



Food and Drug Administration  
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August 10, 2016

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

Re: K161100

Trade/Device Name: Optimum GP with HPT (rofluocon C, D, and E)  
Daily Wear Contact Lenses

Regulation Number: 21 CFR 886.5916

Regulation Name: Rigid Gas Permeable Contact Lens

Regulatory Class: Class II

Product Code: HQD

Dated: June 23, 2016

Received: June 27, 2016

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,

 Kesia Alexander

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)  
K161100

Device Name  
Optimum GP with HPT (rofluocon C, D, and E) Daily Wear Contact Lenses

*Indications for Use (Describe)*

The Optimum GP with HPT (rofluocon 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 (rofluocon 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 (rofluocon 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 (rofluocon 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.

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)

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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: **K161100**

### Applicant information:

Date Prepared:	June 23 <sup>rd</sup> , 2016
Name:	<b>Contamac Ltd.</b>
Address:	Carlton House Shire Hill Saffron Walden Essex CB11 3AU
Contact Person:	Robert McGregor Managing Director
Phone number:	44-1799 542 000
Consultant:	Bret Andre EyeReg Consulting, Inc. 6119 Canter Ln. West Linn, OR 97068
Phone number:	(503) 372-5226

### Device Information:

Device Classification:	Class II
Product Code:	HQD
Classification Name:	Daily Wear Rigid Gas Permeable Contact Lens (21 CFR 886.5916)
Trade Name:	<b>Optimum GP with HPT (rofluvocon C, D, and E) Daily Wear Contact Lenses</b>

**Purpose of 510(k) Submission:****~ New Technology ~**

The Optimum GP Daily Wear Contact Lenses—cleared under 510(k) K033594 and K070628—are modified to include Hydra-PEG Technology (HPT), which is a thin, polyethylene glycol (PEG)-based polymer designed to improve the wettability of the contact lenses. Specifically, HPT treated contact lenses demonstrate a measureable improvement in the contact angle in comparison with the untreated lenses. The application of HPT to the surface of Optimum GP with HPT Daily Wear Contact Lenses does not change the design or indications for use in comparison with the untreated lenses, the predicate device (K033594 and K070628).

**Predicate Devices:**

The **Optimum GP with HPT (rofluvocon C, D, and E) Daily Wear Contact Lenses** are substantially equivalent to the following predicate devices:

**“Optimum GP (rofluvocon A, B, C, D, and E) Daily Wear Contact Lenses”**

By Contamac Ltd.

510(k) number; **K033594 and K070628**

-primary predicate

**“IntelliWave4 with HPT (safrofilcon A)”**

by Art Optical Contact Lens, Inc.

510(k) number; **K152046**

-reference predicate

**Device Description:**

The **Optimum GP with HPT (rofluvocon C, D, and E) Daily Wear Contact Lens** is a rigid gas permeable methacrylate copolymer of Methyl methacrylate, 1,1,1,3,3,3 - Hexafluoroisopropyl Methacrylate, Methacryloxypropyl Tris(trimethylsiloxy) silane, 1,3-bis(methacryloxypropyl)-1,1,3,3-tetrakis(trimethyl siloxy)disiloxane, 2-Hydroxyethyl Methacrylate, and Methacrylic acrylic acid cross-linked with Ethylene Glycol Dimethacrylate.

The **Optimum GP with HPT (rofluvocon C, D, and E) Daily Wear Contact Lens** is treated to incorporate Hydra-PEG Technology (HPT)—which is a thin polyethylene glycol (PEG)-based polymer that is covalently (permanently) 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 HPT, the underlying material (rofluvocon C, D, and E) is encapsulated in a thin layer of polymer that results in measurable improvement of wettability (dynamic contact receding angle) compared to untreated lenses. The resulting layer is hydrophilic and approximately 30nm in thickness. The following table depicts the enhanced contact angle of the **Optimum GP with HPT Daily Wear Contact Lens** versus the predicate device:

	roflucocon C		roflucocon D		roflucocon E	
	Uncoated	HPT Coated	Uncoated	HPT Coated	Uncoated	HPT Coated
<b>Average Captive Bubble Dynamic Contact Angle (degrees) n=3</b>	95.30	40.28	93.28	40.40	93.64	36.90
<b>Standard Deviation</b>	0.55	6.44	2.13	5.05	3.47	8.04
<b>% Standard Deviation</b>	0.58	15.98	2.28	12.51	3.71	21.78

The **Optimum GP with HPT** (roflucocon C, D, and E) Daily Wear Contact Lens are packaged and shipped “wet” in a polypropylene contact lens case. The primary container for shipping the **Optimum GP with HPT** lenses is the PolyVial Contact Lens Case. The **Optimum GP with HPT** lenses are 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 with HPT** (roflucocon C, D, and E) Daily Wear Contact Lens incorporates a visibility tint to make the lens more visible for handling. The tinted lenses contain one or more of the following color additives: D&C Green No.6, C.I. Solvent yellow No. 18, and FD&C Red No. 17.

In the **Optimum GP with HPT** (roflucocon C, D, and E) Daily Wear Contact Lens with UV Blocker, a Benzophenone UV blocking monomer is used to block UV radiation. The UV Blocker is 2,2'-Dihydroxy-4,4'-dimethoxybenzophenone. The UV blocking for OPTIMUM GP averages > 98% in the UVB range of 280nm – 315nm and 95% in the UVA range of 316 – 380nm.

The physical properties of the **Optimum GP with HPT** Contact Lens are as follows:

	(roflucocon c)	(roflucocon d)	(roflucocon e)
<b>Refractive Index</b>	1.4406	1.4333	1.4332
<b>Light Transmission (clear)</b>	>97%	>97%	>97%
<b>Light Transmission (tinted)</b>	>90%	>90%	>90%
<b>Specific Gravity</b>	1.178	1.166	1.155
<b>Oxygen Permeability (Dk) ISO/FATT Method</b>	$65 \times 10^{-11}$ (cm <sup>2</sup> /sec) (ml O <sub>2</sub> /ml x mm Hg @ 35°C)	$100 \times 10^{-11}$ (cm <sup>2</sup> /sec) (ml O <sub>2</sub> /ml x mm Hg @ 35°C)	$125 \times 10^{-11}$ (cm <sup>2</sup> /sec) (ml O <sub>2</sub> /ml x mm Hg @ 35°C)
<b>Visitint lenses contain one or more of the following color additives conforming to: 21 CFR Part 73 &amp; 74, Subpart D</b>	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, FD & C Red No. 17, CI Solvent Yellow 18

The **Optimum GP with HPT** (rofluvocon C, D, and E) Daily Wear Contact Lens is available in the Spherical, Toric, Multifocal/Bifocal, Irregular Cornea (Scleral) design configurations, within the following lens parameters:

- Chord Diameter: 7.0mm to 22.0mm
- Center Thickness: Varies
- Base Curve: 5.0mm to 8.0mm
- Spherical Powers: -20.00 Diopters to +20.00 Diopters
- Toric Powers: up to -10.00 Diopters
- Add Powers: up to +4.00 Diopters

### **Intended Use:**

The **Optimum GP with HPT** (rofluvocon 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** (rofluvocon 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** (rofluvocon 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** (rofluvocon 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.

### **Testing:**

**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 the **Optimum GP with HPT** (rofluvocon C, D, and E) Daily Wear Contact Lens packaged in glass 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 **Optimum GP with HPT** Daily Wear Contact Lens 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 Unique pH at ambient temperatures,
- The physical properties of the lens are stable following 30 days of storage in Unique pH at ambient temperatures, and
- The surface properties of the lens are stable following 30 days of accelerated aging in buffered saline solution.

Clinical Testing      The clinical safety and effectiveness has been previously established for contact lenses manufactured from (rofluocon C, D, and E) and contact lenses treated with Hydra-PEG.

## Conclusions Drawn from Studies

### 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 **Optimum GP with HPT** (rofluocon C, D, and E) Daily Wear Contact Lens is 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.

## Substantial Equivalence:

Comparison to Predicate Device(s):

The **Optimum GP with HPT** (rofluocon C, D, and E) Daily Wear Contact Lens is substantially equivalent to the **Optimum GP** (rofluocon A, B, C, D, and E) Daily Wear Contact Lens (cleared under K033594 and K070628) in terms of the following:

- contact lens material (rofluocon C, D, and E)
- lathe cut manufacturing process
- indications for use

The **Optimum GP with HPT** (rofluocon C, D, and E) Daily Wear Contact Lens is substantially equivalent to the IntelliWave4 with HPT (cleared under K152046) in terms of the following:

- Hydra-PEG surface coating

The following matrix illustrates the production method, lens function and material characteristics of the **Optimum GP with HPT** (roflufocon C, D, and E) Daily Wear Contact Lens, as well as the predicate devices.

### Substantial Equivalence Matrix

	<b>Optimum GP with HPT (roflufocon C, D, E) New Device</b>	<b>Optimum GP (roflufocon A, B, C, D, E) (uncoated) Predicate Device</b>	<b>Art Optical IntelliWave4 with HPT, Silicone Hydrogel (safrofilcon A) Predicate Device</b>
<b>Intended Use</b>	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.	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.	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.
<b>Functionality</b>	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
<b>Indications</b>	Daily Wear	Daily Wear	Daily Wear
<b>Production Method</b>	Lathe-Cut, custom manufactured	Lathe-Cut, custom manufactured	Lathe-Cut, custom manufactured
<b>USAN name</b>	roflufocon C, D, E	roflufocon A, B, C, D, E	safrofilcon A
<b>Water Content (%)</b>	<1%	<1%	65±2%
<b>Wettability (captive bubble advancing contact angle)</b>	Roflufocon C: 40.28° Roflufocon D: 40.40° Roflufocon E: 36.90°	Roflufocon C: 95.30° Roflufocon D: 93.28° Roflufocon E: 93.64°	46°
<b>UV Absorber/Blocker Available</b>	YES	YES	YES
<b>Includes Hydra-PEG Surface Coating</b>	Yes	No	Yes