June 02, 2020

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

Re: K200528
Trade/Device Name: Bausch + Lomb (kalifilcon A) Soft (hydrophilic) Contact Lens
Bausch + Lomb (kalifilcon A) Soft (hydrophilic) Contact Lens for Astigmatism
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: May 4, 2020
Received: May 6, 2020

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200528

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

Indications for Use *(Describe)*

Kalifilcon A Contact Lens

Bausch + Lomb kalifilcon A Contact Lens is indicated for the daily wear 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

Bausch + Lomb kalifilcon A Contact Lens for Astigmatism is indicated for the daily wear 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.

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
K200528

Submitter Information:

Date Prepared:	May 4, 2020
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
Email:	Barbara.Klube-Falso@bausch.com

Device Information:

Trade Name:	Bausch + Lomb (kalifilcon A) Soft (hydrophilic) Contact Lens Bausch + Lomb (kalifilcon A) Soft (hydrophilic) Contact Lens for Astigmatism
Regulation Name:	Soft (hydrophilic) Contact Lens
Device Classification:	Class II (21 CFR 886.5925)

Predicate Device:

Bausch + Lomb kalifilcon A Contact Lens is substantially equivalent to the following predicate device:

Bausch + Lomb Biotrue ONEday (nesofilcon A) Contact Lens cleared under K113703.

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 with 0.5% poloxamine solution. 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 Bausch + Lomb kalifilcon A Contact Lens is to be prescribed for single-use disposable wear.

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 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
Cylinder Power (Toric)	-0.75D to -5.00D
Cylinder Axis	0^o to 180^0

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:

Kalifilcon A Contact Lens
Bausch + Lomb kalifilcon A Contact Lens is indicated for the daily wear 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
Bausch + Lomb kalifilcon A Contact Lens for Astigmatism is indicated for the daily wear 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 kalifilcon A contact lens is to be prescribed for single-use disposable wear and is to be discarded after each removal.

Technological Characteristics (comparison to predicate devices)

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

Property	**Predicate Device** Bausch + Lomb Biotrue ONEday (nesofilcon A) Contact Lens	**Subject Device** Bausch + Lomb kalifilcon A Contact Lens
Intended Use	Indicated for the daily wear correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes that exhibit refractive astigmatism up to 2.00 diopters or less, that does not interfere with visual acuity. The lens is to be prescribed for single-use disposable wear and is to be discarded after each removal.	Same as predicate
Functionality	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	Same as predicate
Modality	Daily wear contact lens	Same as predicate
Manufacturing Method	Cast Molded	Same as predicate
Material Group	Group II Hydrogel (high water, non-ionic)	Group 5-B Silicone Hydrogel (high water, non-ionic)
USAN Name	nesofilcon A	kalifilcon A
Water Content	78%	55%
Oxygen Permeability[1] (edge corrected)	42	107
Specific Gravity	1.039	1.029
UV Blocker	Yes	Yes

[1]- Oxygen Permeability shown was determined by the polarographic method:
x 10^{-11}[cm^3O_2(STP) x cm]/(sec x cm^2 x mmHg)@35°C

Summary of Non-Clinical Testing:

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

Summary of Clinical Performance Data

Bausch + Lomb conducted a 3 month, controlled clinical study with approximately 247 patients, comparing the safety and efficacy of the Bausch + Lomb kalifilcon A Contact Lens to the Bausch + Lomb Biotrue ONEday (nesofilcon A) Contact Lens.

The primary safety endpoint was any slit lamp finding greater than Grade 2 over the course of the study. the primary efficacy endpoint was contact lens corrected distance high-contrast visual acuity averaged over all scheduled visits. All primary endpoints were achieved, and the results of the study indicate the test lens is safe and effective.

Substantial Equivalence Conclusion:

The cumulative results of laboratory, *in vitro, in vivo* testing as well as the clinical study sponsored by Bausch + Lomb demonstrate that the safety, effectiveness and performance of the Bausch + Lomb kalifilcon A Contact Lens are substantially equivalent to the Bausch + Lomb Biotrue ONEday (nesofilcon A) Contact Lens.