



Food and Drug Administration  
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February 9, 2016

Boston Foundation for Sight  
c/o Mr. Bret Andre  
Principal Consultant  
EyeReg Consulting, Inc.  
6119 Canter Ln  
West Linn, OR 97068

Re: K153066

Trade/Device Name: BostonSight IC Corneal Lens;  
BostonSight IC Scleral Lens

Regulation Number: 21 CFR 886.5916

Regulation Name: Rigid gas permeable contact lens

Regulatory Class: Class II

Product Code: HQD

Dated: December 29, 2015

Received: December 31, 2015

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" (21CFR 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)

K153066

Device Name

BostonSight IC Corneal Lens

BostonSight IC Scleral Lens

Indications for Use (Describe)

The BostonSight IC Corneal & Scleral Lenses for Daily Wear are indicated for the correction of refractive error in aphakic and not aphakic persons. 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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**Purpose of Submission:**

~ *New Device* ~

**Equivalent Devices:**

The **BostonSight IC Corneal & Scleral Lenses** for daily wear are substantially equivalent to the following predicate device(s)

*Predicate device:*

<b>Predicate device manufacturer</b>	<b>Device name</b>	<b>510(k) number</b>
Contamac Ltd.	OPTIMUM EXTRA (Oxygen Permeable) Daily Wear Contact Lenses (roflufocon D) OPTIMUM EXTREME (Oxygen Permeable) Daily Wear Contact Lenses (roflufocon E)	K033594
Bausch & Lomb, Inc.	Boston EQUALENS II (oprifocon A) Rigid Gas Permeable Contact Lenses	K022128
Bausch & Lomb, Inc.	Boston XO <sub>2</sub> (hexafocon B) Daily Wear Contact Lens	K071266

**Device Description:**

The **BostonSight Irregular Cornea (IC) Corneal & Scleral Lenses** are lathe cut and fabricated from one of the following hydrophobic rigid gas permeable (RGP) lens materials:

- roflufocon D supplied by Contamac Ltd.
- roflufocon E supplied by Contamac Ltd.
- oprifocon A supplied by Bausch and Lomb, Inc.
- hexafocon B supplied by Bausch and Lomb, Inc.

The description of the roflufocon D, roflufocon E, oprifocon A, and hexafocon B RGP materials are addressed in K033594, K022128, and K071266 respectively.

The **BostonSight IC Corneal & Scleral Lenses** for daily wear 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 following refractive (e.g. LASIK) surgery.

The **BostonSight IC Scleral Lens** is a large diameter RGP lens design that vaults over the cornea and rests on the conjunctiva overlying the sclera.

The **BostonSight IC Corneal & Scleral Lenses** may be shipped “dry” or “wet” in a polypropylene contact lens case. The primary container for shipping the **BostonSight IC Corneal & Scleral Lenses** is the Bausch & Lomb Frequent Replacement Contact Lens Case, with clearance under 510(k) K896685.

When shipped “wet”, The **BostonSight IC Corneal & Scleral Lenses** manufactured from material supplied by Bausch & Lomb, inc. may be packaged and shipped in Boston Advance Comfort Formula Conditioning Solution (K974466) or Boston SIMPLUS Multi-Action solution (K024289). The **BostonSight IC Corneal & Scleral Lenses** manufactured from material supplied by Contamac, Ltd. may be packaged and shipped “wet” in in the OPTIMUM by Lobob Cleaning and Disinfecting Storage solution, with clearance under 510(k) K014162.

The physical properties of the **BostonSight IC Corneal & Scleral Lenses** manufactured from the various materials are as follows:

	<b>roflufocon D</b>	<b>roflufocon E</b>	<b>oprifocon A</b>	<b>hexafocon B</b>
<b>Refractive Index</b>	1.4333	1.4332	1.4230	1.4240
<b>Light Transmission (clear)</b>	>97%	>97%	>95%	>95%
<b>Light Transmission (tinted)</b>	>90%	>90%	>90%	>83%
<b>Specific Gravity</b>	1.166	1.155	1.24	1.19
<b>Oxygen Permeability (Dk)</b> <b>ISO/FATT Method</b>	100 x 10 <sup>-11</sup> (cm <sup>2</sup> /sec) (ml O <sub>2</sub> /ml x mm Hg @ 35°C)	125 x 10 <sup>-11</sup> (cm <sup>2</sup> /sec) (ml O <sub>2</sub> /ml x mm Hg @ 35°C)	85 x 10 <sup>-11</sup> (cm <sup>2</sup> /sec) (ml O <sub>2</sub> /ml x mm Hg @ 35°C)	141 x 10 <sup>-11</sup> (cm <sup>2</sup> /sec) (ml O <sub>2</sub> /ml x mm Hg @ 35°C)
<b>Visitint lenses contain one or more of the following color additives conforming to: 21 CFR Part 73 &amp; 74, Subpart D</b>	D & C Green No. 6, FD & C Red No. 17, CI Solvent Yellow 18	D & C Green No. 6, FD & C Red No. 17, CI Solvent Yellow 18	D&C Green No.6 and D&C Yellow No.10	D&C Green No. 6; C.I. Solvent Yellow No. 18; D&C Violet No. 2; D&C Red No. 17; C.I. Solvent Yellow No.18
<b>UV Light Blocking (UVB – 280nm – 315nm; UVA 316nm – 380nm)</b>	>98% UVB >95% UVA	>98% UVB >95% UVA	>95% UVB >97% UVA	>95% UVB >97% UVA
<b>Dynamic Receding Contact Angle</b>	3°	6°	56°	40°

Lens parameters:

- \* Chord Diameter: 8.0 mm to 26.0 mm
- \* Center Thickness: 0.05mm to 0.60 mm
- \* Base Curve: 5.0 mm to 9.0 mm
- \* Spherical Powers: -25.00 Diopters to +35.00 Diopters

### Indication for Use:

The **BostonSight IC Corneal & Scleral Lenses for Daily Wear** are indicated for the correction of refractive error in aphakic and not aphakic persons. 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 profiles for finished lenses manufactured from the roflufocon D, roflufocon E, oprifocon A, and hexafocon B rigid gas permeable (RGP) materials are demonstrated in K033594, K071266, and K022128 respectively—which address the following areas:

- Biocompatibility
- Shelf Life (Wet Shipping)
- Solution Compatibility
- Clinical Evaluation

Additionally, the following testing was performed:

*Bench Testing*—manufacturing verification testing was conducted to demonstrate the ability of Boston Foundation for Sight to manufacture lenses, on a repeatable basis, from supplied lens blanks to a variety of prescribed parameters. All lenses were manufactured to established finished product specifications within the ANSI Z80.20 tolerance.

*Bioburden Testing*—bioburden testing conducted on rigid gas permeable lenses manufactured at Boston Foundation for Sight demonstrated that the colony forming units (CFU) per lens was less than 1, which is within the established acceptance criteria of less than 100 CFU per lens.

### ~ Conclusions Drawn from Testing ~

Testing presented in this submission demonstrate no significant differences from the predicate devices—supporting the substantial equivalence claim of these **BostonSight IC Corneal & Scleral Lenses** to the already marketed roflufocon D, roflufocon E, oprifocon A, and hexafocon B RGP contact lenses.

### **Substantial Equivalence:**

The **BostonSight IC Corneal & Scleral Lenses for Daily Wear** are substantially equivalent to the predicate devices and *do not raise* different questions of safety and effectiveness than the predicate devices identified previously.

### ~ Discussion of Similarities and Differences ~

The **BostonSight IC Corneal & Scleral Lenses** are identical to the predicate devices in terms of material (USAN), indications, lens design, and production method. There are no significant differences to report between the **BostonSight IC Corneal & Scleral Lenses** and the predicate devices.

The following table depicts the pre-clinical characteristics of the **BostonSight IC Corneal & Scleral Lenses**, as well as the predicate device.

	<b>BostonSight IC Corneal &amp; Scleral Lenses</b>	<b>OPTIMUM GP (OPTIMUM EXTRA &amp; OPTIMUM EXTREME)</b>	<b>BOSTON Equalens II</b>	<b>BOSTON XO<sub>2</sub></b>
	<i>Subject Device</i>	<i>Predicate Device</i>	<i>Predicate Device</i>	<i>Predicate Device</i>
<b>Indication for Use</b>	The <b>BostonSight IC Corneal &amp; Scleral Lenses for Daily Wear</b> are indicated for the correction of refractive error in aphakic and not aphakic persons. 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.	The <b>OPTIMUM GP</b> (roflucocon D & E) Daily Wear Contact Lens 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.	The <b>BOSTON Equalens II</b> 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 <b>Boston XO<sub>2</sub></b> (hexafocon B) RGP contact lenses may be prescribed in otherwise non-diseased eyes that require a rigid contact lens for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.
<b>Device and Classification</b>	Class II Daily wear, Rigid Gas Permeable RGP Contact Lens HQD	Class II Daily wear, Rigid Gas Permeable RGP Contact Lens HQD	Class II Daily wear, Rigid Gas Permeable RGP Contact Lens HQD	Class II Daily wear, Rigid Gas Permeable RGP Contact Lens HQD
<b>Production Method</b>	Lathe-cut	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	Group # 3 Fluoro Silicone Acrylate
<b>Water Content</b>	<1%	<1%	<1%	<1%
<b>UV Absorber/Blocker available</b>	YES	YES	YES	YES