April 25, 2018

Contamac, Ltd.
% Bret Andre
Principal Consultant
EyeReg Consulting, Inc.
6119 Canter Ln
West Linn, OR 97068

Re: K180616
Trade/Device Name: OPTIMUM GP (roflufocon D, roflurocon E) Daily Wear Contact Lens, HEXA100 (hexafocon A) Daily Wear Contact Lens
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Permeable Contact Lens
Regulatory Class: Class II
Product Code: HQD
Dated: March 5, 2018
Received: March 8, 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,

J Angelo Green -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180616

Device Name
OPTIMUM GP (roflufocon D, roflufocon E) Daily Wear Contact Lens;
HEXA100 (hexafocon A) Daily Wear Contact Lens

Indications for Use *(Describe)*
OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear Contact Lenses are indicated for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and non aphakic persons with non-diseased eyes. Also, the lenses may be prescribed in otherwise non-diseased eyes that require a rigid contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive surgery.

Furthermore, eyes suffering from certain ocular surface disorders may benefit from the physical protection, aqueous hydrated environment and the saline bath provided by scleral lens designs. OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear Contact Lenses are indicated for therapeutic use for the management of irregular and distorted corneal surfaces where the subject:

1. cannot be adequately corrected with spectacle lenses
2. requires a rigid gas permeable contact lens surface to improve vision
3. is unable to wear a corneal rigid gas permeable lens due to corneal distortion or surface irregularities

Common causes of corneal distortion include but are not limited to corneal infections, trauma, tractions as a result of scar formation secondary to refractive surgery (e.g. LASIK or radial keratotomy) or corneal transplantation. Causes may also include corneal degeneration (e.g. keratoconus, keratoglobus, pellucid marginal degeneration, Salzmann's nodular degeneration) and corneal dystrophy (e.g., lattice dystrophy, granular corneal dystrophy, Reis-Bucklers dystrophy, Cogan's dystrophy). The OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear Contact Lenses are also indicated for therapeutic use in eyes with ocular surface disease (e.g. ocular Graft-versus-Host disease, Sjögren’s syndrome, dry eye syndrome and Filamentary Keratitis), limbal stem cell deficiency (e.g. Stevens-Johnson syndrome, chemical radiation and thermal burns), 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 a distorted cornea or ocular surface disease, the OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear Contact Lenses may concurrently provide correction of refractive error.

The lenses may be disinfected using a chemical disinfection (not heat) system only.

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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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: K180616

I. SUBMITTER

Date Prepared: April 10th, 2018

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II. DEVICE

Trade Name: **OPTIMUM GP (roflufocon D, roflufocon E) Daily Wear Contact Lens; HEXA100 (hexafocon A) Daily Wear 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

The **OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear Contact Lenses** are substantially equivalent to the following predicate device:

- "Boston XO® (hexafocon A) and Boston XO2® (hexafocon B) Rigid Gas Permeable Contact Lens"
  By Bausch + Lomb Inc.
  510(k) number; **K171404**

IV. DEVICE DESCRIPTION

The **OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear Contact Lenses** are lathe cut from one of the following hydrophobic, FDA Group #3 fluoro-silicone acrylate materials: roflufocon D, roflufocon E, or hexafocon A—with the following properties:

	ROFLUFOCON D	**ROFLUFOCON E**	**HEXAFOCON A**
Refractive Index	1.4333	1.4332	1.414
Light Transmission (clear)	>97%	>97%	-
Light Transmission (tinted)	>90%	>90%	>91%
Water Content	<1%	<1%	<1%
Specific Gravity	1.166	1.155	1.266
Shore D Hardness	75	77	80
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)	113×10^{-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	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 >84% UVA

The **OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear Contact Lenses** are available with or without 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 compared to untreated lenses.

The surface properties of roflufocon D, roflufocon E, and hexafocon A materials uncoated and coated with Tangible Hydra-PEG are depicted in the following table:

	roflufocon D	**roflufocon E**	**hexafocon A**
Captive Bubble Contact Angle ± Standard Deviation	Coated: 40.40°±5.05° Uncoated: 93.28°±2.13°	Coated: 36.90°±8.04° Uncoated: 93.64°±3.47°	Coated: 49.1°±5.81° Uncoated: 96.4°±2.79°

The **OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear Contact Lenses** may be packaged and shipped "dry" or "wet" in a polypropylene contact lens case. The primary container for shipping the **OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear Contact Lenses** is the PolyVial Contact Lens Case. When shipped "wet", the lenses may be packaged and shipped in the Unique pH contact lens care system by Menicon Co., Ltd**.** The active ingredients in Unique pH solution are Edetate Disodium 0.01% and Polyquaternium 10.0011%.

The **OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear Contact Lenses** are available in the following lens parameters:

Parameter	**Range**	**Tolerance**
Base Curve	5.00mm to 8.00mm	± 0.05 mm
Center Thickness	0.20mm to 0.50mm	± 0.02 mm
Diameter	7.00mm to 22.00mm	± 0.10mm
Spherical Power	-20.00 D to +20.00 D (in 0.25D 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	Up to -10.00 D (in 0.25 D steps)	± 0.25 (0 to </= 2D) ± 0.37 (2 to </= 4D) ± 0.50 (over 4D)
Cylindrical Axis	1° to 180° (in 1° steps)	± 5°
Multifocal Power	+1.00 D to 4.00 D (in 0.25 D steps)	± 0.25D

V. INDICATIONS FOR USE

OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear Contact Lenses are indicated for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and non aphakic persons with non-diseased eyes. Also, the lenses may be prescribed in otherwise non-diseased eyes that require a rigid contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive surgery.

Furthermore, eyes suffering from certain ocular surface disorders may benefit from the physical protection, aqueous hydrated environment and the saline bath provided by scleral lens designs. **OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear Contact Lenses** are indicated for therapeutic use for the management of irregular and distorted corneal surfaces where the subject:

1. cannot be adequately corrected with spectacle lenses
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3. is unable to wear a corneal rigid gas permeable lens due to corneal distortion or surface irregularities

Common causes of corneal distortion include but are not limited to corneal infections, trauma, tractions as a result of scar formation secondary to refractive surgery (e.g. LASIK or radial keratotomy) or corneal transplantation. Causes may also include corneal degeneration (e.g. keratoconus, keratoglobus, pellucid marginal degeneration, Salzmann's nodular degeneration) and corneal dystrophy (e.g., lattice dystrophy, granular corneal dystrophy, Reis-Bucklers dystrophy, Cogan's dystrophy). The **OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear Contact Lenses** are also indicated for therapeutic use in eyes with ocular surface disease (e.g. ocular Graft-versus-Host disease, Sjögren’s syndrome, dry eye syndrome and Filamentary Keratitis), limbal stem cell deficiency (e.g. Stevens-Johnson syndrome, chemical radiation and thermal burns), 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 a distorted cornea or ocular surface disease, the **OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear Contact Lenses** may concurrently provide correction of refractive error.

The lenses may be disinfected using a chemical disinfection (not heat) system only.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The **OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear Contact Lenses** are substantially equivalent to the Boston XO® (hexafocon A) and Boston XO2®(hexafocon B) Rigid Gas Permeable Contact Lenses (cleared under K171404) in terms of the following:

- Intended use – daily wear contact lenses
- Indications for use – therapeutic (scleral)
- Actions
- Classification – Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)
- FDA material group – group # 3 fluoro silicone acrylate
- Production method – lathe cut

The following matrix illustrates the production method, lens function and material characteristics of the **OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear Contact Lenses**, as well as the predicate device.

Substantial Equivalence Matrix

	OPTIMUM GP and HEXA100 Daily Wear Contact Lenses	**Boston XO® and Boston XO2® RGP Contact Lenses**
	Subject Device	**Predicate Device (K171404)**
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
USAN	roflufocon D, roflufocon E, hexafocon A	hexafocon A, hexafocon B
Production Method	Same as predicate	Lathe-Cut
Actions	Same as predicate	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina. When placed on the eye for therapeutic use, the lens replaces or supports impaired ocular surface function.
Intended Use	Same as predicate	Daily Wear

Indication for Use	Same as predicate	Indicated for therapeutic use for the management of irregular and distorted corneal surfaces where the subject: 1. cannot be adequately corrected with spectacle lenses 2. requires a rigid gas permeable contact lens surface to improve vision 3. is unable to wear a corneal rigid gas permeable lens due to corneal distortion or surface irregularities Common causes of corneal distortion include but are not limited to corneal infections, trauma, tractions as a result of scar formation secondary to refractive surgery or corneal transplantation. Causes may also include corneal degeneration and corneal dystrophy. Also indicated for therapeutic use in eyes with ocular surface, limbal stem cell deficiency, disorders of the skin, neurotrophic keratitis, and corneal exposure that might benefit from the presence of an expanded tear reservoir and protection against an adverse environment.
Specific Gravity	roflufocon D: 1.166 roflufocon E: 1.155 hexafocon A: 1.266	hexafocon A: 1.266 hexafocon B: 1.190
Shore D Hardness	roflufocon D: 75 roflufocon E: 77 hexafocon A: 80	hexafocon A: 80 hexafocon B: 78
Oxygen Permeability x 10^{11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35oC)	roflufocon D: 100 roflufocon E: 125 hexafocon A: 111	hexafocon A: 111 hexafocon B: 141
Refractive Index	roflufocon D: 1.433 roflufocon E: 1.433 hexafocon A: 1.415	hexafocon A: 1.415 hexafocon B: 1.424
Water Content (%)	<1%	<1%
UV Absorber Available	Yes	Yes
Hydra-PEG Surfacing Available	Yes	No

VII. PERFORMANCE DATA

~ Non-Clinical Studies ~

The purpose of this application is to modify the labeling of previously FDA cleared RGP contact lenses/materials to include a therapeutic indication for use. Non-clinical testing to demonstrate the safety and effectiveness of contact lenses manufactured from roflufocon D, roflufocon E, and hexafocon A materials has been addressed in previous applications.

~ Clinical Studies ~

Clinical performance data to demonstrate the safety and effectiveness of contact lenses manufactured from roflufocon D, roflufocon E, and hexafocon A has been previously addressed.

VIII. CONCLUSIONS

Substantial Equivalence

Information presented in this Premarket Notification establishes that **OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear Contact Lenses** 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.