October 25, 2024

Bruno Vision Care, LLC
% Christina Kuhn
Special Counsel
Covington & Burling LLP
850 10th St NW
Washington, DC 20001

Re: K240918
Trade/Device Name: Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens with UV Blocking for Myopia and Hyperopia; Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens with UV Blocking for Astigmatism
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: September 24, 2024
Received: September 25, 2024

Dear Christina Kuhn:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240918

Device Name

Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens with UV Blocking for Myopia and Hyperopia;
Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens with UV Blocking for Astigmatism

Indications for Use *(Describe)*

The Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens with UV Blocking for Myopia and Hyperopia is indicated for daily disposable wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may have 1.00D or less of astigmatism.

Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens with UV Blocking for Astigmatism is indicated for daily disposable wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may have 4.00D or less of astigmatism

The Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens with UV Blocking lenses are to be prescribed for single-use disposable wear, and are to be discarded after each removal.

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.

510(k) Summary

510(k) Number: **K240918**

Date Prepared: October 21, 2024

Submitter:

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Device:

Trade/Proprietary Name:	Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens with UV Blocking for Myopia and Hyperopia; Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens with UV Blocking for Astigmatism
Common Name:	Soft, daily wear contact lens
Classification Name:	Soft (Hydrophilic) Contact Lens
Device Classification:	21 CFR 886.5925
Regulatory Class:	Class II
Product Code:	LPL, MVN
Panel:	Ophthalmic
Predicate Device:	K051900 Vistakon (etafilcon A) soft (Hydrophilic) Contact Lens Clear and Tinted Product Code: LPL
Reference Device:	K090806 Safi-Gel (methafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lens Product Code: LPL

Description of Device:

The Deseyne (vifilcon C) Daily Disposable Soft (hydrophililic) Contact Lenses with UV Blocking are manufactured in spherical or toric configurations. The lens material, vifilcon C is a hydrophilic polymer of 2-hydroxyethyl methacrylate, methacrylic acid and n-vinyl-2-pyrrolidone (NVP) crosslinked with ethylene glycol dimethacrylate (EGDMA) and using

azobisisobutyronitrile (AIBN) as the initiator. A UV absorbing monomer, 2-[3-(2H- Benzotriazol-2yl)-4-hydroxyphenyl] ethyl methacrylate, is incorporated into the lens polymer and used to block UV radiation. The lens contains 60% water by weight in a saline solution containing hyaluronic acid and TSP (Tamarind Seed Polysaccharide) polymers. The lens is visibility tinted using Pigment Blue 15 (Copper phthalocyanine) to make the lens more visible for handling.

Indications for Use:

The Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens with UV Blocking for Myopia and Hyperopia is indicated for daily disposable wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may have 1.00D or less of astigmatism.

Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens with UV Blocking for Astigmatism is indicated for daily disposable wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or a.phakic persons with non- diseased eyes that may have 4.00D or less of astigmatism.

The Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens with UV Blocking lenses are to be prescribed for single-use disposable wear, and are to be discarded after each removal.

Material Properties:

The Deseyne (vifilcon C) Daily Disposable Soft (hydrophililic) Contact Lenses with UV Blocking for Myopia and Hyperopia has the following optical characteristics:

Powers:	From -20.00D to +20.00D
Cylinder:	none
Axis:	none
Base Curve:	8.60
Diameter:	14.10
Center Thickness:	0.05
Optic Zone:	10.00

The Deseyne (vifilcon C) Daily Disposable Soft (hydrophililic) Contact Lenses with UV Blocking for Astigmatism has the following optical characteristics:

Powers:	From -20.00D to +20.00D
Cylinder:	From -1.00D to -3.50D
Axis:	From 5° to 180° with 5° step
Base Curve:	8.50
Diameter:	14.40
Center Thickness:	0.08
Optic Zone:	8.00

The tolerances for the above optical characteristics are as follows:

Powers:	0.00 D ~ ± 10 D, ± 0.25 D ± 10.12 D ~ ± 20 D, ± 0.50 D
Base Curve:	± 0.20 mm Diameter: ± 0.20 mm

Center Thickness: ± 0.010 mm + 10%
Surface Appearance: No Surface Defect, No Edge Defect, No Bubble

The physical properties of the lenses are:

Refractive Index: 1.403
Light Transmittance: >90%
UV Transmittance: τUVB <0.05τV
τUVA <0.50τV
Oxygen Permeability: 27.5×10-11 (cm2/s) [mL O2 / (mL mmHg)]
Water Content: 60%

Substantial Equivalence Comparison:

Intended Use: The indications for use for the subject device and predicate device are similar and within the same intended use for the correction of hyperopia, myopia and astigmatism.

Technological Comparison: The differences in technological characteristics, including the different lens material and difference in wetting agent, do not raise different questions of safety and effectiveness. The safety and effectiveness of the lens material was demonstrated in a clinical study and through biocompatbility testing.

Characteristics	**Subject Device: Deseyne (vifilcon C) Soft (hydrophilic) Contact Lens**	**Predicate Device: Vistakon (etafilcon A) Soft (hydrophilic) Contact Lens (clear and tinted (visibility tint) with UV Blocker for Daily Wear**	**Reference Device: Safi-gel Daily Disposable (methafilcon A) Soft (hydrophilic) Contact Lens**
510(k) Number		K051900	K090806
FDA Group	Group IV >50% water	Group IV >50% water	Group IV >50% water
Indication	Daily Disposable	Daily Wear	Daily Disposable
Surface Character	Ionic	Ionic	Ionic
USAN Name	vifilcon C	etafilcon A	methafilcon A
Water Content	60%	58%	55%
Refractive Index	1.403	1.40	1.41
Oxygen Permeability	27.5 X 10-11 Dk-Fatt Method (cm2/ sec)* (ml O2/ ml*mmHg)	28.0 x 10-11 Dk-Fatt Method (cm2/sec)* (ml O2/ ml*mmHg)	18.9 X 10-11 Coulometric@35 degree C
Wetting Agent	Hyaluronic Acid (HA) and TSP co- polymer		Hyaluronic Acid (HA)

Characteristics	Subject Device: Deseyne (vifilcon C) Soft (hydrophilic) Contact Lens	Predicate Device: Vistakon (etafilcon A) Soft (hydrophilic) Contact Lens (clear and tinted (visibility tint) with UV Blocker for Daily Wear	Reference Device: Safi-gel Daily Disposable (methafilcon A) Soft (hydrophilic) Contact Lens
Light Transmittance	>90%	Minimum 85%	90.3%
Base Curve	8.5mm	7.85mm to 10.0mm	8.40mm-9.3mm
Diameter	14.10mm to 14.4mm	12.0mm to 15.0mm	14.0mm to 15.0mm
Center Thickness	0.05mm to 0.08mm	0.06mm to 1.00mm	0.06mm to 0.40mm
Powers	-20.00D to +20.00D	-20.00D to +20.00D	-20.00D to +12.00D
UV Transmittance	UVB: <0.05tV UVA: <0.50tV	<5%UVB (280-315mm) <30%UVA (20-385mm)	9.3% UVB
Package Storage Sale Solultion	0.10% HA and 0.05% TSP in normal saline	Borate buffered salne w/ povidone	0.2% HA co-polymer in normal saline

List of Applicable ISO Standards

- ISO 10993-1: 2009. Biological Evaluation of Medical Devices- Part 1: Evaluation and testing within a risk management process
- ISO 10993-5: 2009. Biological Evaluation of Medical Devices- Part 5: Tests for in-vitro cytotoxicity.
- ISO 10993-10: 2010. Biological Evaluation of Medical Devices- Part 10: Tests for irritation and skin sensitization.
- ISO 10993-11: 2006. Biological Evaluation of Medical Devices- Part 11: Tests for Systemic Toxicity
- ISO 10993-12: 2012. Biological Evaluation of Medical Devices- Part 12: Sample preparation and reference materials.
- ISO 10993-23: 2021. Biological Evaluation of Medical Devices- Part 23: Test for Acute Ocular Irritation.
- ISO 11987-2012: Ophthalmic Optics-Contact Lenses: Determination of Shelf Life.
- ISO 17665-1: 2006. Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
- ISO 18369-2: 2006. Ophthalmic Optics-Contact lenses-Part 2: Tolerances.
- ISO 18369-3: 2006. Ophthalmic Optics-Contact lenses-Part 3: Measurement methods
- ISO 18369-4: 2006. Ophthalmic Optics-Contact lenses- Part 4: physicochemical

properties of contact lens materials

Summary of Non-Clinical Testing Data

Bench Testing:

- Physico-Chemical Properties
- Finished Lens Parameters
- Transmittance
- Refractive Index
- Water Content
- Oxygen Permeability
- Extractables
- Mechanical properties (Modulus, Tesnile Strength, Elongation, Toughness)
- Leachables
- Specific Gravity

Reference to all material testing listed above pertains to the following ISO Standards and meet or exceed all properties and tolerances associated with each test conducted.

- ISO 18369-2 Ophthalmic Optics-Contact lenses-Part 2: Tolerances.
- ISO 18369-3 Ophthalmic Optics-Contact lenses-Part 3: Measurement methods
- ISO 18369-4 Ophthalmic Optics-Contact lenses- Part 4: physicochemical properties of contact lens materials

Biocompatibility Testing on Deseyne (vifilcon C) Daily Disposable Contact Lens:

- Ocular Irritation: Acute occular irritation testing was performend in accordance with ISO-10993-23:2021 on extracts from finished lenses, which produced no evidence of ocular irritation.
- In Vitro Cytotoxicity: Cytotoxicity testing was performed in accordance with ISO-10993-5:2009 and the results indicated that the finished lenses are not cytotoxic.
- Systemic Injection: The finished lenses meet the requirements of the systemic injection test in accordance with ISO 10993-11. The extracts from finished lenses produced no evidence of systemic toxicity.Sensitization: Sensitization testing was performed in accordance with ISO 10993-10:2010 and the finished lenses were demonstrated to be not sensitizing.

Biocompatibility Testing on Storage Solution:

- Ocular Irritation: Acute occular irritation testing was performed in accordance with ISO-10993-23:2021 on the neat storage solution, which produced no evidence of ocular irritation.
- In Vitro Cytotoxicity: Cytotoxicity testing was performed in accordance with ISO-10993-5:2009 and the results indicated that the neat storage solution is not cytotoxic.
- Sensitization: Sensitization testing was performed in accordance with ISO 10993-10:2017 and the storage solution was demonstrated to be not sensitizing.

Biocompatibility Testing for the Primary Packaging Material:

- The primary packing material (blister and foil) is identical to the primary packaging material (blister and foil) used in the reference device K090806 in formulation, processing, manufacturing and sterilization. K090806 is held by Safilens S.R.L, the

parent company for Bruno Vision Care LLC.

Clinical Testing

A 3-month multi-arm (2), randomized, un-masked, active control study was conducted on the test material, the Deseyne (vifilcon C) daily disposable soft (hydrophilic) contact lens in comparison to a daily disposable control soft (hydrophilic) contact lens. The study was conducted at five (5) clinical sites, all in the United States.

The objective of this clinical study was to provide clinical performance data comparing the test lens (Deseyne [vifilcon C] daily disposable soft contact lens) to a control lens (1-Day Acuvue® Moist® [etafilcon A] daily disposable soft contact lens) in the same indication for use (single use prior to removal followed by a fresh lens upon the next lens wear exposure).

Study participation was 90 days in duration and consisted of 81 subjects assigned in a 2:1 ratio to test or control lens bilaterally, respectively. Subjects selected were healthy male or female between the ages of 18-40, and exhibited myopia between -1.00 diopter (D) and -6.00 D and astigmatism no greater than 1.00 D that did not interfere with visual acuity (VA).

There were 2 primary effectiveness endpoints for the study:

1. Change from baseline to each post-baseline visit in distance logMAR VA by eye.
2. Number and percentage of subjects, where there was no more than a -5logMAR letters read loss from baseline (change from baseline in number of letters read ≥ -5-logMAR).

The Primary Effectiveness Endpoints were met in accordance with the parameters outlined in the protocol.

Secondary effectiveness endpoints were symptoms/complaints and subjective assessments; lens wettability, centration, and movement; and lens deposits and a visual function satisfaction survey.

Primary safety evaluation was addressed by the proportion of eyes with any slit lamp findings. Secondary safety endpoints included adverse reactions (serious and incidental) and adverse device effects, including conjunctival hyperemia, keratometry, slit lamp biomicroscopy, lens discontinuation rates at any follow-up visit, and use of unpreserved lubricant eyedrops or artificial tears during the study.

At no time during the study was there any loss of vision of 2 or more lines of vision. There were three adverse reactions attributed to the use of the control lenses, none to the test lens, All subjects completed the study with VA within one line of initial visual acuity.

There were a total of 3 discontinuations out of 81 subjects who were enrolled in the protocol. 78 subjects completed the clinical trial. Of the 3 discontinuations during tthe study one subject preferred habitual lenses, one-subject for poor lens movement and centration at the fitting visit, and one subject for voluntary withdrawal at the screening visit. Each of these discontinuations were from the Control Group. There were no discontinuations associated with findings related to safety or for visual acuity.

There were 4 reports of excessive use of lens lubrication that were attributed to prior sensitivities or dry eye; all with the test lens, none with the control lens. Nevertheless, there

were no associated findings with slit lamp biomicrosopy, or notations of red-eye. Low levels of hyperemia resolved and all subjects with these findings completed the protocol successfully.

The Primary Safety Endpoints were met in accordance with the definitions of the protocol.

Patient Accountability:

Stage	Investigational Device Arm Total	Control Arm Total	Total
Enrollment	53	28	81
Treatment	53	25	78
Primary Safety Endpoint Analysis	53	25	78
Primary Effectiveness Endpoint Analysis	53	25	78

Conclusions:

Evaluations of non-clinical and clinical tests demonstrate that the subject device-the Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens is as safe, as effective, and performs as well as or better that the legally marketed device identified in the protocol and study.

Summary of Substantial Equivalence:

The Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) contact lens is substantially equivalent to the predicate 1-Day (etafilcon A) Daily Disposable Soft (hydrophilic) contact lens as both devices have the same intended use, same indications for use (daily disposable lenses), are both defined in the same lens classification group (Group IV, high water, ionic surface characteristic), are both polyhema materials of similar water content and material primary polymers. The principal difference is the water content (Deseyne-60%, 1-Day Acuvue-58%, however considered similar enough to demonstrate similar physio-chemical and material characteristics. The clinical performance demonstrated substantial equivalence in primary and secondary outcomes. In conclusion, substantial equivalence of the subject lens has been established when compared to the predicate device.