e.g. ocular Graft-versus-Host disease, Sjögren's syndrome, dry eye syndrome), limbal stem cell deficiency (e.g.Stevens-Johnson syndrome, chemical and thermal burns, radiation), disorders of the skin (e.g. atopy, ectodermal dysplasia), neurotrophic keratitis (e.g. Herpes simplex, Herpes zoster, Familial Dysautonomia), and corneal exposure (e.g. anatomic, paralytic) that might benefit from the presence of an expanded tear reservoir and protection against an adverse environment. When prescribed for therapeutic use for distorted cornea or ocular surface disease, the BostonSight PD Prosthetic Device may incidentally provide correction of refractive error.	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 of following penetrating keratoplasty or following refractive (e.g. LASIK) surgery.
Device and Classification	Class II Lenses, Rigid Gas Permeable, Daily Wear HQD	Class II Lenses, Rigid Gas Permeable, Daily Wear HQD	Class II Lenses, Rigid Gas Permeable, Daily Wear HQD
Production Method	Lathe-cut	Lathe-cut	Lathe-cut
USAN	Roflufocon D Roflufocon E	Roflufocon D Roflufocon E Oprifocon A Hexafocon B	Roflufocon A Roflufocon B Roflufocon C Roflufocon D Roflufocon E
FDA Group #	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate
Water Content	<1%	<1%	<1%
UV Absorber/Blocker available	YES	YES	YES