March 17, 2022

Contamac Ltd.
℅ Bret Andre
Consultant
EyeReg Consulting Inc.
6119 Canter Lane
West Linn, OR 97068

Re: K212631
Trade/Device Name: Optimum Infinite (tisilfocon A) Daily Wear Contact Lenses
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Permeable Contact Lens
Regulatory Class: Class II
Product Code: HQD, MUW
Dated: February 4, 2022
Received: February 7, 2022

Dear 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/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 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 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, 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)*
K212631

Device Name
Optimum Infinite (tisilfocon A) Daily Wear Contact Lenses

Indications for Use *(Describe)*
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 of refractive 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) MULTIFOCAL/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) ORTHOKERATOLOGY 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, 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 Infinite (tisilfocon A) SCLERAL lenses may concurrently provide correction of refractive error.

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)

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: K212631

I. SUBMITTER

Date Prepared: March 9th, 2022

Name: **Contamac Ltd.**
Address: Carlton House
Shire Hill
Saffron Walden
Essex CB11 3AU

Contact Person: Robert McGregor
Managing Director
Phone number: 01799 514800

Consultant: Bret Andre
EyeReg Consulting, Inc.
6119 Canter Ln.
West Linn, OR 97068
Phone number: (503) 372-5226

II. DEVICE

Trade Name: **Optimum Infinite (tisilfocon A) Daily Wear 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; MUW

~Reason for Submission~ *New Indications for Use*

III. PREDICATE DEVICE

The **Optimum Infinite (tisilfocon A) Daily Wear Contact Lenses** are substantially equivalent to the following predicate devices:

- "Hyper GP (tisilfocon A) Daily Wear Contact Lens"
  By Contamac Ltd.
  510(k) number; **K182304**
- "OPTIMUM GP (roflufocon D, roflufocon E) Daily Wear Contact Lens; HEXA100 (hexafocon A) Daily Wear Contact Lens"
  By Contamac Ltd.
  510(k) number; **K180616**
- "BostonSight PD Prosthetic Device"
  Manufactured by Boston Foundation for Sight
  510(k) number; **K161461**
- "Ampleye Scleral RGP Lens (roflufocon D, roflufocon E, hexafocon A, paflufocon D)"
  By Art Optical Contact Lens, Inc.
  510(k) number; **K172314**

IV. DEVICE DESCRIPTION

The **Optimum Infinite (tisilfocon A) Daily Wear Contact Lenses** are manufactured from a machine latheable rigid gas permeable material composed of siloxanyl fluoromethacrylate copolymer that is tinted for visibility and available with or without an ultraviolet (UV) light absorber. The lenses may be plasma treated during the manufacturing process.

In the **Optimum Infinite (tisilfocon A) Daily Wear Contact Lens** with UV Blocker, a Benzophenone UV blocking monomer is used to block >99% of UV radiation in the UVB range (280nm – 315nm) and >85% in the UVA range (316 – 380nm).

The **Optimum Infinite (tisilfocon A) Daily Wear Contact Lenses** incorporate a visibility tint to make the lens more visible for handling. The tinted lenses contain one or more of the following color additives: D&C Green No. 6, C.I. Solvent Yellow No. 18, D&C Violet No. 2 and D&C Red No. 17.

The **Optimum Infinite (tisilfocon A) Daily Wear Contact Lenses** may be prescribed in a daily wear orthokeratology fitting program for the temporary reduction of myopia of up to 5.00 diopters in non-diseased eyes.

The **Optimum Infinite (tisilfocon A) Daily Wear Contact Lenses** may be treated to incorporate 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 properties of the underlying material. When treated with Tangible™ Hydra-PEG, the underlying material (tisilfocon A) is encapsulated in a thin layer of polymer that results in measurable improvement of wettability (sessile drop contact angle) compared to untreated lenses. The resulting layer is hydrophilic and approximately 30nm in thickness. The following table depicts the contact angle of the coated vs. uncoated lenses:

	Hyper GP tisilfocon A	
	Uncoated	**Tangible™ Hydra-PEG Coated**
Average Sessile Drop Contact Angle (degrees) n=30	106.2	37.34
Standard Deviation	5.31	5.30

The **Optimum Infinite (tisilfocon A) Daily Wear Contact Lenses** may be packaged and shipped "dry" or "wet" in a polypropylene contact lens case. The primary container for shipping the **Optimum Infinite (tisilfocon A) Daily Wear Contact Lens** is the PolyVial Contact Lens Case. When shipped "wet", the **Optimum Infinite (tisilfocon A) Daily Wear Contact Lens** may be packaged and shipped in the Unique pH contact lens care system by Menicon Co., Ltd**.** The active ingredients in Unique pH solution are Edetate Disodium 0.01% and Polyquaternium 10.0011%.

The physical properties of the **Optimum Infinite (tisilfocon A) Daily Wear Contact Lenses** are as follows:

	Hyper GP (tisilfocon A)	**Hyper GP (tisilfocon A) with Tangible™ Hydra-PEG**
Refractive Index (dry)	1.4378	1.4398
Light Transmission (@380-780nm)	91.694	93.427
UVA Transmission (@316-380nm)	14.241	16.105
UVB Transmission (@280-315nm)	0.011	0.020
Oxygen Permeability (Dk) ISO/FATT Method	180×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)	180×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)
Visitint lenses contain one or more of the following color additives conforming to: 21 CFR Part 73 & 74, Subpart D	D&C Green No. 6, C.I. Solvent Yellow No. 18, D&C Violet No. 2 and D&C Red No. 17	D&C Green No. 6, C.I. Solvent Yellow No. 18, D&C Violet No. 2 and D&C Red No. 17

The **Optimum Infinite (tisilfocon A) Daily Wear Contact Lenses** are available in the Spherical, Toric, Multifocal/Bifocal, Irregular Cornea (Scleral) design configurations, within the following lens parameters:

Parameter	Range	Tolerance
Base Curve	4.00mm to 12.00mm	± 0.05 mm
Center Thickness	Varies	± 0.02 mm
Chord Diameter	7.00mm to 22.00mm	± 0.10mm
Spherical Power	-30.00 D to +30.00 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

The **Optimum Infinite (tisilfocon A) Daily Wear Contact Lenses** for daily wear orthokeratology is available in following lens parameters:

Parameter	Range	Tolerance
Base Curve (BC)	4.0mm to 12.00mm	± 0.05 mm
Center Thickness	0.10mm to 0.70mm	± 0.02 mm
Diameter	6.50mm to 11.50mm	± 0.10mm
Secondary Curves	0.10mm to 2.00mm (flatter or steeper than BC)	± 0.10mm
Peripheral Curves	0.10mm to 2.00mm (flatter or steeper than BC)	± 0.10mm
Spherical Power	-10.00 D to +3.00 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)

V. INDICATIONS FOR USE

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 of refractive 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) MULTIFOCAL/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) ORTHOKERATOLOGY** 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, 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 Infinite (tisilfocon A) SCLERAL** lenses may concurrently provide correction of refractive error.

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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The **Optimum Infinite (tisilfocon A) Daily Wear Contact Lenses** are substantially equivalent to the predicate devices (cleared under K180616, K161461, and K172314) in terms of the following:

- Intended use – daily wear contact lenses
- Indications for use - therapeutic
- Actions
- Classification – Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)
- FDA material group – group # 3 fluoro silicone acrylate
- Production method – lathe cut

The **Optimum Infinite (tisilfocon A) Daily Wear Contact Lenses** are substantially equivalent to the Hyper GP (tisilfocon A) Daily Wear Contact Lens predicate device (cleared under K182304) in terms of the following:

- Intended use – daily wear contact lenses
- Actions
- Classification – Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)

- FDA material group – group # 3 fluoro silicone acrylate
- USAN material (tisilfocon A)
- Production method – lathe cut
- Final packaging and shipping

The following matrix illustrates the production method, lens function and material characteristics of the **Optimum Infinite (tisilfocon A) Daily Wear Contact Lenses**, as well as the predicate device.

	Optimum Infinite Daily Wear Contact Lenses	**Hyper GP Daily Wear Contact Lenses**	**OPTIMUM GP & HEXA100 Daily Wear Contact Lenses**	**BostonSight PD Prosthetic Device**	**Ampleye Scleral RGP Lens**
	Subject Device	**Predicate Device (K182304)**	**Predicate Device (K180616)**	**Predicate Device (K161461)**	**Predicate Device (K172314)**
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
Product Code	HQD; MUW	HQD; MUW	HQD; MUW	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
Material (USAN)	tisilfocon A	tisilfocon A	roflufocon D, roflufocon E, hexafocon A,	roflufocon D, roflufocon E, oprifocon A, and hexafocon B	roflufocon D, roflufocon E, hexafocon A, paflufocon D
Production Method	Lathe-Cut	Lathe-Cut	Lathe-Cut	Lathe-Cut	Lathe-Cut
Intended Use	Daily Wear	Daily Wear	Daily Wear	Daily Wear	Daily Wear
Water Content (%)	<1%	<1%	<1%	<1%	<1%
UV Absorber Available	Yes	Yes	Yes	Yes	Yes

	Indications for Use
Optimum Infinite Daily Wear Contact Lenses (Subject Device)	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 of refractive 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) MULTIFOCAL/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) ORTHOKERATOLOGY** 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, 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 Infinite (tisilfocon A) SCLERAL** lenses may concurrently provide correction of refractive error. 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.
Hyper GP Daily Wear Contact Lenses (K182304)	The Hyper GP (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 Hyper GP (tisilfocon A) TORIC 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 10.00 diopters.

	The Hyper GP (tisilfocon A) MULTIFOCAL/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 Hyper GP (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 Hyper GP (tisilfocon A) ORTHOKERATOLOGY 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. 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.
OPTIMUM GP & HEXA100 Daily Wear Contact Lenses	**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.

BostonSight PD Prosthetic Device (K161461)	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.
Ampleye Scleral RGP Lens (roflufocon D, roflufocon E, hexafocon A, paflufocon D) (K172314)	The **Ampleye Scleral RGP Lens (roflufocon D, roflufocon E, hexafocon A, paflufocon D)** for daily wear is indicated for use for the management of irregular astigmatism, corneal degeneration or dystrophy caused by keratoconus, keratoglobus, pellucid marginal degeneration (PMD), post corneal trauma/scaring, post keratoplasty, post K-Pro, post RK, post PRK, post LASIK, Salzmann's nodular degeneration, Cogan's dystrophy, granular corneal dystrophy, lattice corneal dystrophy or Reis-Bucklers dystrophy. The **Ampleye Scleral RGP Lens (roflufocon D, roflufocon E, hexafocon A, paflufocon D)** is also indicated for therapeutic management of ocular surface disease from dry eye including ocular pemphigoid, Stevens-Johnson syndrome, symblepharon formation, graft vs host disease, persistent epithelial defect, exposure keratitis, neurotrophic keratopathy(herpes simplex, herpes zoster, familial dysautonomia), Sjogern's syndrome, filamentary keratitis, limbal stem cell deficiency, atopy, ectodermal dysplasia. When prescribed for therapeutic use for irregular astigmatism or ocular surface diseases, the **Ampleye Scleral RGP Lens** may also provide correction of refractive error including myopia, hyperopia, presbyopia and regular astigmatism. 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. PERFORMANCE DATA

~ Non-Clinical Studies ~

Non-clinical testing to demonstrate the safety and effectiveness of the **Optimum Infinite (tisilfocon A) Daily Wear Contact Lenses** have been addressed through previously cleared 510(k) premarket notifications.

~ Clinical Studies ~

Six (6) independent practitioners evaluated 62 patients (115 total eyes) presenting with various conditions therapeutically managed using scleral contact lenses manufactured from Optimum Infinite (tisilfocon A) material. The practitioners were instructed to review all patients treated with the Optimum Infinite (tisilfocon A) scleral contact lenses for at least 3 months, and to report the outcome of each patient—including any ocular adverse reactions or worsening of the patients' conditions—over the treatment period. All patients were fit with successful outcomes over a treatment follow-up period. Fifty-five (55) of the eyes were treated for irregular cornea, whilst 62 eyes involved management of ocular surface disease. There were no serious or significant adverse reactions reported. For all patients, the ocular condition(s) and vision remained stable or improved during management with the Optimum Infinite (tisilfocon A) scleral contact lenses. The successful therapeutic fitting of 115 eyes over a total of 15,017 days without any serious adverse reaction reported supports the conclusion that the Optimum Infinite (tisilfocon A) scleral contact lenses are safe and effective for therapeutic management of ocular surface diseases and irregular corneal conditions.

VIII. CONCLUSIONS

Substantial Equivalence

Information presented in this premarket notification establishes that the **Optimum Infinite (tisilfocon A) Daily Wear Contact Lenses** 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.