



December 23, 2025

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

Re: K251683

Trade/Device Name: Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens for Presbyopia with Extended Depth of Focus (EDOF)

Regulation Number: 21 CFR 886.5925

Regulation Name: Soft (hydrophilic) contact lens

Regulatory Class: Class II

Product Code: LPL, MVN

Dated: November 21, 2025

Received: November 21, 2025

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 CFR 830.300(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

OHT1: Office of Ophthalmic, Anesthesia,

Respiratory, ENT, and Dental Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known)
K251683

Device Name

Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens for Presbyopia with Extended Depth of Focus (EDOF)

Indications for Use (Describe)

Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens for Presbyopia with Extended Depth of Focus (EDOF) is indicated for the optical correction of refractive ametropia (myopia and hyperopia) in presbyopic phakic and aphakic persons with non-diseased eyes who exhibit 1.00D or less of astigmatism that does not interfere with visual acuity. The lens mitigates the effects of presbyopia by providing an Extended Depth of Focus (EDOF).

Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens for Presbyopia with Extended Depth of Focus (EDOF) is 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**510(k) Summary
K251683**

Date: December 22, 2025

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Contact Person: Christina Kuhn
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Device: Soft (Hydrophilic) Contact Lens

Trade/Proprietary Name: Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens for Presbyopia with Extended Depth of Focus (EDOF)

Classification Name: Soft (hydrophilic) Contact Lens
Common Name: Soft Contact Lenses, Daily Wear
Device Classification: 21CFR 886.5925
Regulatory Class: Class II
Product Code: LPL, MVN
Panel: Ophthalmic

Purpose of 510(k): Traditional (Original)

Predicate Devices: K240918, Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens with UV Blocking for Myopia and Hyperopia

Description of Device: Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens for Presbyopia with Extended Depth of Focus (EDOF) 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.

The anterior surface of the contact lens is designed with a spherical geometry across the optical zone. The lens includes a centrally located zone with a diameter of 1.0 mm and a dome-shaped profile. This central zone allows the transmission of light but is not intended to focus light to produce distinct retinal images. The curvature of the central zone is steeper than that of the surrounding optical power zone and is designed to provide a power difference relative to the base spherical power of at least +6.00 diopters. The central, functional optically inactive zone is intended to increase the depth of focus for the wearer.

Indications for Use:

Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens for Presbyopia with Extended Depth of Focus (EDOF) is indicated for the optical correction of refractive ametropia (myopia and hyperopia) in presbyopic phakic and aphakic persons with non-diseased eyes who exhibit 1.00D or less of astigmatism that does not interfere with visual acuity. The lens mitigates the effects of presbyopia by providing an Extended Depth of Focus (EDOF).

Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens for Presbyopia with Extended Depth of Focus (EDOF) is to be prescribed for single-use disposable wear and are to be discarded after each removal.

Material Properties:

The device has the following optical characteristics:

Powers:	-0.00D to -6.00D (0.25D increments) -6.50D to -10.00D (0.50D increments) +0.25D to +4.00D (0.25D increments) +4.50D to +8.00D (0.50D increments)
Cylinder:	None
Axis:	None
Base Curve:	8.60mm
Diameter:	14.10mm
Central Zone Radius:	0.5mm
Central Zone Power Difference:	8.0D
Center Thickness:	0.07mm

The manufacturing tolerances for the above optical characteristics are as follows:

Powers:	$\pm 0.25D$ for powers from 0.00D to $\pm 10D$
Base Curve:	$\pm 0.20mm$
Diameter:	$\pm 0.20mm$
Central Zone Radius:	$\pm 0.10mm$
Central Zone Power Difference:	$\geq 6.00D$
Center Thickness:	$\pm 0.010 mm$

The physical properties of the lenses are:

Refractive Index:	1.403
Light Transmittance:	>90%
UV Transmittance:	$\tau_{UVB} < 0.05\tau_V$ $\tau_{UVA} < 0.50\tau_V$
Oxygen Permeability:	$27.5 \times 10^{-11} (cm^2/s)$ [mL O ₂ / (mL mmHg)]
Water Content:	60%

Substantial Equivalence Comparison:

The indications for use for the subject device and predicate device are similar and within the same intended use for the correction of hyperopia and myopia.

The only difference in technological characteristics from the predicate device is the different lens design for presbyopia, which does not raise different questions of safety and effectiveness. The safety and effectiveness of the lens design was demonstrated in a clinical study.

Characteristics	Subject Device: Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens for Presbyopia with Extended Depth of Focus (EDOF)	Predicate Device: Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens with UV Blocking or Myopia and Hyperopia (K240918)
FDA Group	Group IV >50% water	Group IV >50% water
Indication	Daily Disposable	Daily Disposable
Surface Character	Ionic	Ionic
USAN Name	vifilcon C	vifilcon C
Water Content	60%	60%
Refractive Index	1.403	1.403

Characteristics	Subject Device: Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens for Presbyopia with Extended Depth of Focus (EDOF)	Predicate Device: Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens with UV Blocking or Myopia and Hyperopia (K240918)
Oxygen Permeability	27.5 X 10 ⁻¹¹ Dk-Fatt Method (cm ² / sec)* (ml O ₂ / ml*mmHg)	27.5 X 10 ⁻¹¹ Dk-Fatt Method (cm ² / sec)* (ml O ₂ / ml*mmHg)
Wetting Agent	Hyaluronic Acid (HA) and TSP co-polymer	Hyaluronic Acid (HA) and TSP co-polymer
Light Transmittance	>90%	>90%
Base Curve	8.6mm	8.6mm
Diameter	14.10mm	14.10mm
Central Zone Radius	0.5mm	N/A
Central Zone Power Difference	8.0D	N/A
Center Thickness	0.07mm	0.05mm
Powers	-0.00D to -6.00D -6.50D to -10.00D +0.25D to +4.00D +4.50D to +8.00D	-20.00D to +20.00D
UV Transmittance	UVB: <0.05tV UVA: <0.50tV	UVB: <0.05tV UVA: <0.50tV
Package Storage Solution	0.10% HA and 0.05% TSP in normal saline	0.10% HA and 0.05% TSP in normal saline

Summary of Non-Clinical Testing

Bench Testing was provided that demonstrates the Finished Lens Parameters, Transmittance, Refractive Index, Water Content, Oxygen Permeability and Mechanical Properties (Modulus, Tensile Strength, Elongation, Toughness). This testing followed the below ISO Standards and meet or exceed all properties and tolerances associated with each test conducted.

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

As the subject device has the same lens material, packaging solution and packaging material as

the predicate device, there are no changes in formulation, processing, sterilization, and no other chemicals have been added, and per recommendations of Attachment F of FDA’s 2023 Biocompatibility Guidance “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process’” (<https://www.fda.gov/media/142959/download>), biocompatibility testing on the subject device (i.e., contact lens, wetting agent/packaging solution, packaging materials-blister and foil) is not required.

Clinical Testing

A multi-center, randomized, active-controlled, double-masked, crossover study design was used to evaluate the clinical performance of the subject lens. The study compared the Deseayne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens for Presbyopia with Extended Depth of Focus (EDOF) to a control lens (1-Day Acuvue® Moist® [etafilcon A] daily disposable soft contact lens for single vision). The study was a 1-day crossover study and consisted of 78 subjects (78 study eyes [all study eyes were right eyes]) randomly assigned in-office to wear the investigational lens or the control lens first. A 30-minute washout period was scheduled before the crossover. The study was conducted at three sites within the United States.

The primary effectiveness endpoint was the monocular (study [right] eye only) photopic negative lens-induced distance-corrected depth of focus (DOF) at the 0.2 logMAR (Snellen equivalent 20/32) visual acuity (VA) threshold. This study met its primary effectiveness endpoint, showing a statistically significant improvement for the subject device lenses in photopic negative lens-induced distance-corrected DOF in the study eye compared with the control lenses by more than 0.5 D (-0.78 [-0.93, -0.63] D; p=0.0002).

The secondary effectiveness endpoints were mean monocular photopic distance-corrected intermediate VA (DCIVA) at 66 cm and mean monocular photopic distance-corrected near VA (DCNVA) at 40 cm, as shown in the table below.

		Investigational Lens	Control Lens
Photopic DCIVA at 66 cm in the study eye	Mean:	0.015 logMAR (20/20)	0.158 logMAR (20/29)
	Standard Deviation:	0.114 logMAR	0.136 logMAR
Photopic DCNVA at 40 cm in the study eye	Mean:	0.196 logMAR (20/31)	0.353 logMAR (20/45)
	Standard Deviation:	0.115 logMAR	0.171 logMAR

The primary safety endpoint was all adverse events (AEs). No AEs were reported in the study.

There was 1 discontinuation (voluntary withdrawal out of 78 subjects who were enrolled in the protocol; 77 subjects completed the clinical trial and were included in the analysis of the primary endpoints, as shown in the table below.

Stage	Investigational Lens First	Control Lens First	Total
Randomized Subjects	40	38	78
Completed Study	40	37	77
Discontinued Early	0	1	1
Primary Safety Endpoint Analysis	40	38	78
Primary Effectiveness Endpoint Analysis	40	38	78

Conclusions:

Evaluations of non-clinical and clinical tests demonstrate that the subject device-the Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens for Presbyopia (EDOF) is as safe and effective as the predicate device

Summary of Substantial Equivalence:

The Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) Contact Lens for Presbyopia with Extended Depth of Focus (EDOF) is substantially equivalent to the predicate Deseyne (vifilcon C) Daily Disposable Soft (hydrophilic) contact lens as both devices have similar indications for use as daily disposable lenses and the same intended use (correction of refractive ametropia (myopia and hyperopia), are both defined in the same lens classification group (Group IV, high water, ionic surface characteristic), and are both polyhema materials with the same water content and material primary polymers. The principal difference is the addition of the presbyopic design of the subject device. Otherwise, the subject device and predicate device are equivalent in all other respects. The clinical performance testing demonstrated a statistically significant increase in negative lens-induced depth of focus of 0.78D as compared to the control lens. Adequate information was given to demonstrate substantial equivalence to the predicate device.