



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 27, 2016

Advanced Vision Technologies
% Mr. Bret Andre
Principal Consultant
EyeReg Consulting, Inc.
6119 Canter Lane
West Linn, OR 97068

Re: K152724

Trade/Device Name: EyePrintPRO (rofluocon D) Scleral GP Lenses
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Permeable Contact Lens
Regulatory Class: Class II
Product Code: HQD
Dated: March 15, 2016
Received: March 18, 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)
K152724

Device Name
EyePrintPRO (rofluocon D) Scleral GP Lenses

Indications for Use (Describe)

The EyePrintPRO (rofluocon D) Scleral GP Lenses are indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with myopia or hyperopia. The lenses 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)

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: K152724

Applicant information:

Date Prepared: April 25th, 2016

Name: **Advanced Vision Technologies**
969 South Kipling Parkway
Lakewood, CO 80226
United States

Contact Person: Keith Parker
Vice President

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Consultant: Bret J Andre
EyeReg Consulting, Inc.
6119 Canter Ln.
West Linn, OR 97068
United States

Phone number: (503) 372-5226

Device Information:

Device Classification: Class II

Product Code: HQD

Classification Name: Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)

Trade Name: **EyePrintPRO (rofluvocon D) Scleral GP Lenses**

Purpose for Submission:

~ Labeling Change ~

Equivalent Devices:

The **EyePrintPRO (rofluvocon D) Scleral GP Lenses** are substantially equivalent to the following predicate devices:

Predicate devices:

- **“OPTIMUM GP”** -Primary Predicate
By Contamac ltd.
510(k) number; K070628 & K033594

Device Description:

The **EyePrintPRO (rofluvocon D) Scleral GP Lens** is a rigid gas permeable (RGP) lens designed from measurements of the ocular surface obtained by the EyePrint Impression Process. The vinyl polysiloxane (VPS) impression material used for the EyePrint Impression process is Panasil Initial Contact Light, with 510(k) clearance under K083701. The lenses are manufactured from the hydrophobic contact lens material (rofluvocon D). When placed on the human cornea, the **EyePrintPRO** RGP lenses act as a refracting medium to focus light rays upon the retina.

The **EyePrintPRO (rofluvocon D) Scleral GP Lenses** are available as lathe cut lenses manufactured from (rofluvocon D) optical blanks, which incorporate a handling tint using the following FDA listed color additives: D & C Green No. 6, FD & C Red No. 17, CI Solvent Yellow 18.

In the **EyePrintPRO (rofluvocon D) Scleral GP Lenses** with UV Blocker, a Benzophenone UV absorbing monomer is used to block UV radiation. The UV Blocker is 2,2'-Dihydroxy-4,4'-dimethoxybenzophenone.

The UV blocking for **EyePrintPRO (rofluvocon D) Scleral GP Lenses** averages > 98% in the UVB range of 280nm – 315nm and 95% in the UVA range of 316 – 380nm.

The physical and mechanical properties of the lens are:

Refractive Index	1.4333
Light Transmission (clear)	greater than 97%
Light Transmission (tinted)	greater than 90%
Wetting Angle	3°
Specific Gravity	1.166
Oxygen Permeability	$100 \times 10^{-11} \text{ (cm}^2\text{/sec)(mlO}_2\text{)/(ml x mmHg @ 35°C)}$
Flexural Strength (Mpa)	49.0
Modulus (Mpa)	76.7
Shore D Hardness	77.5

Packaging:

The **EyePrintPRO (rofluvocon D) Scleral GP Lens** may be shipped “dry” or “wet” in a contact lens case. The primary container for shipping the **EyePrintPRO (rofluvocon D) Scleral GP Lens** is the #750/750U by Pelican Products, Inc./Paragon Vision Sciences, with clearance under 510(k) K030987. The lens is shipped (wet) non-sterile in the OPTIMUM by Lobob Cleaning and Disinfecting Storage solution, with clearance under 510(k) K014162. The solution contains lauryl sulfate salt of imidazoline, octylphenoxy polyethoxyethanol and preserved with benzyl alcohol. The **EyePrintPRO (rofluvocon D) Scleral GP Lenses** are manufactured to the following specifications:

Chord Diameter	13.0 mm to 20.00 mm
Center Thickness	0.25 mm to 0.90 mm
Base Curve	6.0 mm to 10.0 mm
Power Range	-25.00D to +25.00D in 0.12 steps

Indications for Use:

The **EyePrintPRO (rofluvocon D) Scleral GP Lenses** are indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with myopia or hyperopia. The lenses 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.

Description of Safety:

The safety profile for finished contact lenses manufactured from (rofluvocon D) may be referenced in 510(k) K033594. Additional studies were conducted to evaluate the safety and effectiveness of the **EyePrintPRO (rofluvocon D) Scleral GP Lenses**. A summary of the results are presented below:

Bioburden

Bioburden testing was performed on rigid gas permeable lenses manufactured at the Advanced Vision Technologies facility. Testing resulted in less than 1 colony forming units (CFU) per lens. The acceptance criteria is less than 100 CFU per lens.

Clinical Evaluation of EyePrint Impression Process

Non-invasive tear break up time (NITBUT), ocular surface redness, and corneal staining were evaluated (n = 8) before and after the EyePrint Impression Process. No significant changes from baseline were observed

Conclusions Drawn from Studies

Studies presented demonstrate that the EyePrint Impression Process is safe for the ocular surface, and the **EyePrintPRO (roflucocon D) Scleral GP Lenses** are substantially equivalent and do not raise different questions of safety and effectiveness than the previously marketed OPTIMUM GP contact lenses (roflucocon D), 510(k) cleared under K070628 & K033594.

Substantial Equivalence:

The **EyePrintPRO (roflucocon D) Scleral GP Lenses** are identical to the predicate device in terms of contact lens material (roflucocon D), lathe cut manufacturing processes, and indications for use.

The **EyePrintPRO (roflucocon D) Scleral GP Lenses** are substantially equivalent and do not raise different questions of safety and effectiveness than the predicate device identified previously.

The following comparison table depicts characteristics of the **EyePrintPRO (roflucocon D)** contact lens, as well as the predicate device.

Substantial Equivalence Matrix

	AVT EyePrintPRO Subject Device	Contamac Ltd. Optimum GP Predicate Device
Functionality	Same as predicate device	After machining from the optical blank, the contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.
Indication for Use	Same as predicate device	Daily Wear, Rigid Gas Permeable (RGP) Contact Lenses
Production Method	Lathe-cut; EyePrint Impression Process for lens design specifications	Lathe-cut; Corneal Topographer or Keratometer readings for lens design specifications
USAN name	Same as predicate device	roflucocon D
FDA Group #	Same as predicate device	Group # 3 Fluoro Silicone Acrylate
Oxygen Permeability	Same as predicate device	100×10^{-11} (cm ² /sec)(mlO ₂)/(ml x mmHg @ 35°C)) (revised Fatt method)
Water Content (%)	Same as predicate device	<1%