August 14, 2024

Boston Foundation for Sight, Inc. d/b/a BostonSight
Sara Yost
President & CEO
464 Hillside Ave
Suite 205
Needham, MA 02494

Re: K241571
Trade/Device Name: BostonSight® Specialty Lenses (roflufocon D, roflufocon E, tisilfocon A, hexafocon B, oprifocon A, fluoroxyfocon A)
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Permeable Contact Lens
Regulatory Class: Class II
Product Code: HQD
Dated: May 31, 2024
Received: June 18, 2024

Dear Sara Yost:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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)*
K241571

Device Name
BostonSight® Specialty Lenses (roflufocon D, roflufocon E, tisilfocon A, hexafocon B, oprifocon A, fluoroxyfocon A)

Indications for Use *(Describe)*
The BostonSight® Specialty Lenses (roflufocon D, roflufocon E, tisilfocon A, hexafocon B, oprifocon A, fluoroxyfocon A) for daily wear are indicated 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 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 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.

The BostonSight Specialty Lenses for daily wear in the scleral lens designs are indicated for therapeutic use in eyes with ocular surface disease including, but not limited to, 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.

Additionally, the BostonSight Specialty Lenses for daily wear in the scleral lens designs are indicated for therapeutic use for the management of irregular and distorted corneal surfaces. 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). When prescribed for therapeutic use for a distorted cornea or ocular surface disease, the BostonSight Specialty Scleral Lenses for daily wear may concurrently provide correction of refractive error.

Eye care 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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I. SUBMITTER

Date Prepared: May 31, 2024

Name: **BostonSight**
Address: 464 Hillside Avenue, Suite 205
Needham, MA 02494

Contact Person: Sara A. Yost
President and CEO
Phone number: 781-726-7337

II. DEVICE

Trade Name: **BostonSight® Specialty Lenses**
(roflufocon D, roflufocon E, tisilfocon A, hexafocon B, oprifocon A, fluoroxyfocon A)

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

III. REASON FOR SUBMISSION

The reason for submitting this 510(k) application for the **BostonSight® Specialty Lenses** (roflufocon D, roflufocon E, tisilfocon A, hexafocon B, oprifocon A, fluoroxyfocon A) for daily wear is to combine all approved FDA Group #3 fluoro-silicone acrylate rigid gas permeable (RGP) lens materials and Tangible® Hydra-PEG coating for the approved materials (roflufocon D, roflufocon E, tisilfocon A, hexafocon B, fluoroxyfocon A) into one 510(k), Package Insert and Patient Information Booklet. Additionally, the Package Insert and Patient Information Booklet have been reorganized and clarified to provide a more structured approach to care, disinfection, and handling of **BostonSight Specialty Lenses**.

IV. PREDICATE DEVICES

The **BostonSight® Specialty Lenses** (roflufocon D, roflufocon E, tisilfocon A, hexafocon B, oprifocon A, fluoroxyfocon A) for daily wear are substantially equivalent to the following predicate devices:

- "BostonSight Scleral"
  By BostonSight
  510(k) number; **K183175**

Product Code: HQD

- "OPTIMUM GP (roflufocon D, roflufocon E) Daily Wear Contact Lens; HEXA100 (hexafocon A) Daily Wear Contact Lens"
  By Contamac Ltd.
  510(k) number; **K180616**
  Product Code: HQD
- "Hyper GP (tisilfocon A) Daily Wear Contact Lens"
  By Contamac Ltd.
  510(k) number; **K212631**
  Product Code: HQD
- "Boston ES® (enflufocon A), Boston EO® (enflufocon B), Boston XO® (hexafocon A) and Boston XO2® (hexafocon B) Rigid Gas Permeable Contact Lenses"
  By Bausch + Lomb Inc.
  510(k) number; **K183167**
  Product Code: HQD
- "Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lens; Acuity 100™ (hexafocon A) Rigid Gas Permeable Contact Lens; Acuity 200™ with Tangible® Hydra-PEG (fluoroxyfocon A) Rigid Gas Permeable Contact Lens; Acuity 100™ with Tangible® Hydra-PEG (hexafocon A) Rigid Gas Permeable Contact Lens"
  By Acuity Polymers, Inc.
  510(k) number; **K240618**
  Product Code: HQD

V. DEVICE DESCRIPTION

The **BostonSight® Specialty Lenses** for daily wear are lathe cut from one of the following hydrophobic, FDA Group #3 fluoro-silicone acrylate rigid gas permeable (RGP) lens materials:

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

The **BostonSight Specialty Lenses** for daily wear fabricated from roflufocon D, roflufocon E, tisilfocon A, hexafocon B, fluoroxyfocon A are available with or without Tangible® 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 and optical properties of the underlying material. The **BostonSight Specialty Lenses** for daily wear fabricated from oprifocon A are not available with Tangible® Hydra-PEG.

The **BostonSight Specialty Lenses** for daily wear may be shipped "dry" or "wet" in a polypropylene contact lens case. The primary container for shipping the **BostonSight Specialty Lenses** for daily wear is the Bausch & Lomb "US Lens Case W&B", with clearance under 510(k) K013232. When shipped "wet", the **BostonSight Specialty Lenses** for daily wear are packaged non-sterile in Boston SIMPLUS® Multi-Action Solution (K024289).

The physical properties of the **BostonSight Specialty Lenses** for daily wear are as follows:

	roflufocon D	**roflufocon E**	**tisilfocon A**	**hexafocon B**	**oprifocon A**	**fluoroxyfocon A**
Refractive Index	1.4333	1.4332	1.4378	1.4240	1.4230	1.430
Light Transmission (clear)	>97%	>97%	-	>95%	>95%	-
Light Transmission (tinted)	>90%	>90%	>91%	>83%	>90%	>87%
Water Content	<1%	<1%	<1%	<1%	<1%	<1%
Specific Gravity	1.166	1.155	1.20	1.19	1.24	1.18
Oxygen Permeability (Dk) ISO/FATT Method	100 x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35ºC)	125 x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35ºC)	180 x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35ºC)	141 x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35ºC)	85 x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35ºC)	200 x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35ºC)
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, C.I. Solvent Yellow No. 18, D&C Violet No. 2, D&C Red No. 17	D&C Green No. 6, C.I. Solvent Yellow No. 18, D&C Violet No. 2, D&C Red No. 17	D&C Green No.6, D&C Yellow No.18	D&C Green No. 6, D&C Violet No. 2, Solvent Yellow 18, D&C Red No. 17
UV Light Blocking	Yes	Yes	Yes	Yes	Yes	Yes
Dynamic Receding Contact Angle	3°	6°	-	40°	56°	-
Tangible® Hydra-PEG Available	Yes	Yes	Yes	Yes	No	Yes

The **BostonSight Specialty Lenses** for daily wear are available in the following lens parameters:

Parameter	**Range**	**Tolerance**
Base Curve	5.00mm to 11.5mm	± 0.05 mm
Center Thickness	0.05mm to 0.75mm	± 0.02 mm

Chord Diameter	7.00mm to 26.00mm	± 0.10mm
Spherical Power	-25.00 D to +35.00 D (in 0.25D steps)	± 0.12 (0 to </= 5D) ± 0.18 (5 to </= 10.0D) ± 0.25 (10 to </= 15D) ± 0.37 (15 to </= 20D) ± 0.50 (over 20D)
Cylindrical Power	Up to -10.00 D (in 0.25 D steps)	± 0.25 (0 to </= 2D) ± 0.37 (2 to </= 4D) ± 0.50 (over 4D)
Cylindrical Axis	1° to 180° (in 1° steps)	± 5°
Multifocal Power	+1.00 D to 4.00 D (in 0.25 D steps)	± 0.25D

VI. INDICATIONS FOR USE

The **BostonSight® Specialty Lenses** (roflufocon D, roflufocon E, tisilfocon A, hexafocon B, oprifocon A, fluoroxyfocon A) for daily wear are indicated 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 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 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.

The **BostonSight Specialty Lenses** for daily wear in the scleral lens designs are indicated for therapeutic use in eyes with ocular surface disease including, but not limited to, 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.

Additionally, the **BostonSight Specialty Lenses** for daily wear in the scleral lens designs are indicated for therapeutic use for the management of irregular and distorted corneal surfaces. 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). When prescribed for therapeutic use for a distorted cornea or ocular surface disease, the **BostonSight Specialty Scleral Lenses** for daily wear may concurrently provide correction of refractive error.

Eye care 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.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The **BostonSight® Specialty Lenses** for daily wear are substantially equivalent to the predicate device, BostonSight SCLERAL, cleared under K183175, in terms of the following:

Intended Use:	Daily wear contact lenses
Classification:	Class II, Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)
Product Code:	HQD
FDA Material Group:	Group # 3 fluoro silicone acrylate
USAN Materials:	roflufocon D, roflufocon E, oprifocon A and hexafocon B
Production method:	Lathe cut
Actions	
Indications for use	
Final Packing and Shipping	
Manufacturing facility, procedures, and controls	

The **BostonSight Specialty Lenses** for daily wear are substantially equivalent to the predicate device, OPTIMUM GP (roflufocon D, roflufocon E) Daily Wear Contact Lens; HEXA100 (hexafocon A) Daily Wear Contact Lens, cleared under K180616, in terms of the following:

Intended Use:	Daily wear contact lenses
Classification:	Class II, Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)
Product Code:	HQD
FDA Material Group:	Group # 3 fluoro silicone acrylate
USAN Materials:	roflufocon D, roflufocon E
Production method:	Lathe cut
Actions	
Indications for use	

The **BostonSight Specialty Lenses** for daily wear are substantially equivalent to the predicate device, Hyper GP (tisilfocon A) Daily Wear Contact Lens, cleared under K212631, in terms of the following:

Intended Use:	Daily wear contact lenses
Classification:	Class II, Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)
Product Code:	HQD
FDA Material Group:	Group # 3 fluoro silicone acrylate
USAN Materials:	tisilfocon A
Production method:	Lathe cut
Actions	
Indications for use	

The **BostonSight Specialty Lenses** for daily wear are substantially equivalent to the predicate device, Boston ES® (enflufocon A), Boston EO® (enflufocon B), Boston XO® (hexafocon A) and Boston XO2® (hexafocon B) Rigid Gas Permeable Contact Lenses, cleared under K183167, in terms of the following:

Intended Use:	Daily wear contact lenses
Classification:	Class II, Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)
Product Code:	HQD
FDA Material Group:	Group # 3 fluoro silicone acrylate
USAN Materials:	hexafocon B
Production method:	Lathe cut
Actions	
Indications for use	

The **BostonSight Specialty Lenses** for daily wear are substantially equivalent to the predicate device, Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lens; Acuity 100™ (hexafocon A) Rigid Gas Permeable Contact Lens; Acuity 200™ with Tangible® Hydra-PEG (fluoroxyfocon A) Rigid Gas Permeable Contact Lens; Acuity 100™ with Tangible® Hydra-PEG (hexafocon A) Rigid Gas Permeable Contact Lens, cleared under K240618, in terms of the following:

Intended Use:	Daily wear contact lenses
Classification:	Class II, Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)
Product Code:	HQD
FDA Material Group:	Group # 3 fluoro silicone acrylate
USAN Materials:	fluoroxyfocon A
Production method:	Lathe cut

Actions
Indications for use

The following matrix illustrates the production method, lens function and material characteristics of the **BostonSight Specialty Lenses** for daily wear, as well as the predicate devices.

Substantial Equivalence Matrix

	Subject Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device
Trade Name	BostonSight® Specialty Lenses	BostonSight SCLERAL	OPTIMUM GP Daily Wear Contact Lens; HEXA100 Daily Wear Contact Lens	Hyper GP Daily Wear Contact Lens	Boston ES®, Boston EO®, Boston XO®, and Boston XO2® Rigid Gas Permeable Contact Lenses	Acuity 200™ Rigid Gas Permeable Contact Lens; Acuity 100™ Rigid Gas Permeable Contact Lens; Acuity 200™ with Tangible® Hydra-PEG Rigid Gas Permeable Contact Lens; Acuity 100™ with Tangible® Hydra-PEG Rigid Gas Permeable Contact Lens
510(K) Number	-	K183175	K180616	K212631	K183167	K240618
Intended Use	Daily Wear	Daily Wear	Daily Wear	Daily Wear	Daily Wear	Daily Wear
Classification	Class II Lenses, Rigid Gas Permeable, Daily Wear 21 CFR 886.5916	Class II Lenses, Rigid Gas Permeable, Daily Wear 21 CFR 886.5916	Class II Lenses, Rigid Gas Permeable, Daily Wear 21 CFR 886.5916	Class II Lenses, Rigid Gas Permeable, Daily Wear 21 CFR 886.5916	Class II Lenses, Rigid Gas Permeable, Daily Wear 21 CFR 886.5916	Class II Lenses, Rigid Gas Permeable, Daily Wear 21 CFR 886.5916
Product Code	HQD	HQD	HQD	HQD	HQD	HQD
FDA Group #	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate

Material (USAN)	roflufocon D, roflufocon E, oprifocon A, hexafocon B, tisilfocon A, fluoroxyfocon A	roflufocon D, roflufocon E, oprifocon A, hexafocon B	roflufocon D, roflufocon E, hexafocon A	tisilfocon A	enflufocon A, enflufocon B, hexafocon A, hexafocon B	fluoroxyfocon A, hexafocon A
Water Content (%)	<1%	<1%	<1%	<1%	<1%	<1%
UV Absorber Available	Yes	Yes	Yes	Yes	Yes	Yes
Actions	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina. When placed on the eye for therapeutic use, the lens replaces or supports impaired ocular surface function.	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina. When placed on the eye for therapeutic use, the lens replaces or supports impaired ocular surface function.	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina. When placed on the eye for therapeutic use, the lens replaces or supports impaired ocular surface function.	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina. When placed on the eye for therapeutic use, the lens replaces or supports impaired ocular surface function.	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina. When placed on the eye for therapeutic use, the lens replaces or supports impaired ocular surface function.	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina. When placed on the eye for therapeutic use, the lens replaces or supports impaired ocular surface function.
Production Method	Lathe-Cut	Lathe-Cut	Lathe-Cut	Lathe-Cut	Lathe-Cut	Lathe-Cut
Includes Hydra-PEG Surface Coating	Yes	No	Yes	Yes	Yes	Yes

Indications for Use

BostonSight® Specialty Lenses (Subject Device)	The **BostonSight Specialty Lenses** for daily wear are indicated 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 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 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. The **BostonSight Specialty Lenses** for daily wear in the scleral lens designs are indicated for therapeutic use in eyes with ocular surface disease including, but not limited to, 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. Additionally, the **BostonSight Specialty Lenses** for daily wear in the scleral lens designs are indicated for therapeutic use for the management of irregular and distorted corneal surfaces. 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). When prescribed for therapeutic use for a distorted cornea or ocular surface disease, the **BostonSight Specialty Scleral Lenses** for daily wear may concurrently provide correction of refractive error. The lens may be disinfected using a chemical disinfection (not heat) system only.
BostonSight SCLERAL (K183175)	BostonSight Scleral daily wear contact lenses are indicated for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and non aphakic persons. Also, the lenses may be prescribed in eyes that require a rigid contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, keratoglobus, post-LASIK ectasia, or following penetrating keratoplasty or refractive 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. BostonSight Scleral daily wear contact lenses 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 BostonSight Scleral daily wear contact lenses are also indicated for therapeutic use in eyes with ocular surface disease including, but not limited to, 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 BostonSight Scleral daily wear contact lenses may concurrently provide correction of refractive error. The lenses may be disinfected using a chemical disinfection (not heat) system only.
OPTIMUM GP Daily Wear Contact Lens; HEXA100 Daily Wear Contact Lens (K180616)	OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear Contact Lenses are indicated 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 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. OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear Contact Lenses

	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 OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear Contact Lenses 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 OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear Contact Lenses may concurrently provide correction of refractive error. The lenses may be disinfected using a chemical disinfection (not heat) system only.
Optimum Infinite (tisilfocon A) Daily Wear Contact Lenses (K212631)	The Optimum Infinite (tisilfocon A) SPHERICAL Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The Optimum Infinite (tisilfocon A) TORIC Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction ofrefractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10.00 diopters. The Optimum Infinite (tisilfocon A) MUL TIFOCAL/BIFOCAL Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 4 diopters and are presbyopic requiring add power of up to +4.00 diopters. The Optimum Infinite (tisilfocon A) IRREGULAR CORNEA 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 Optimum Infinite (tisilfocon A) ORTHOKERA TOLOGY contact lenses are 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. 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. Optimum Infinite (tisilfocon A) SCLERAL lenses 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 Optimum Infinite (tisilfocon A) SCLERAL lenses are indicated for therapeutic use in eyes with ocular surface disease (e.g. ocular Graft-versus-Host disease, Sjogren'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 Optimum Infinite (tisilfocon A) SCLERAL lenses may concurrently provide correction of refractive error. Eye care 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.
Boston ES®, Boston EO®, Boston XO® and Boston XO2® Rigid Gas Permeable Contact Lenses (K183167)	The Boston ES® (enflufocon A) and Boston EO® (enflufocon 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-versusHost 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.
Acuity 200™, Acuity 100™, Acuity 200™ with Tangible® Hydra-PEG, and Acuity 100™ with Tangible® Hydra-PEG Rigid Gas Permeable Contact Lenses (K240618)	The Acuity 200™ (fluoroxyfocon A), Acuity 100™ (hexafocon A), Acuity 200™ with Tangible® Hydra-PEG (fluoroxyfocon A), and Acuity 100™ with Tangible® Hydra-PEG Rigid Gas Permeable Contact Lenses are indicated for daily wear for the correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be prescribed for daily wear 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 Acuity 200™ (fluoroxyfocon A), Acuity 100™ (hexafocon A), Acuity 200™ with Tangible® Hydra-PEG (fluoroxyfocon A), and Acuity 100™ with Tangible® Hydra-PEG Rigid Gas Permeable Contact Lenses 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 lens may concurrently provide correction of refractive error. The Acuity 200™ (fluoroxyfocon A), Acuity 100™ (hexafocon A), Acuity 200™ with Tangible® Hydra-PEG (fluoroxyfocon A), and Acuity 100™ with Tangible® Hydra-PEG Rigid Gas Permeable Contact Lenses may be cleaned and disinfected using a chemical (not heat) lens care system.

VIII. PERFORMANCE DATA

~ Non-Clinical Studies ~

Non-clinical testing to demonstrate the safety and effectiveness of contact lenses manufactured from roflufocon D, roflufocon E, tisilfocon A, hexafocon B, oprifocon A, and fluoroxyfocon A materials has been addressed by reference to previous 510(k) clearances.

~ Clinical Studies ~

Clinical testing to demonstrate the safety and effectiveness of contact lenses manufactured from roflufocon D, roflufocon E, tisilfocon A, hexafocon B, oprifocon A, fluoroxyfocon A with the labeled indications for use has been addressed through previous 510(k) clearances.

IX. CONCLUSIONS

Substantial Equivalence

Information presented in this premarket notification establishes that **BostonSight® Specialty Lenses** for daily wear are as safe and effective as the predicate devices when used in accordance with the labeled directions for use and for the proposed indications.

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.