July 26, 2018

E&E Optics Inc.
% Bret Andre
Principal Consultant
EyeReg Consulting, Inc.
6119 Canter Ln
West Linn, OR 97068

Re: K181579
Trade/Device Name: eLens (hexafocon A, hexafocon B and oprifocon A) Rigid Gas Permeable Contact Lens for Daily Wear,
eLens (hexafocon A, hexafocon B and oprifocon A) Rigid Gas Permeable Contact Lens for Daily Wear Ortho-K
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Permeable Contact Lens
Regulatory Class: Class II
Product Code: HQD, MUW
Dated: June 13, 2018
Received: June 15, 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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)*
K181579

Device Name
eLens (hexafocon A, hexafocon B and oprifocon A) Rigid Gas Permeable Contact Lenses for Daily Wear;
eLens (hexafocon A, hexafocon B and oprifocon A) Rigid Gas Permeable Contact Lenses for Daily Wear Ortho-K

Indications for Use *(Describe)*
The eLens (hexafocon A, hexafocon B and oprifocon A) Rigid Gas Permeable Contact Lenses for Daily Wear are indicated for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not aphakic persons with non-diseased eyes. Also, the lenses may be prescribed in otherwise non-diseased eyes that require a gas permeable contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g., LASIK) surgery. The lenses may be disinfected using a chemical disinfection system only.

The eLens (hexafocon A, hexafocon B and oprifocon A) Rigid Gas Permeable Contact Lenses for Daily Wear Ortho-K is 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. The lenses may be disinfected using a chemical disinfection system only.

Note: To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule.

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: **K181579**

I. SUBMITTER

Date Prepared: July 11th, 2018

Name: **E&E Optics Inc.**
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United States

Contact Person: Bonnie Wan
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Consultant: Bret Andre
EyeReg Consulting, Inc.
6119 Canter Ln.
West Linn, OR 97068
Phone number: (503) 372-5226

II. DEVICE

Trade Name: **eLens (hexafocon A, hexafocon B and oprifocon A) Rigid Gas Permeable Contact Lenses for Daily Wear;**
eLens (hexafocon A, hexafocon B and oprifocon A) Rigid Gas Permeable Contact Lenses for Daily Wear Ortho-K

Common Name: Daily wear rigid gas permeable (hydrophobic) contact lens;
Daily wear rigid gas permeable (hydrophobic) contact lens (Orthokeratology)

Classification Name: Rigid gas permeable contact lens. (21 CFR 886.5916)

Regulatory Class: Class II

Product Code: HQD; MUW

III. PREDICATE DEVICE

The **eLens (hexafocon A, hexafocon B and oprifocon A) Rigid Gas Permeable Contact Lenses for Daily Wear** and **eLens (hexafocon A, hexafocon B and oprifocon A) Rigid Gas Permeable Contact Lenses for Daily Wear Ortho-K** are substantially equivalent to the following predicate devices:

- "Boston XO (hexafocon A) Contact Lens for Daily Wear Orthokeratology"
  By Bausch + Lomb Inc.
  510(k) number; **K001960**
- "Boston Equalens II (oprifocon A) Contact Lens for Daily Wear Orthokeratology"
  By Bausch + Lomb Inc.
  510(k) number; **K003933**
- "Boston XO2 (hexafocon B) Contact Lens for Daily Wear (Orthokeratology)"
  By Bausch + Lomb Inc.
  510(k) number; **K071266**
- "Boston XO (Hexafocon A) Rigid Gas Permeable Contact Lens"
  By Bausch + Lomb Inc.
  510(k) number; **K071043**
- "Acuity 85 (Oprifocon A) Rigid Gas Permeable Contact Lens"
  By Acuity Polymers Inc.
  510(k) number; **K170001**

IV. DEVICE DESCRIPTION

The **eLens (hexafocon A, hexafocon B and oprifocon A) Rigid Gas Permeable Contact Lenses for Daily Wear** and **eLens (hexafocon A, hexafocon B and oprifocon A) Rigid Gas Permeable Contact Lenses for Daily Wear Ortho-K** are lathe cut from one of the following hydrophobic, FDA Group #3 fluoro-silicone acrylate materials: hexafocon A, hexafocon B, or oprifocon A—with the following properties:

	HEXAFOCON A	**HEXAFOCON B**	**OPRIFOCON A**
Refractive Index	1.414	1.424	1.423
Water Content	<1%	<1%	<1%
Specific Gravity	1.266	1.19	1.24
Wetting Angle	49°	38°	30°
Oxygen Permeability (Dk) ISO/FATT Method (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)	100×10^{-11}	141×10^{-11} (edge corrected) 161×10^{-11} (non-edge corrected)	85×10^{-11}
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, and D&C Violet No. 2	D&C Green No. 6, C.I. Solvent Yellow No. 18, and D&C Violet No. 2	D & C Green No. 6, FD & C Red No. 17, CI Solvent Yellow 18

The **eLens (hexafocon A, hexafocon B and oprifocon A) Rigid Gas Permeable Contact Lenses for Daily Wear** are available in the following lens parameters:

Parameter	Range	Tolerance
Base Curve	4.00mm to 9.00mm	± 0.05 mm
Center Thickness	0.20mm to 0.50mm	± 0.02 mm
Diameter	7.00mm to 21.00mm	± 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 -9.00 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 3.75 D (in 0.25 D steps)	± 0.25D

The **eLens (hexafocon A, hexafocon B and oprifocon A) Rigid Gas Permeable Contact Lenses for Daily Wear Ortho-K** are available in the following lens parameters:

Parameter	Range	Tolerance
Base Curve	6.50mm to 11.00mm	± 0.05 mm
Center Thickness	0.10mm to 0.30mm (low minus lens) 0.20mm to 0.70mm (plus lens)	± 0.02 mm
Diameter	6.50mm to 11.50mm	± 0.10mm
Secondary Curves	0.10mm to 2.00mm (flatter or steeper than base curve)	± 0.10mm
Peripheral Curves	0.10mm to 2.00mm (flatter or steeper than base curve)	± 0.10mm
Spherical Power	-10.00 D to +30.00 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)
Aspheric Lens Eccentricity	-1.5 to 1.5 (oblate, prolate, or tangent conic)	-

V. INDICATIONS FOR USE

The **eLens (hexafocon A, hexafocon B and oprifocon A) Rigid Gas Permeable Contact Lenses for Daily Wear** are indicated for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not aphakic persons with non-diseased eyes. Also, the lenses may be prescribed in otherwise non-diseased eyes that require a gas permeable contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g., LASIK) surgery. The lenses may be disinfected using a chemical disinfection system only.

The **eLens (hexafocon A, hexafocon B and oprifocon A) Rigid Gas Permeable Contact Lenses for Daily Wear Ortho-K** is 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. The lens may be disinfected using a chemical disinfection system only.

Note: To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The following matrix illustrates the production method, intended use and materials of the **eLens (hexafocon A, hexafocon B and oprifocon A) Rigid Gas Permeable Contact Lenses for Daily Wear** and **eLens (hexafocon A, hexafocon B and oprifocon A) Rigid Gas Permeable Contact Lenses for Daily Wear Ortho-K**, as well as the predicate device.

Substantial Equivalence Matrix

	eLens RGP Contact Lenses	**Boston XO RGP Contact Lens**	**Boston XO2 RGP Contact Lens**	**Boston Equalens II RGP Contact Lens**
	Subject Device	**Predicate Device (K001960)**	**Predicate Device (K071266)**	**Predicate Device (K003933)**
Classification	Same as predicate	Class II Lenses, Rigid Gas Permeable, Daily Wear 21 CFR 886.5916	Class II Lenses, Rigid Gas Permeable, Daily Wear 21 CFR 886.5916	Class II Lenses, Rigid Gas Permeable, Daily Wear 21 CFR 886.5916
Product Code	Same as predicate	HQD; MUW	HQD; MUW	HQD; MUW
FDA Group #	Same as predicate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate
USAN	Same as predicate	hexafocon A	hexafocon B	oprifocon A
Production Method	Same as predicate	Lathe-Cut	Lathe-Cut	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. (orthokeratology)	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina. (orthokeratology)	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina. (orthokeratology)
Intended Use	Same as predicate	Daily Wear	Daily Wear	Daily Wear
Indication for Use	Same as predicate	Indicated for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not aphakic persons with non-diseased eyes. Also, the lenses may be prescribed in otherwise non-diseased eyes that require a gas permeable contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g., LASIK) surgery. Also, 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.	Indicated for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not aphakic persons with non-diseased eyes. Also, the lenses may be prescribed in otherwise non-diseased eyes that require a gas permeable contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g., LASIK) surgery. Also, 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.	Indicated for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not aphakic persons with non-diseased eyes. Also, the lenses may be prescribed in otherwise non-diseased eyes that require a gas permeable contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g., LASIK) surgery. Also, 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.

VII. PERFORMANCE DATA

~ Non-Clinical Studies ~

The non-clinical performance data to establish the safety and effectiveness of contact lenses manufactured from hexafocon A, hexafocon B, and oprifocon A has been addressed by reference to the predicate devices.

~ Clinical Studies ~

Clinical performance data to demonstrate the safety and effectiveness of contact lenses manufactured from hexafocon A, hexafocon B, and oprifocon A has been addressed in previous applications.

VIII. CONCLUSIONS

<u>Substantial Equivalence</u>

Information presented in this Premarket Notification establishes that **eLens (hexafocon A, hexafocon B and oprifocon A) Rigid Gas Permeable Contact Lenses for Daily Wear** and **eLens (hexafocon A, hexafocon B and oprifocon A) Rigid Gas Permeable Contact Lenses for Daily Wear Ortho-K** 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.