May 5, 2023

Paragon Vision Sciences, Inc.
Vimala Punsammy
Global Regulatory Affairs Manager
2120 W. Guadalupe Rd.
Gilbert, AZ 52233

Re: K221768
Trade/Device Name: Oxfore®100 (hexafocon A) Rigid Gas Permeable Contact Lenses
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Permeable Contact Lens
Regulatory Class: Class II
Product Code: HQD
Dated: March 30, 2023
Received: March 31, 2023

Dear Vimala Punsammy:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 titled, "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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

J. Angelo Green, Ph.D.
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221768

Device Name
Oxfore®100 (hexafocon A) Rigid Gas Permeable Contact Lenses

Indications for Use *(Describe)*
The Oxfore®100 (hexafocon A) Rigid Gas Permeable Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and non aphakic persons with non-diseased eyes. The lenses may be disinfected using a chemical disinfection system only.

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

1. SUBMITTER

Date Prepared: April 27, 2023

Name and Address: Paragon Vision Sciences, Inc.
2120 W. Guadalupe Rd.
Gilbert, AZ 85233-2810
(800) 825-8279

Contact Person: Vimala Punsammy
Regulatory Affairs Consultant
Telephone: (646)-639-5458
E-Mail: vpunsammy@coopervisionsec.com

2. DEVICE

Proprietary/Trade Name: Oxfore®100 (hexafocon A) Rigid Gas Permeable Contact Lenses

Regulation Number: 21 CFR 886.5916 (Rigid Gas Permeable Contact Lenses

Device Classification: Class II

Device Product Code: HQD

3. PREDICATE DEVICES

The Oxfore®100 (hexafocon A) RGP contact lenses for daily wear are substantially equivalent to the Boston XO™ (hexafocon A) Daily Wear Contact Lens (K171404) in terms of the following:

- Intended Use – daily wear contact lenses
- Actions
- Classifications – Lenses, Rigid Gas Permeable, Daily Wear Contact Lens; Class II (21 CFR 886.5916)
- FDA material group – group #3 fluoro silicon acrylate
- Production method – lathe cut
- USAN – hexafocon A

4. DEVICE DESCRIPTION

The Oxfore®100 (hexafocon A) Rigid Gas Permeable Contact Lenses are daily wear rigid gas permeable contact lenses lathe cut into the following designs:

- Spherical
- Aspherical
- Toric
- Mulifocal
- Scleral
- Semi-scleral

Oxfore100 (hexafocon A) may incorporate an ultraviolet light absorber and is available in a variety of tints. The material (hexafocon A) from which these lenses are made and the contact lenses described herein are substantially equivalent to the Boston XO (hexafocon A) Material and Contact Lenses described in K171404.

These devices will not be marketed with multiple components or any required accessories.

5. INDICATION FOR USE

The Oxfore®100 (hexafocon A) Rigid Gas Permeable Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and non aphakic persons with non-diseased eyes. The lenses may be disinfected using a chemical disinfection system only.

6. SUBSTANTIAL EQUIVALENCE

Substantial equivalence is based on:

For design: The predicate lenses, the Boston XO™ RGP lenses for daily wear, have several designs including spherical, aspherical, toric and scleral.. The new lenses, the Oxfore®100 RGP lenses for daily wear have the same substantially equivalent designs.

For material: The predicate lens materials are comprised of a siloxanyl fluoromethacrylate copolymer (hexafocon A). The new lens material also is comprised of a siloxanyl fluoromethacrylate copolymer (hexafocon A).

The new lenses in this submission therefore are substantially equivalent to the lenses cleared under K171404.

The table below shows a side-by side comparison of Oxfore®100 with the predicate device

	NEW LENS	***PREDICATE LENS***
Lens Characteristics	Oxfore®100 (hexafocon A) RGP Lens	Boston XO™ (hexafocn A) RGP Lens
Manufacturer	Paragon Vision Sciences, Inc.	Bausch + Lomb
Material	hexafocon A	hexafocon A
Production method	Lathe Cut	Lathe Cut
Actions/Operational Principles	When placed on the eye the Rigid Gas Permeable Contact Lens acts as a refracting medium to focus light rays on the retina to improve visual acuity	When placed on the eye the Rigid Gas Permeable Contact Lens acts as a refracting medium to focus light rays on the retina to improve visual acuity
Product Code	HQD	HQD
Common Name	Contact Lens, Rigid Gas Permeable	Contact Lens, Rigid Gas Permeable
Device Class	II	II
CFR Reference	21 CFR 886.5916	21 CFR 886.5916
FDA Group #	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate
Indications for Use	The Oxfore®100 (hexafocon A) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and non aphakic persons with non-diseased eyes. The lenses may be disinfected using a chemical disinfection system only.	The Boston XO™ (hexafocon A) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and non 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. Furthermore, eyes suffering from certain ocular surface disorders may benefit from the physical protection, aqueous hydrated environment and the saline bath provided by scleral lens designs. The Boston XO™ (hexafocon A) Contact Lenses (Scleral) for daily wear are indicated for therapeutic use for the management of irregular and distorted corneal surfaces where the subject: 1.cannot be adequately corrected with spectacle lenses 2.requires a rigid gas permeable contact lens surface to improve vision

		3.is unable to wear a corneal rigid gas permeable lens due to corneal distortion or surface irregularities Common causes of corneal distortion include but are not limited to corneal infections, trauma, tractions as a result of scar formation secondary to refractive surgery (e.g. LASIK or radial keratotomy) or corneal transplantation. Causes may also include corneal degeneration (e.g. keratoconus, keratoglobus, pellucid marginal degeneration, Salzmann's nodular degeneration) and corneal dystrophy (e.g., lattice dystrophy, granular corneal dystrophy, Reis-Bucklers dystrophy, Cogan's dystrophy). The Boston XO™ (hexafocon A) Scleral Lens designs for daily wear are also indicated for therapeutic use in eyes with ocular surface disease (e.g. ocular Graft-versus-Host disease, Sjögren's syndrome, dry eye syndrome and Filamentary Keratitis), limbal stem cell deficiency (e.g. Stevens-Johnson syndrome, chemical radiation and thermal burns), disorders of the skin (e.g. atopy, ectodermal dysplasia), neurotrophic keratitis (e.g. Herpes simplex, Herpes zoster, Familial Dysautonomia), and corneal exposure (e.g. anatomic, paralytic) that might benefit from the presence of an expanded tear reservoir and protection against an adverse environment. When prescribed for therapeutic use for a distorted cornea or ocular surface disease, the Boston Scleral Lenses may concurrently provide correction of refractive error. The lenses may be disinfected using a chemical disinfection (not heat) system only.
Refractive Index (RGP)	1.415	1.415
Oxygen Permeability (RGP Center)	100	100
Specific Gravity (RGP)	1.27	1.27
Hardness (Shore D)	81	81
Modulus (MPa)	1500	1500
Tint	Visibility Tints – various D&C Green No. 6, D&C Violet No. 2, D&C Yellow No. 18, D&C Red No. 17	Visibility Tints – various D&C Green No. 6, D&C Violet No. 2, D&C Yellow No. 18
Water Content (Soft Skirt)	<1%	<1%
Lens Type	RGP	RGP

In the evaluation of RGP materials, various properties are measured to ascertain the material's ability to meet the intended application requirements. The properties which characterize the materials classification and use are refractive index, oxygen permeability, specific gravity, hardness, modulus and water content. Those properties are described in the above comparison table. These properties or characteristics are important to the function of the final lens and form the basis for the determination of use. These material values meet the minimum values required for use in the manufacture (lathing) of RGP lenses.

Based on the data generated from the chemical/physical testing (See Side by Side Comparison) of Oxfore®100 (hexafocon A) Rigid Gas Permeable Contact Lens, it is concluded that the material and contact lens made thereof meet the requirements of a daily wear rigid contact lens and is substantially equivalent to Boston XO™ (hexafocon A) Daily Wear Contact Lens.

7. PERFORMANCE DATA

Clinical

Clinical studies for the Oxfore®100 (hexafocon A) material have been deemed as not necessary in support of clearance of this premarket notification as no new or additional questions of safety or effectiveness have been raised as a result of the preclinical testing and evaluation of the material.

Non-Clinical

The hexafocon A lens material manufactured by Paragon Vision Sciences, Inc. has been tested and found to meet the biocompatibility requirements listed in the FDA Daily Wear Contact Lens Guidance Document, May 1994 and ISO 10993-1 (2009) for a surface device, limited contact. The chemical, mechanical and optical characteristics of the new lens have been shown to be equivalent to the predicate lenses.

8. CONCLUSION

The Oxfore®100 (hexafocon A) Rigid Gas Permeable Contact Lenses are as safe and effective as the predicate device when used in accordance with the labeling for the proposed indications.

The risks related to Oxfore®100 (hexafocon A) are the same as those normally associated to wearing rigid gas permeable daily wear contact lenses. The benefits to the patients are the same as those for associated with similar RGP contact lenses.