May 24, 2021

Bausch + Lomb Incorporated
Barbara Klube-Falso
Director, Regulatory Affairs
1400 North Goodman Street
Rochester, NY 14609

Re: K210975
Trade/Device Name: Bausch + Lomb (kalifilcon A) Soft (hydrophilic) Contact Lens for Presbyopia
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: March 30, 2021
Received: April 1, 2021

Dear Barbara Klube-Falso:

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)*
K210975

Device Name
Bausch + Lomb (kalifilcon A) Soft (hydrophilic) Contact Lens for Presbyopia

Indications for Use *(Describe)*
Bausch + Lomb (kalifilcon A) Soft (hydrophilic) Contact Lens for Presbyopia is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic and/or non-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D with add powers ranging from +0.75D to +5.00D.

The lens is to be prescribed for single-use disposable wear, and is 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K210975

510(k) Summary

Submitter Information:

Date Prepared:	May 14, 2021
Name:	Bausch & Lomb Incorporated
Address:	1400 North Goodman Street Rochester, NY 14609
Contact Person:	Barbara Klube-Falso Director, Regulatory Affairs
Phone Number:	(585) 338-8503 (585) 338-0702 (fax)
Email:	barbara.klube-falso@bausch.com

Device Information:

Trade Names:	Bausch + Lomb (kalifilcon A) Soft (hydrophilic) Contact Lens for Presbyopia
Common Name:	Soft daily disposable contact lens
Classification Name:	Soft (hydrophilic) contact lens (21 CFR 886.5925)
Device Classification:	Class II
Product Code:	LPL, MVN

Predicate Devices:

- Bausch + Lomb kalifilcon A Contact Lens (K200528) cleared on June 2, 2020.
- Bausch + Lomb Biotrue ONEday for Presbyopia (nesofilcon A) Soft (Hydrophilic) Contact Lens (K132715) cleared on December 20, 2013.

Device Description:

The Bausch + Lomb kalifilcon A material is made from a hydrophilic siloxane copolymer of 2-hydroxyethyl methacrylate and N-vinyl pyrrolidone and is 55% water by weight when immersed in a sterile phosphate buffered saline solution with poloxamine, poloxamer 181, glycerin, and erythritol. A UV-absorbing monomer is used to block UV radiation. The transmittance

characteristics are less than 5% in the UVB range of 280nm to 315nm and less than 50% in the UVA range of 316nm to 380nm. This lens is tinted blue with Reactive Blue Dye 246.

The physical properties of the lens are:

Refractive index	1.4011
Light transmission	97%
Water Content	55%
Specific Gravity	1.029
Oxygen Permeability	107 x 10^{-11}[cm^3O_2(STP) x cm]/(sec x cm^2 x mmHg)@35°C (polarographic method)

The multifocal lenses will be manufactured with the following parameters:

Diameter	13.5mm to 15.0mm
Center Thickness	0.05mm to 0.75mm
Base Curve	7.8mm to 9.5mm
Power Range	+20.00D to -20.00D
Add Power (Multifocal)	+0.75D to +5.00D

The lenses are packaged in disposable blister packages containing phosphate buffered saline solution. Blister packages are labeled with lot number, expiration date and applicable lens parameters. Expiration dating is supported by product stability, package integrity, and validation of the sterilization process.

Intended Use:

Bausch + Lomb (kalifilcon A) Soft (hydrophilic) Contact Lens for Presbyopia is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic and/or non-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D with add powers ranging from +0.75D to +5.00D.

The lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal.

Table 1: Technological Characteristics (comparison to predicate device)

A side-by-side comparison of the predicate devices to the new device:

Property	**Predicate Device** Bausch + Lomb kalifilcon A Contact Lens **K200528**	**Predicate Device** Bausch + Lomb Biotrue® ONEday for Presbyopia (nesofilcon A) Contact Lens **K132715**	**Subject Device** Bausch + Lomb (kalifilcon A) Soft (hydrophilic) Contact Lens for Presbyopia **K210975**
Functionality	The contact lens acts as a refractive medium that focus light rays from near and distant objects on the retina.	Same	Same
Lens Design	Spherical and Toric	Multifocal	Same Multifocal (K132715)
Indications for Use	Kalifilcon A Contact Lens: Indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or non-aphakic persons with non-diseased eyes that exhibit refractive astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D. Kalifilcon A Contact Lens for Astigmatism: Indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes, exhibiting astigmatism of up to 5.00 diopters. The lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal. Not Indicated for Multifocal	Indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens provides a power range of +20.00 to -20.00 diopters with add power ranging from +0.75D to +5.00D. The lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal.	Indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic and/or non-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D with add powers ranging from +0.75D to +5.00D. The lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal.
Modality	Daily Disposable	Same	Same
Manufacturing Method	Cast Molded	Same	Same

Material Group	Group 5-B Silicone Hydrogel (high water, non-ionic)	Group II (high water, no ionic polymers)	Same Group 5-B (K200528)
USAN Name	Kalifilcon A	Nesofilcon A	Same Kalifilcon A (K200528)
Water Content	55%	78%	Same 55% (K200528)
UV Blocker	Yes	Same	Same
Sterilization	Air Over Steam	Same	Same
Packaging	Polypropylene blister with plastic coated aluminium foil blister	Same	Same
Packaging Solution	Phosphate Buffered Saline	Borate Buffered Saline	Same Phosphate Buffered Saline (K200528)

Summary of Non-Clinical Performance Data:

The testing performed on the Bausch + Lomb kalifilcon A Contact Lens demonstrated that the device functions in a safe and effective manner. Performance testing included conformance to predetermined specifications, functional test results verify that the device performs as expected and is equivalent to the predicate without creating additional risk to the user.

In addition, Bausch + Lomb followed the *Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses,* May 1994, the following tests were conducted:

Toxicology / Biocompatibility

In-Vitro Cytotoxicity

Ocular Irritation Study

Systemic Toxicity

Chemistry / Leachables

Physical, Chemical and Spectral Properties

Leachable Monomer and Additives

The testing performed on the predicate device, Bausch + Lomb kalifilcon A contact lens, K200528, demonstrated that the device functions in a safe and effective manner. The subject device is of the identical lens material, manufacturing process, sterilization process, and packaging as the predicate device, and the finished lens parameters fall within the ranges previously cleared for the predicate device and therefore the previous testing is fully applicable.

Summary of Clinical Performance Data

Clinical performance data to confirm safety and effectiveness of the kalifilcon A lens material was obtained and provided in K200528. Because the subject device is of the identical lens material, kalifilcon A, the clinical study performed on the predicate device is applicable and no additional clinical study was performed.

Substantial Equivalence Conclusion:

The information submitted in this premarket notification supports the determination that the Bausch + Lomb (kalifilcon A) Soft (hydrophilic) Contact Lens for Presbyopia is substantially equivalent in principles of operation, technology, materials and indications for use to the predicate devices listed above.