



February 12, 2019

Bausch & Lomb, Incorporated  
% Mr. Bret Andre  
Principal Consultant  
EyeReg Consulting Inc.  
6119 Canter Lane  
West Linn, OR 97068

Re: K183167

Trade/Device Name: Boston ES<sup>®</sup> (enfluocon A); Boston EO<sup>®</sup> (enfluocon B); Boston XO<sup>®</sup> (hexafocon A); and Boston XO2<sup>®</sup> (hexafocon B) 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: January 11, 2019

Received: January 15, 2019

Dear Mr. 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

  
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

## Indications for Use

510(k) Number (if known)

K183167

### Device Name

Boston ES® (enfluocon A), Boston EO® (enfluocon B), Boston XO® (hexafocon A) and Boston XO2® (hexafocon B) Rigid Gas Permeable Contact Lenses

### Indications for Use (Describe)

The Boston ES® (enfluocon A) and Boston EO® (enfluocon 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 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 Boston XO® (hexafocon A) and 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 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) and Boston XO2® (hexafocon B) 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) and Boston XO2® (hexafocon B) 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.



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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)

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**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:

K183167

### I. SUBMITTER

Date Prepared: November 1<sup>st</sup>, 2018

Name: **Bausch & Lomb Incorporated**  
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Rochester, NY 14609  
United States

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Consultant: Bret Andre  
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West Linn, OR 97068  
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### II. DEVICE

Trade Name: Boston ES<sup>®</sup> (enfluocon A), Boston EO<sup>®</sup> (enfluocon B), Boston XO<sup>®</sup> (hexafocon A) and Boston XO2<sup>®</sup> (hexafocon B) Rigid Gas Permeable Contact Lenses

Common Name: Daily wear rigid gas permeable contact lens

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

Regulatory Class: Class II

Product Code: HQD

### **Purpose of 510(k) Submission:**

Boston ES<sup>®</sup> (enfluocon A), Boston EO<sup>®</sup> (enfluocon B), Boston XO<sup>®</sup> (hexafocon A) and Boston XO2<sup>®</sup> (hexafocon B) Rigid Gas Permeable Contact Lenses—cleared under 510(k) K053124, K013762, K071266, K071043 and K171404—are modified to include the Tangible<sup>™</sup> Hydra-PEG surface coating—which is a thin, polyethylene glycol (PEG)-based polymer designed to improve the wettability of the contact lenses. Specifically, Tangible Hydra-PEG treated contact lenses demonstrate a measurable improvement in the contact angle compared to untreated lenses.

### **III. PREDICATE DEVICE**

The Boston ES<sup>®</sup> (enfluocon A), Boston EO<sup>®</sup> (enfluocon B), Boston XO<sup>®</sup> (hexafocon A) and Boston XO2<sup>®</sup> (hexafocon B) Rigid Gas Permeable Contact Lenses with Tangible<sup>™</sup> Hydra-PEG are substantially equivalent to the following predicate devices:

- “Boston ES<sup>®</sup> (enfluocon A), Boston EO<sup>®</sup> (enfluocon B), Boston XO<sup>®</sup> (hexafocon A) and Boston XO2<sup>®</sup> (hexafocon B) Rigid Gas Permeable Contact Lenses”  
By Bausch & Lomb Incorporated  
510(k) numbers; **K053124, K013762, K071266, K071043 and K171404**
- “Optimum GP with HPT (rofluocon C, D, and E) Daily Wear Contact Lenses”  
By Contamac Ltd.  
510(k) number; **K161100**  
-reference predicate

### **IV. DEVICE DESCRIPTION**

Boston ES<sup>®</sup> (enfluocon A), Boston EO<sup>®</sup> (enfluocon B), Boston XO<sup>®</sup> (hexafocon A) and Boston XO2<sup>®</sup> (hexafocon B) Rigid Gas Permeable Contact Lenses are available as lathe cut rigid gas permeable contact lenses for daily wear only. The lenses are manufactured from the following currently marketed contact lens materials: enfluocon A, enfluocon B, hexafocon A, and hexafocon B. Non-proprietary names were assigned by the United States Adopted Names Council (USAN). These materials are thermoset copolymers derived from fluorosilicone acrylate monomers. The lenses may be tinted to offer a handling aid for locating the lens. The lenses may be available with an ultraviolet absorber.

The Boston ES<sup>®</sup> (enfluocon A), Boston EO<sup>®</sup> (enfluocon B), Boston XO<sup>®</sup> (hexafocon A) and Boston XO2<sup>®</sup> (hexafocon B) Rigid Gas Permeable Contact Lenses are treated to incorporate Tangible<sup>™</sup> 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<sup>™</sup> Hydra-PEG, the underlying material is encapsulated in a thin layer of polymer that results in measurable improvement of wettability (sessile drop contact angle) compared to untreated lenses.

The surface properties of: enfluocon A, enfluocon B, hexafocon A, and hexafocon B materials uncoated and coated with Tangible Hydra-PEG are depicted in the following table:

	enfluocon A	enfluocon B	hexafocon A	hexafocon B
<b>Sessile Drop Contact Angle <math>\pm</math> Standard Deviation</b>	Coated: $10.2^{\circ} \pm 1.2^{\circ}$ Uncoated: $59.6^{\circ} \pm 5.9^{\circ}$	Coated: $10.0^{\circ} \pm 0.0^{\circ}$ Uncoated: $62.7^{\circ} \pm 6.0^{\circ}$	Coated: $10.0^{\circ} \pm 0.0^{\circ}$ Uncoated: $63.4^{\circ} \pm 4.0^{\circ}$	Coated: $10.0^{\circ} \pm 0.0^{\circ}$ Uncoated: $65.4^{\circ} \pm 3.3^{\circ}$

The Boston ES<sup>®</sup> (enfluocon A), Boston EO<sup>®</sup> (enfluocon B), Boston XO<sup>®</sup> (hexafocon A) and Boston XO2<sup>®</sup> (hexafocon B) Rigid Gas Permeable Contact Lenses are available in the same design configurations and available parameters as the predicate devices, cleared under K053124, K013762, K071266, K071043 and K171404.

## V. INDICATIONS FOR USE

The Boston ES<sup>®</sup> (enfluocon A) and Boston EO<sup>®</sup> (enfluocon 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 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 Boston XO<sup>®</sup> (hexafocon A) and Boston XO2<sup>®</sup> (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 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<sup>®</sup> (hexafocon A) and Boston XO2<sup>®</sup> (hexafocon B) 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<sup>®</sup> (hexafocon A) and Boston XO2<sup>®</sup> (hexafocon B) 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.

## **VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE**

The Boston ES<sup>®</sup> (enfluocon A), Boston EO<sup>®</sup> (enfluocon B), Boston XO<sup>®</sup> (hexafocon A) and Boston XO2<sup>®</sup> (hexafocon B) Contact Lenses with Tangible<sup>™</sup> Hydra-PEG surface technology are substantially equivalent to the uncoated lenses (predicate devices cleared under K053124, K013762, K071266, K071043 and K171404) in terms of the following:

- Proprietary contact lens material formulation and USAN
- Intended use – daily wear contact lenses
- Actions
- Indications for use / Contraindications
- Lens designs and available parameters

The Boston ES<sup>®</sup> (enfluocon A), Boston EO<sup>®</sup> (enfluocon B), Boston XO<sup>®</sup> (hexafocon A) and Boston XO2<sup>®</sup> (hexafocon B) Contact Lenses with Tangible<sup>™</sup> Hydra-PEG surface technology are substantially equivalent to the Optimum GP with HPT (rofluocon C, D, and E) Daily Wear Contact Lenses (cleared under K161100) in terms of the following:

- Thermoset copolymers derived from fluorosilicone acrylate monomers
- Tangible<sup>™</sup> Hydra-PEG surface coating

The following matrix illustrates the production method, lens function and material characteristics of the Boston ES<sup>®</sup> (enfluocon A), Boston EO<sup>®</sup> (enfluocon B), Boston XO<sup>®</sup> (hexafocon A) and Boston XO2<sup>®</sup> (hexafocon B) Contact Lenses with Tangible<sup>™</sup> Hydra-PEG surface technology, as well as the predicate devices.



	Boston ES® (enfluocon A), Boston EO® (enfluocon B), Boston XO® (hexafocon A) and Boston XO2® (hexafocon B) with Tangible™ Hydra-PEG	Boston ES® (enfluocon A), Boston EO® (enfluocon B), Boston XO® (hexafocon A) and Boston XO2® (hexafocon B)	Optimum GP with Tangible™ Hydra- PEG (roflufocon C, D, E)
	New Device	Predicate Device (K053124, K013762, K071266, K071043 and K171404)	Predicate Device (K161100)
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
Intended Use	Daily Wear	Daily Wear	Daily Wear
Indication for Use	<p>The Boston ES® (enfluocon A) and Boston EO® (enfluocon 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 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.</p> <p>The Boston XO® (hexafocon A) and 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 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.</p> <p>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>The Boston XO® (hexafocon A) and Boston XO2® (hexafocon B) Contact Lenses (Scleral) 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>1. cannot be adequately corrected with spectacle lenses</li> <li>2. requires a rigid gas permeable contact lens surface to improve vision</li> <li>3. 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-Bucklers</p>	<p>The Boston ES® (enfluocon A) and Boston EO® (enfluocon 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 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.</p> <p>The Boston XO® (hexafocon A) and 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 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.</p> <p>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>The Boston XO® (hexafocon A) and Boston XO2® (hexafocon B) Contact Lenses (Scleral) 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>1. cannot be adequately corrected with spectacle lenses</li> <li>2. requires a rigid gas permeable contact lens surface to improve vision</li> <li>3. 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</p>	<p>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.</p>

	<p>dystrophy, Cogan's dystrophy).</p> <p>The Boston XO® (hexafocon A) and Boston XO2® (hexafocon B) 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.</p> <p>The lenses may be disinfected using a chemical disinfection (not heat) system only.</p>	<p>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).</p> <p>The Boston XO® (hexafocon A) and Boston XO2® (hexafocon B) 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.</p> <p>The lenses may be disinfected using a chemical disinfection (not heat) system only.</p>	
<b>Production Method</b>	Lathe-Cut	Lathe-Cut,	Lathe-Cut
<b>USAN name</b>	enflufocon A enflufocon B hexafocon A hexafocon B	enflufocon A enflufocon B hexafocon A hexafocon B	roflufocon C, D, E
<b>Water Content (%)</b>	<1%	<1%	<1%
<b>Wettability (sessile drop advancing contact angle)</b>	enflufocon A: 10.2° enflufocon B: 10.0° hexafocon A: 10.0° hexafocon B: 10.0°	enflufocon A: 59.6° enflufocon B: 62.7° hexafocon A: 63.4° hexafocon B: 65.4°	-
<b>Includes Hydra-PEG</b>	Yes	No	Yes

## VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

### 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 Boston ES® (enflufocon A), Boston EO® (enflufocon B), Boston XO® (hexafocon A) and Boston XO2® (hexafocon B) Rigid Gas Permeable Contact Lenses with Tangible™ Hydra-PEG surface technology. 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 device demonstrate that:

- The finished lenses are not toxic and not irritating,
- Bioburden levels are below the acceptance criteria (<100 cfu/lens) initially and following 30 days of storage in solution (Boston Simplus and Boston Advance) at ambient temperatures,

- The surface properties of the lens are stable following 30 days of accelerated aging, and
- The physicochemical and mechanical properties of the contact lenses are unchanged after the addition of Tangible™ Hydra-PEG, with the exception of wettability (contact angle).

### Clinical Testing

The clinical safety and effectiveness of finished rigid gas permeable contact lenses manufactured from Boston ES® (enfluocon A), Boston EO® (enfluocon B), Boston XO® (hexafocon A) and Boston XO2® (hexafocon B) materials have been demonstrated by predicate devices. Additionally, the clinical safety and effectiveness for contact lenses treated with Hydra-PEG has been previously demonstrated.

## **VIII. CONCLUSIONS**

### 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 510(k) Premarket Notification establishes that the Boston ES® (enfluocon A), Boston EO® (enfluocon B), Boston XO® (hexafocon A) and Boston XO2® (hexafocon B) rigid gas permeable contact lenses with Tangible™ Hydra-PEG are as safe and effective as the predicate devices 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.