



Food and Drug Administration  
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July 17, 2017

BAUSCH + LOMB Incorporated  
% Ellen M. Beucler  
Vice President  
Foresight Regulatory Strategies, Inc.  
187 Ballardvale Street, Suite A250  
Wilmington, MA 01887

Re: K171404

Trade/Device Name: BOSTON XO<sup>®</sup> (hexafocon A), BOSTON XO<sub>2</sub><sup>®</sup> (hexafocon B)

Regulation Number: 21 CFR 886.5916

Regulation Name: Rigid Gas Permeable Contact Lens

Regulatory Class: Class II

Product Code: HQD

Dated: May 10, 2017

Received: May 12, 2017

Dear Ellen M. Beucler:

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

## Indications for Use

510(k) Number (if known)  
K171404

Device Name

BOSTON XO® (hexafocon A) Rigid Gas Permeable Contact Lens

Indications for Use (Describe)

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 rigid 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).

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.

Boston XO Scleral Lens designs 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 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.

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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## Indications for Use

510(k) Number (if known)  
K171404

Device Name

BOSTON XO2® (hexafocon B) Rigid Gas Permeable Contact Lens

Indications for Use (Describe)

BOSTON XO2® (hexafocon B) 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 rigid 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).

BOSTON XO2 Contact Lenses are 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. Note: To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule.

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.

Boston XO2 Scleral Contact Lens designs 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 XO2 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.

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. Applicant Information

Bausch + Lomb Inc.  
1400 North Goodman Street  
Rochester, NY 14609 USA

Contact: Glenn Davies, O.D.  
Senior Director Regulatory Affairs  
Phone: (585) 338-8215  
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Date Prepared: July 11, 2017

### 2. Device Information

Classification name: Rigid Gas Permeable Contact Lens  
Device classification: Class II  
Regulation number: 21 CFR 886.5916 (Rigid Gas Permeable Contact Lenses)  
Product code: HQD  
Proprietary name: Boston XO® (hexafocon A) and Boston XO<sub>2</sub>®  
(hexafocon B) Rigid Gas Permeable Contact Lens

### 3. Predicate Devices

Bausch + Lomb Inc. claims substantial equivalence to Boston Scleral Contact Lens, PMA No. P860022/S40 approved March 1, 1994 and BostonSight PD Prosthetic Device cleared in K161461 on July 25, 2016.

### 4. Description of Device

The Boston XO and Boston XO<sub>2</sub> Rigid Gas Permeable (RGP) Contact Lenses are fluoro silicone acrylate copolymer rigid gas permeable contact lenses available in a variety of tints and may contain an ultraviolet light absorber. The hemispherical shells are available in several lens designs including spherical, aspherical, bifocal, toric, scleral and irregular cornea designs.

## 5. Indications for Use

Boston XO (hexafocon A) and Boston XO<sub>2</sub> (hexafocon B) 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 rigid 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 Boston XO<sub>2</sub> (hexafocon B) Contact Lenses are 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. Note: To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule.

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 and XO<sub>2</sub> Scleral Lens designs 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).

## 5. Indications for Use (continued)

The Boston XO and XO<sub>2</sub> 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.

## 6. Performance Data

There are no changes to the Boston XO (hexafocon A) and Boston XO<sub>2</sub> (hexafocon B) Rigid Gas Permeable contact lens material or lens designs as part of this application. These materials have been previously cleared for scleral lens designs. This application is for labeling revisions. No performance data is required.

## 7. Substantial Equivalence

In support of the expanded indications for Boston XO and XO<sub>2</sub> to include scleral lens indications the following statements apply.

- Boston XO and XO<sub>2</sub> Rigid Gas Permeable Scleral Contact Lenses are fluoro silicone acrylate contact lenses that use similar actions and technological characteristics as the predicate devices (see Table 1 and Table 2).
- The Boston XO and XO<sub>2</sub> Rigid Gas Permeable Scleral Lenses present the same risks and benefits as the predicate devices and are as safe and effective as the predicate devices when used according to the labeled directions for use and requested indications.

Therefore, the Boston XO and XO<sub>2</sub> Rigid Gas Permeable Scleral Lenses are substantially equivalent to the BostonSight PD Prosthetic Device and the Boston Scleral Contact Lens.

**Table 1 Substantial Equivalence - Device Comparison**

Indication for Use	Boston XO & XO <sub>2</sub> Scleral Lens (hexafocon A and hexafocon B)	BostonSight PD Prosthetic Device (oprifocon A)	Boston Scleral Lens (oprifocon A)
	<p><b>K171404</b></p> <p><b>Subject Device</b></p> <p>BOSTON XO (hexafocon A) and XO2® (hexafocon B) Contact Lenses are indicated for daily wear for the correction of refractive anisometropia (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 rigid 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). BOSTON XO2 Contact Lenses are 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. Note: To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule. 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.</p> <p>Boston Xo and XO2 Scleral Contact Lens designs for daily wear are indicated for therapeutic use for the management of irregular and distorted corneal surfaces where the subject:</p> <ol style="list-style-type: none"> <li>cannot be adequately corrected with spectacle lenses</li> <li>requires a rigid gas permeable contact lens surface to improve vision</li> <li>is unable to wear a corneal rigid gas permeable lens due to corneal distortion or surface irregularities</li> </ol> <p>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-Bücklers dystrophy, Cogan's dystrophy). The Boston XO and XO2 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 irritation 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 a distorted cornea or ocular surface disease, the Boston Scleral Lenses may concurrently provide correction of refractive error.</p>	<p><b>K161461</b></p> <p><b>Predicate Device</b></p> <p>Indicated for therapeutic use in eyes with ocular surface disease from dry eye (e.g. ocular Graft-versus-Host disease, Sjögren's syndrome, dry eye syndrome), limbal stem cell deficiency (e.g. Stevens-Johnson syndrome, chemical and thermal burns, radiation), 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 distorted cornea or ocular surface disease, the BostonSight PD Prosthetic Device may incidentally provide correction of refractive error.</p>	<p><b>P860022/S040</b></p> <p><b>Predicate Device</b></p> <p>Indicated for eyes having significantly reduced vision due to the presence of a distorted corneal surface that:</p> <ol style="list-style-type: none"> <li>precludes satisfactory spectacle lens correction</li> <li>demonstrates significantly improved rigid contact lens corrected vision</li> <li>is incapable of wearing traditional corneal lenses because of the inability to achieve adequate lens centration/stability and/or tolerance to physical contact with a lens.</li> </ol> <p>Furthermore, eyes suffering from certain ocular surface disorders may benefit from the physical protection and the saline bath provided by a scleral lens.</p>
<b>Actions/Operational Principles</b>	<p>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.</p>	<p>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.</p>	<p>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.</p>
<b>Product Code</b>	HQD	HQD	HQD
<b>Common name</b>	Contact Lens, Rigid Gas Permeable	Contact Lens, Rigid Gas Permeable	Contact Lens, Rigid Gas Permeable
<b>Device Class</b>	II	II	II*
<b>CFR Reference</b>	21 CFR 886.5916	21 CFR 886.5916	21 CFR 886.5916
<b>Production Method</b>	Lathe Cut	Lathe cut	Lathe cut
<b>FDA Group #</b>	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate

**Table 2 Substantial Equivalence - Physical Comparison**

	Boston XO & XO <sub>2</sub> Contact Lens		BostonSight PD Prosthetic Device (oprifocon A)	Boston Scleral Lens (oprifocon A)
	K171404		K161461	P860022/S040
	Subject Devices		Predicate Device	Predicate Device
	Boston XO (hexafocon A)	Boston XO <sub>2</sub> (hexafocon B)		
<b>Refractive Index</b>	1.415	1.424	1.423	1.423
<b>Specific Gravity</b>	1.27	1.19	1.24	1.24
<b>Wetting Angle</b>	49°	38°	56°	56°
<b>Hardness</b>	81	78	81	81
<b>Modulus</b>	1500 Mpa	1160 Mpa	1300 Mpa	1300 Mpa
<b>Visible Light Transmittance</b>	> 92%	> 95%	> 95%	> 95%
<b>Tint*</b>	Clear, Blue, Ice Blue, Violet, Green	Clear, Blue, Ice Blue, Violet, Green	Clear	Clear
<b>Water Content</b>	<1%	<1%	<1%	<1%
<b>Oxygen Permeability**</b>	100	141	85	85

{x 10<sup>-11</sup> (cm<sup>3</sup> O<sub>2</sub> • cm) / (cm<sup>2</sup> • sec • mmHg) @ 35° C}

\*\*polarographic method (ISO/Fatt)

\*Blue/Ice Blue Contains D&C Green No. 6

\*Violet Contains D&C Violet No. 2

\*Green Contains D&C Green No. 6

and C.I. Solvent Yellow No. 18