DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 13, 2016

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

Re: K160859
Trade/Device Name: OPTIMUM GP OK (Orthokeratology) Daily Wear Contact Lens (roflufocon D & E)
Regulation Number: 21 CFR 886.5916
Regulation Name: Daily Wear Rigid Gas Permeable (hydrophobic) Contact Lens (Orthokeratology)
Regulatory Class: Class II
Product Code: MUW
Dated: May 25, 2016
Received: June 1, 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,

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 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K160859

Device Name
OPTIMUM GP OK (Orthokeratology) Daily Wear Contact Lens (roflufocon D & E)

Indications for Use *(Describe)*
The OPTIMUM GP OK 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.

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: **K160859**

Applicant information:

Date Prepared:	March 23rd, 2016
Name:	**Contamac Ltd.**
Address	Carlton House Shire Hill Saffron Walden Essex CB11 3AU
Contact Person:	Robert McGregor Managing Director
Phone number:	44-1799 542 000
Consultant:	EyeReg Consulting, Inc. Bret Andre 6119 Canter Ln West Linn, OR 97068
Phone number	(503) 372-5226
Fax number	(503) 419-4475

Device Information:

Device Classification:	Class II
Product Code:	MUW
Classification Name:	Daily Wear Rigid Gas Permeable (hydrophobic) Contact Lens (Orthokeratology) (21 CFR 886.5916)
Trade Name:	**OPTIMUM GP OK (Orthokeratology)** **Daily Wear Contact Lens (roflufocon D & E)**

Purpose of Submission:

~ New Indication ~

Predicate Devices:

The **OPTIMUM GP OK** for daily wear is substantially equivalent to the following predicate device(s)

Predicate device:

Predicate device manufacturer	Device name	510(k) number
Contamac Ltd.	OPTIMUM GP (Oxygen Permeable) Daily Wear Contact Lenses (roflufocon A, B, C, D, & E)	K033594
Contex, Inc.	CONTEX OK (orthokeratology) contact lens	K973697
Polymer Technology	Boston $X0_2$ (hexafocon B) Daily Wear Contact Lens	K071266

Device Description:

The **OPTIMUM GP OK Daily Wear Contact Lens (roflufocon D & E)** may be prescribed in a daily wear orthokeratology fitting program for the temporary reduction of myopia of up to 5.00 diopters in non-diseased eyes.

The **OPTIMUM GP OK Daily Wear Contact Lens (roflufocon D & E)** 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 acid cross-linked with Ethylene Glycol Dimethacrylate.

The **OPTIMUM GP OK Daily Wear Contact Lens (roflufocon D & E)** may be packaged and shipped "dry" or "wet" in a polypropylene contact lens case. The primary container for shipping the OPTIMUM GP OK lenses is the PolyVial /PolyPack Contact Lens Case. When shipped "wet", the OPTIMUM GP OK lenses may be packaged and shipped in the Optimum Cleaning, Disinfecting and Storage (CDS) GP solution**.** The active ingredients in Optimum GP Cleaning Disinfecting and Storage solution are Lauryl salt of imidazoline, octylphenoxypolyethoxyethanol, and preserved with benzyl alcohol 0.3% and disodium edetate 0.5%.

The **OPTIMUM GP OK Daily Wear Contact Lens (roflufocon D & E)** 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 OK Daily Wear Contact Lens (roflufocon D & E)** 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 OK** 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%
Wetting Angle (Dynamic contact receding angle)	3°	6°
Specific Gravity	1.166	1.155
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)
Visitint lenses 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

The lens parameters of the **OPTIMUM GP OK** Contact Lens are as follows:

* Chord Diameter: 6.5 to 11.5 mm
* Center Thickness: 0.10 to 0.70 mm
* Base Curve (BC): 6.5 to 11.0 mm
* Secondary Curves: 0.10 to 2.0 mm (flatter or steeper than BC)
* Peripheral Curves: 0.10 to 2.0 mm (flatter or steeper than BC)
* Spherical Powers: -10.00 to +3.00 D

Indication for Use:

The **OPTIMUM GP OK** 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.

Description of Safety:

The safety profile for finished lenses manufactured from the (roflufocon D & E) rigid gas permeable (RGP) materials is demonstrated in K033594—which addresses the following areas:

- Biocompatibility
- Shelf Life (Wet Shipping)
- Solution Compatibility
- Clinical Performance

Substantial Equivalence:

Comparison to Predicate Device(s):

The **OPTIMUM GP OK Daily Wear Contact Lens (roflufocon D & E)** is substantially equivalent to the OPTIMUM GP (Oxygen Permeable) Daily Wear Contact Lenses (roflufocon A, B, C, D, & E)—cleared under K033594—in terms of the following:

- contact lens material (roflufocon D, & E)—including physicochemical and mechanical properties of finished lenses
- lathe cut manufacturing process
- manufacturing facility
- final packaging and wet shipping procedures

The **OPTIMUM GP OK Daily Wear Contact Lens (roflufocon D & E)** is substantially equivalent to the Boston X02 (hexafocon B) Daily Wear Contact Lens and CONTEX OK—cleared under K071266 and K973697, respectively—in terms of the following:

- indications for use (daily wear orthokeratology)
- orthokeratology lens design

The **OPTIMUM GP OK Daily Wear Contact Lens (roflufocon D & E)** are substantially equivalent to the predicate device as depicted in the following table, and *do not raise* different questions of safety and effectiveness than the predicate device identified previously.

The following table depicts the pre-clinical characteristics of the **OPTIMUM GP OK Daily Wear Contact Lens (roflufocon D & E)**, as well as the predicate device.

	OPTIMUM GP OK (Orthokeratology)	**OPTIMUM GP**	**CONTEX OK**	**BOSTON XO_2**
	Subject Device	***Predicate Device***	***Predicate Device***	***Predicate Device***
Indication for Use	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.	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.	Indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 3.00 diopters in non-diseased eyes. To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule.	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.
Device and Classification	Class II Daily Wear Rigid Gas Permeable (hydrophobic) Contact Lens (21 CFR 886.5916)	Class II Daily Wear Rigid Gas Permeable (hydrophobic) Contact Lens (21 CFR 886.5916)	Class II Daily Wear Rigid Gas Permeable (hydrophobic) Contact Lens (21 CFR 886.5916)	Class II Daily Wear Rigid Gas Permeable (hydrophobic) Contact Lens (21 CFR 886.5916)
Product Code	MUW	HQD	MUW	MUW
Production Method	Lathe-cut	Lathe-cut	Lathe-cut	Lathe-cut
USAN	roflufocon D, & E	roflufocon A, B, C, D, & E	siflufocon A	hexafocon B
FDA Group #	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate
Oxygen Permeability x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)	Roflufocon D: 100 Roflufocon E: 125	Roflufocon D: 100 Roflufocon E: 125	81	141
Water Content	<1%	<1%	<1%	<1%
UV Absorber/Blocker available	YES	YES	NO	YES