DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 25, 2016

BostonSight
% Mr. Bret Andre
Principal Consultant
EyeReg Consulting, Inc.
6119 Canter Ln.
West Linn, OR 97068

Re: K161461
Trade/Device Name: BostonSight PD Prosthetic Device
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Permeable Contact Lens
Regulatory Class: Class II
Product Code: HQD
Dated: May 20, 2016
Received: May 26, 2016

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" (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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)* K161461

Device Name
BostonSight PD Prosthetic Device

Indications for Use *(Describe)*
The Boston Sight PD Prosthetic Device for daily wear is indicated for therapeutic use for the management of a distorted corneal surface that:

1. precludes satisfactory spectacle lens correction
2. demonstrates significant improved rigid contact lens corrected vision
3. 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

Causes of corneal distortion include corneal degeneration (e.g. keratoconus, keratoglobus, pellucid marginal degeneration, Salzmann's nodular degeneration), corneal dystrophy (e.g, lattice dystrophy, Reis-Bucklers dystrophy), and scarring from surgery (e.g. corneal transplant, LASIK, radial keratotomy), infection, or trauma.

The BostonSight PD Prosthetic Device for daily wear is also 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.

The BostonSight PD Prosthetic Device may be cleaned and disinfected using a chemical (not heat) 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: **K161461**

Applicant information:

Date Prepared:	July 22nd, 2016
Name:	**BostonSight**
Address	464 Hillside Avenue, Suite 205 Needham, MA 02494
Contact Person:	Gene P. Guselli President and CEO
Phone number:	781-726-7337
Consultant/Correspondent:	EyeReg Consulting, Inc. Bret Andre
Phone number	(503) 372-5226
Fax number	(503) 419-4475

Device Information:

Device Classification:	Class II
Classification Number:	HQD
Classification Name:	Lenses, Rigid Gas Permeable, Daily Wear
Trade Name:	**BostonSight PD Prosthetic Device**

Predicate Devices:

The **BostonSight PD Prosthetic Device** is substantially equivalent to the following predicate device(s)

- "**BostonSight IC Corneal & Scleral Lens**"
  – Primary Predicate
  Manufactured by Boston Foundation for Sight
  510(k) number; K153066
- "**Boston^{R} Scleral (itafluorofocon B) RGP Contact Lens for Daily Wear**"
  – Reference Predicate
  Manufactured by Boston Foundation for Sight
  PMA number; P860022/S40

Device Description:

The **BostonSight PD Prosthetic Device** is a daily wear, prosthetic device for the ocular surface lathe cut from one of the following fluoro-silicone acrylate materials:

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

The **BostonSight PD Prosthetic Device** is designed to vault over the cornea and rest on the conjunctiva overlying the sclera, resulting in a tear reservoir between the back surface of the prosthetic device and the corneal surface. The tear reservoir masks optical distortions from an irregular corneal surface, and in combination with the device itself, protects the ocular surface from an adverse external environment, including but not limited to dysfunctional eyelids and margins. The design parameters are customized to allow for tear exchange underneath the device.

The **BostonSight PD Prosthetic Device** may be shipped "dry" or "wet" in a polypropylene contact lens case. The primary container for shipping the **BostonSight PD Prosthetic Device** is the Bausch & Lomb Frequent Replacement Contact Lens Case, with clearance under 510(k) K896685. When shipped "wet", The **BostonSight PD Prosthetic Device** 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 PD Prosthetic Device** 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 PD Prosthetic Device** manufactured from the various materials are as follows:

	ROFLUFOCON D	**ROFLUFOCON E**	**OPRIFOCON A**	**HEXAFOCON B**
Refractive Index	1.4333	1.4332	1.4230	1.4240
Light Transmission (clear)	>97%	>97%	>95%	>95%
Light Transmission (tinted)	>90%	>90%	>90%	>83%
Water Content	<1%	<1%	<1%	<1%
Dynamic Contact Angle (Receding)	3°	6°	56°	40°
Specific Gravity	1.166	1.155	1.24	1.19
Modulus	697 MPa	77 MPa	1300 MPa	1160 MPa
Shore D Hardness	75	77	81	78
Oxygen Permeability (Dk) ISO/FATT Method	100×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)	125×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)	85×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)	141×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)
contain one or more of the following color additives conforming to: 21 CFR Part 73 & 74, Subpart D	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
UV Light Blocking (UVB – 280nm – 315nm; UVA 316nm – 380nm)	>98% UVB >95% UVA	>98% UVB >95% UVA	>95% UVB >97% UVA	>95% UVB >97% UVA

The parameters for the **BostonSight PD Prosthetic Device** are as follows:

* Chord Diameter: 18.0 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 **Boston Sight PD Prosthetic Device** for daily wear is indicated for therapeutic use for the management of a distorted corneal surface that:

1. precludes satisfactory spectacle lens correction
2. demonstrates significant improved rigid contact lens corrected vision
3. 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

Causes of corneal distortion include corneal degeneration (e.g. keratoconus, keratoglobus, pellucid marginal degeneration, Salzmann's nodular degeneration), corneal dystrophy (e.g, lattice dystrophy, Reis-Bucklers dystrophy), and scarring from surgery (e.g. corneal transplant, LASIK, radial keratotomy), infection, or trauma.

The **BostonSight PD Prosthetic Device** for daily wear is also 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.

The **BostonSight PD Prosthetic Device** may be cleaned and disinfected using a chemical (not heat) care system.

Description of Safety:

~ Non-Clinical Studies ~

Non-clinical testing to demonstrate the safety and effectiveness of contact lenses manufactured from roflufocon D, roflufocon E, oprifocon A, and hexafocon B has been addressed by reference to the predicate device, BostonSight IC Corneal & Scleral Lens (K153066).

~ Clinical Studies ~

Clinical testing to demonstrate the safety and effectiveness of contact lenses manufactured from roflufocon D, roflufocon E, oprifocon A, and hexafocon B has been addressed by reference to the following:

- OPTIMUM GP(roflufocon D, roflufocon E) Daily Wear Contact Lenses - K033594
- Boston EQUALENS II (oprifocon A) Rigid Gas Permeable Contact Lenses - K022128
- Boston XO2 (hexafocon B) Daily Wear Contact Lens - K071266

Substantial Equivalence:

The **BostonSight PD Prosthetic Device** is substantially equivalent to the Boston^{R} Scleral (itafluorofocon B) RGP Contact Lens for Daily Wear (predicate device) in the following key areas:

- Device Design
- Therapeutic indications for use

The **BostonSight PD Prosthetic Device** is substantially equivalent to the BostonSight IC Corneal & Scleral Lens (predicate device) in the following key areas:

- Components/Materials/Formulation
- Manufacturing Process
- Manufacturing Facility
- Final Packaging & Wet Shipping

The **BostonSight PD Prosthetic Device** is substantially equivalent to the predicate device as depicted in the following table, and *does not raise* different questions of safety and effectiveness than the predicate device identified previously.

The following table depicts the pre-clinical characteristics of the **BostonSight PD Prosthetic Device**, as well as the predicate device(s).

	BostonSight PD Prosthetic Device	**BostonSight IC Corneal & Scleral Lens (K153066)**	**Boston^{R} Scleral (itafluorofocon B) RGP Contact Lens (P860022/S40)**
	Subject Device	***Predicate Device***	***Predicate Device***
Indication for Use	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.	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.	Indicated for eyes having significantly reduced vision due to the presence of a distorted corneal surface that: 1) precludes satisfactory spectacle lens correction 2) demonstrates significantly improved rigid contact lens corrected vision 3) 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. Furthermore, eyes suffering from certain ocular surface disorders may benefit from the physical protection and the saline bath provided by a scleral lens.
Device and Classification	Class II Lenses, Rigid Gas Permeable, Daily Wear HQD	Class II Lenses, Rigid Gas Permeable, Daily Wear HQD	Class II Lenses, Rigid Gas Permeable, Daily Wear HQD (reclassified from Class III to Class II in 1994)
Production Method	Lathe-cut	Lathe-cut	Lathe-cut
FDA Group #	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate
Water Content	<1%	<1%	<1%
UV Absorber/Blocker available	YES	YES	YES