June 16, 2023

Acculens, Inc.
% Bret Andre
Principal Consultant
Eyereg Consulting Inc.
6119 Canter Lane
West Linn, OR 97068

Re: K230910
Trade/Device Name: NewVision SC (tisilfocon A) Scleral Lens; NewVision SC Daily Wear Ortho-K (tisilfocon A) Corneo-Scleral Lens
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Permeable Contact Lens
Regulatory Class: Class II
Product Code: HQD, MUW
Dated: March 31, 2023
Received: March 31, 2023

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 -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)*
K230910

Device Name
NewVision SC (tisilfocon A) Scleral Lens; NewVision SC Daily Wear Ortho-K (tisilfocon A) Corneo-Scleral Lens

Indications for Use *(Describe)*
The NewVision SC Daily Wear Ortho-K (tisilfocon A) Corneo-Scleral Lens is 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.

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 NewVision SC (tisilfocon A) Scleral Lens is 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 NewVision SC (tisilfocon A) Scleral Lens is 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 NewVision SC (tisilfocon A) Scleral Lens may concurrently provide correction of up 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

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K230910**

I. SUBMITTER

Date Prepared:	June 6, 2023
Name:	**Acculens, Inc.**
Address	5353 West Colfax Avenue Lakewood, Colorado 80214 United States
Contact Person:	Troy Miller VP of Operations and Product Development
Phone number:	(303) 232-6244
Consultant/ Correspondent:	EyeReg Consulting, Inc. Bret Andre 6119 Canter Lane West Linn, OR 97068
Phone number	(503) 372-5226

II. DEVICE

Trade Name:	**NewVision SC (tisilfocon A) Scleral Lens;** **NewVision SC Daily Wear Ortho-K (tisilfocon A) Corneo-Scleral Lens**
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

III. PREDICATE DEVICE

The **NewVision SC and NewVision SC Daily Wear Ortho-K (tisilfocon A) Lenses** are substantially equivalent to the following predicate device:

- "**Optimum Infinite (tisilfocon A) Daily Wear Contact Lenses**"
  Manufactured by Contamac Ltd.
  510(k) number; K212631

IV. DEVICE DESCRIPTION

The **NewVision SC (tisilfocon A) Scleral Lens** is a large diameter rigid gas permeable lens designed to vault over the cornea and rest on the conjunctiva overlying the sclera. The **NewVision SC Daily Wear Ortho-K (tisilfocon A) Corneo-Scleral Lens** partly rests on the cornea, centrally or peripherally, and partly on the limbus or conjunctiva over the sclera. The **NewVision SC and NewVision SC Daily Wear Ortho-K (tisilfocon A) Lenses** are lathe cut from tisilfocon A, which is an FDA Group #3 fluoro-silicone acrylate material. The physical properties of the **NewVision SC and NewVision SC Daily Wear Ortho-K (tisilfocon A) Lenses** are as follows:

	TISILFOCON A
Refractive Index	1.4378
Light Transmission (tinted)	>91%
Water Content	<1%
Oxygen Permeability (Dk) ISO/FATT Method	180 x 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, C.I. Solvent Yellow No. 18, D&C Violet No. 2 and D&C Red No. 17
UV Light Blocking (UVB – 280nm – 315nm; UVA 316nm – 380nm)	>98% UVB >85% UVA

The **NewVision SC (tisilfocon A) Scleral Lens** is available in the following parameters:

Parameter	Range	Tolerance
Base Curve	5.5mm to 25.00mm	± 0.2mm
Center Thickness	0.10mm to 3.00mm	± 0.1mm
Diameter	12.00mm to 26.00mm	± 0.20mm
Spherical Power	-35.00 D to +35.00 D (in .12D 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	+10.00 D to -10.00 D (in .12 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°
Bifocal Add	+.12 D to +6.00 D (in .12 D steps)	± 0.25D

The **NewVision SC Daily Wear Ortho-K (tisilfocon A) Corneo-Scleral Lens** 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 13.50mm	± 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 +4.00 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)

The **NewVision SC and NewVision SC Daily Wear Ortho-K (tisilfocon A) Lenses** are shipped "dry" in the Bausch + Lomb Boston® Scleral Lens Case.

V. INDICATIONS FOR USE

The **NewVision SC Daily Wear Ortho-K (tisilfocon A) Corneo-Scleral Lens** is 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.

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 **NewVision SC (tisilfocon A) Scleral Lens** is 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 **NewVision SC (tisilfocon A) Scleral Lens** is 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 **NewVision SC (tisilfocon A) Scleral Lens** 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 **NewVision SC and NewVision SC Daily Wear Ortho-K (tisilfocon A) Lenses** are substantially equivalent to the Optimum Infinite (tisilfocon A) Daily Wear Contact Lenses (predicate device - K212631) in the following areas:

- FDA material group – group # 3 fluoro silicone acrylate
  Components/Materials/Formulation (tisilfocon A)
- Product code (HQD, MUW)
- Classification (Class II) – Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)
- Indications for use (therapeutic – irregular cornea and ocular surface disease, orthokeratology)
- Lathe cut manufacturing process
- Scleral (large diameter) design
- Actions and intended use

The following table depicts the classification and technical characteristics of the **NewVision SC and NewVision SC Daily Wear Ortho-K (tisilfocon A) Lenses** in comparison with the predicate devices.

	NewVision SC and NewVision SC Daily Wear Ortho-K	**Optimum Infinite Daily Wear Contact Lenses**
	Subject Device	***Predicate Device***
510(k) Number		K212631
Intended Use	Daily Wear	Daily Wear
Device and Classification	Class II Lenses, Rigid Gas Permeable, Daily Wear	Class II Lenses, Rigid Gas Permeable, Daily Wear
Product Code	HQD; MUW	HQD; MUW
Production Method	Lathe-cut	Lathe-cut
Material (USAN)	Tisilfocon A	Tisilfocon A
FDA Group #	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate
Water Content	<1%	<1%
UV Absorber/Blocker available	YES	YES
Lens Designs	Large Diameter (Irregular Cornea) Large Diameter (Ocular Surface Disease) Daily Orthok (Corneo-Scleral)	Large Diameter (Irregular Cornea) Large Diameter (Ocular Surface Disease) Daily Orthok (Corneal) Spherical Toric Multifocal/Bifocal

	Indications for Use
NewVision SC and NewVision SC Daily Wear Ortho-K (Subject Device)	The **NewVision SC Daily Wear Ortho-K (tisilfocon A) Corneo-Scleral Lens** is 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. 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 **NewVision SC (tisilfocon A) Scleral Lens** is 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 **NewVision SC (tisilfocon A) Scleral Lens** is 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 **NewVision SC (tisilfocon A) Scleral Lens** 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.
Optimum Infinite Daily Wear Contact Lenses (Predicate Device: 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 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: 4. cannot be adequately corrected with spectacle lenses 5. requires a rigid gas permeable contact lens surface to improve vision 6. 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.

VII. PERFORMANCE DATA

~ Non-Clinical Studies ~

Non-clinical testing to demonstrate the safety and effectiveness of contact lenses manufactured from tisilfocon A has been addressed by reference to previous 510(k) clearances.

Additionally, the following testing was performed on finished **NewVision SC and NewVision SC Daily Wear Ortho-K (tisilfocon A) Lenses**:

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

Bioburden Testing—bioburden testing conducted on rigid gas permeable lenses manufactured at Acculens, Inc. demonstrated that the colony forming units (CFU) per lens was within the established acceptance criteria of less than 100 CFU per lens.

~ Clinical Studies ~

Clinical testing to demonstrate the safety and effectiveness of contact lenses manufactured from tisilfocon A with the labeled indications for use has been addressed through previous 510(k) clearances.

~ Conclusions Drawn from Testing ~

Results from testing and other information presented in this premarket notification supports the substantial equivalence claim by demonstrating no relevant differences regarding the safety and effectiveness of the **NewVision SC and NewVision SC Daily Wear Ortho-K (tisilfocon A) Lenses** compared to the predicate devices.

VIII. CONCLUSIONS

Substantial Equivalence

Information presented in this premarket notification establishes that **NewVision SC and NewVision SC Daily Wear Ortho-K (tisilfocon A) Lenses** for daily wear are as safe and effective as the predicate device 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.