



October 24, 2017

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

Re: K171575
Trade/Device Name: ENFLU 18 (enfluocon 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: September 11, 2017
Received: September 14, 2017

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.

U.S. Food & Drug Administration
10903 New Hampshire Avenue

Silver Spring, MD 20993
www.fda.gov

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 (DICE) 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 (DICE) 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,

Denise L. Hampton -S

for Malvina 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)
K171575

Device Name
ENFLU 18 (enfluocon A) Daily Wear Contact Lens

Indications for Use (Describe)

The ENFLU 18 (enfluocon A) 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 ENFLU 18 (enfluocon A) 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 ENFLU 18 (enfluocon A) 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 ENFLU 18 (enfluocon A) 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.

Eye care 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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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: K171575

Applicant information:

Date Prepared:	May 22 nd , 2017
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:	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)
Common Name:	Rigid Gas Permeable Contact Lens
Trade Name:	ENFLU 18 (enfluocon A) Daily Wear Contact Lens

Purpose of 510(k) Submission: ~ New Device ~

Predicate Devices:

The **ENFLU 18 (enfluocon A) Daily Wear Contact Lenses** are substantially equivalent to the following predicate devices:

“Boston ES (enfluocon A) Daily Wear Contact Lens”

By Bausch & Lomb, Inc.
510(k) number; **K943177**
-primary predicate

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

by Contamac Ltd.
510(k) number; **K161100**
-reference predicate

Device Description:

The **ENFLU 18 (enfluocon A) Daily Wear Contact Lens** is manufactured from a machine latheable rigid gas permeable material composed of siloxanyl fluoroitaconate copolymer that is tinted for visibility and available with or without an ultraviolet (UV) light absorber.

In the **ENFLU 18 (enfluocon A) Daily Wear Contact Lens** with UV Blocker, a Benzophenone UV blocking monomer is used to block UV radiation. The UV blocking for ENFLU 18 averages > 98% in the UVB range of 280nm – 315nm and >83% in the UVA range of 316 – 380nm.

The **ENFLU 18 (enfluocon A) 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, D&C Violet No. 2 and D&C red No. 17.

The **ENFLU 18 (enfluocon A) Daily Wear Contact Lens** may be optionally treated to incorporate 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 (enfluocon A) is encapsulated in a thin layer of polymer that results in measurable improvement of wettability (sessile drop contact angle) compared to untreated lenses. The resulting layer is hydrophilic and approximately 30nm in thickness. The following table depicts the contact angle of the coated vs. uncoated **ENFLU 18 (enfluocon A) Daily Wear Contact Lens**:

	ENFLU 18 - Enflufocon A	
	Uncoated*	Tangible™ Hydra-PEG Coated*
Average Sessile Drop Contact Angle (degrees) n=30	86.5	48.0
Standard Deviation	2.85	4.20
% Standard Deviation	3.30	8.75

*lenses were manufactured and soaked in borate buffered saline for 24 hours prior to contact angle measurement

The **ENFLU 18 (enflufocon A) Daily Wear Contact Lens** may be packaged and shipped “dry” or “wet” in a polypropylene contact lens case. The primary container for shipping the **ENFLU 18 (enflufocon A) Daily Wear Contact Lenses** is the PolyVial Contact Lens Case. When shipped “wet”, the **ENFLU 18 (enflufocon A) Daily Wear Contact 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 physical properties of the **ENFLU 18 (enflufocon A) Daily Wear Contact Lens** are as follows:

	ENFLU 18 (enflufocon A)	ENFLU 18 (enflufocon A) with Tangible HydraPEG
Refractive Index (dry)	1.4436	1.4432
Light Transmission (@380-780nm)	>90%	>90%
UVA Transmission (@316-380nm)	<17%	<14%
UVB Transmission (@280-315nm)	<2%	<1%
Specific Gravity (g/cm ³)	1.221	1.221
Oxygen Permeability (Dk) ISO/FATT Method	21.03 x 10 ⁻¹¹ (cm ² /sec) (ml O ₂ /ml x mm Hg @ 35°C)	23.96 x 10 ⁻¹¹ (cm ² /sec) (ml O ₂ /ml x mm Hg @ 35°C)
Visitant lenses contain one or more of the following color additives conforming to: 21 CFR Part 73 & 74, Subpart D	D&C Green No. 6, C.I. Solvent Yellow No. 18, D&C Violet No. 2 and D&C red No. 17	D&C Green No. 6, C.I. Solvent Yellow No. 18, D&C Violet No. 2 and D&C red No. 17

The **ENFLU 18 (enflufocon A) 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 **ENFLU 18 (enflucocon A) 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 **ENFLU 18 (enflucocon A) 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 **ENFLU 18 (enflucocon A) 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 **ENFLU 18 (enflucocon A) 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.

Eye care 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 **ENFLU 18 (enflucocon A) Daily Wear Contact Lens**. 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 **ENFLU 18 (enflucocon A) Daily Wear Contact Lens** demonstrate that:

- The finished lenses are not toxic and not irritating,
- The physicochemical, mechanical, and optical properties of the lenses are substantially equivalent to the predicate device.
- Bioburden levels are below the acceptance criteria (<100 cfu/lens) initially (dry) and following 30 days of storage in Unique pH at ambient temperatures,
- Physical parameters are stable following 30 days of storage in Menicon Unique pH at ambient temperatures,
- The surface properties of the lens are stable following 24 days of accelerated aging in Menicon Unique pH.

Clinical Testing The clinical safety and effectiveness has been previously established for contact lenses manufactured from (enfluocon A) and contact lenses treated with Tangible™ 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 **ENFLU 18 (enfluocon A) 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 **ENFLU 18 (enfluocon A) Daily Wear Contact Lens** is substantially equivalent to the Boston ES (enfluocon A) Daily Wear Contact Lens (cleared under K943177) in terms of the following:

- contact lens material (enfluocon A)
- production method: lathe cut manufacturing process
- functionality
- indications for use (sphere, toric, multifocal, irregular cornea)

The **ENFLU 18 (enfluocon A) Daily Wear Contact Lens** is substantially equivalent to the Optimum GP with HPT (rofluocon C, D, and E) Daily Wear Contact Lens (cleared under K161100) in terms of the following:

- may optionally incorporate the Tangible™ Hydra-PEG surface coating

The following matrix illustrates the production method, lens function and material characteristics of the **ENFLU 18 (enfluocon A) Daily Wear Contact Lens** as well as the predicate devices.

Substantial Equivalence Matrix

	ENFLU 18 (enfluocon A) New Device	Boston ES (enfluocon A) Predicate Device	Optimum GP with HPT (roflufocon C, D, E) Predicate Device
Intended Use	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.
Functionality	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
Indications	Daily Wear	Daily Wear	Daily Wear
Production Method	Lathe-Cut, custom manufactured	Lathe-Cut, custom manufactured	Lathe-Cut, custom manufactured
USAN name	enfluocon A	enfluocon A	roflufocon C, D, E
Water Content (%)	<1%	<1%	<1%
Specific Gravity	1.221	1.220	Roflufocon C: 1.178 Roflufocon D: 1.166 Roflufocon E: 1.155
Oxygen Permeability (cm^2/sec) ($\text{ml O}_2/\text{ml} \times \text{mm Hg}$ @ 35°C)	Uncoated: 21×10^{-11} Coated: 24×10^{-11}	22×10^{-11}	Roflufocon C: 65×10^{-11} Roflufocon D: 100×10^{-11} Roflufocon E: 125×10^{-11}
Wettability (sessile drop contact angle)	Uncoated: 86.5° Coated: 48.0°	87.5°	Roflufocon C: 40.28° Roflufocon D: 40.40° Roflufocon E: 36.90° (measured by captive bubble advancing contact angle)
UV Absorber/Blocker Available	Yes, Optional	Yes	Yes, Optional
Includes Hydra-PEG Surface Coating	Yes, Optional	No	Yes