November 17, 2023

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

Re: K230954
Trade/Device Name: Samfilcon B Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: October 12, 2023
Received: October 13, 2023

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 (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.

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

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)*
K230954

Device Name
samfilcon B

Indications for Use *(Describe)*

Samfilcon B Contact Lens:
Bausch + Lomb Samfilcon B Contact Lens for daily wear is indicated for the correction of refractive ametropia (myopia or hyperopia) in aphakic and not aphakic persons with non-diseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of 1.50 diopters or less where the astigmatism does not interfere with visual acuity.

Samfilcon B Contact Lens for Astigmatism:
Bausch + Lomb Samfilcon B Contact Lens for Astigmatism for daily wear is indicated for the correction of refractive ametropia (myopia, hyperopia and/or astigmatism) in aphakic and not aphakic persons with non-diseased eyes with refractive astigmatism not exceeding 10.00 diopters.

Samfilcon B Contact Lens for Presbyopia:
Bausch + Lomb Samfilcon B Contact Lens for Presbyopia for daily wear is indicated for the correction of refractive ametropia (myopia or hyperopia) and presbyopia in aphakic and not aphakic persons with non-diseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of 1.50 diopters or less where the astigmatism does not interfere with visual acuity.

Samfilcon B Contact Lens Multifocal for Astigmatism:
Bausch + Lomb Samfilcon B Contact Lens Multifocal for Astigmatism for daily wear is indicated for the correction of refractive ametropia (myopia, hyperopia, and/or astigmatism) and presbyopia in aphakic and not aphakic persons with non-diseased eyes with refractive astigmatism not exceeding 10.00 diopters.

When prescribed for frequent planned replacement wear, the contact lens is to be cleaned, rinsed and disinfected each time it is removed from the patient's eye and discarded after the recommended wearing period prescribed by the eye care practitioner. The lens may be disinfected using a chemical disinfection system.

The Samfilcon B Contact Lens is available for a frequent/planned replacement modality.

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
K230954

Submitter Information:

Date Prepared:	November 17, 2023
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:

Common Name: Soft (hydrophilic) Contact Lens

Trade Name: To Be Determined

Classification: Ophthalmic Medical Device

Device Classification: Class II (21 CFR 886.5925)

Product Code: LPL

Predicate Device:

Bausch + Lomb Ultra (samfilcon A) Contact Lens, K131208 for the material, and

Alden HP 54 Sphere, Toric, Multifocal and Toric Multifocal Soft Contact Lenses, K091327 for the Indications for Use.

Device Description:

The Bausch + Lomb Samfilcon B Contact Lens is made from a silicone hydrogel material and is approximately 41% water by weight when immersed in a sterile phosphate buffered saline solution. This lens is tinted blue with Reactive Blue Dye 246. The color additive conforms with 21 CFR Part 73.3106.

The Bausch + Lomb Samfilcon B Contact Lens is to be prescribed for daily wear.

The physical properties of the lens are:

Refractive index	1.4191
Light transmission	97%
Water Content	41%
Specific Gravity	1.052
Oxygen Permeability	126 x 10^{-11}[cm^3O_2(STP) x cm]/(sec x cm^2 x mmHg)@35°C (polarographic method)

The custom-made lenses will be manufactured in spherical, toric, multifocal and toric multifocal designs with the following parameters:

Diameter	10.0 mm to 16.0 mm
Base Curve	6.5 mm to 9.7 mm
Power Range	+20.00D to -20.00D
Cylinder Power (Toric)	0D to -10.00D
Cylinder Axis	1^{o} to 180^{0}
Add Power (Multifocal)	+0.50D up to +4.00D

The lenses are packaged in borosilicate USP Type 1 glass vials containing phosphate buffered saline solution. A silicone vial stopper and aluminum crimp cap secure the lenses in the vial. Vials 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.

Indications for Use:

Samfilcon B Contact Lens
Bausch + Lomb Samfilcon B Contact Lens for daily wear is indicated for the correction of refractive ametropia (myopia or hyperopia) in aphakic and not aphakic persons with non-diseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of 1.50 diopters or less where the astigmatism does not interfere with visual acuity.

Samfilcon B Contact Lens for Presbyopia
Bausch + Lomb Samfilcon B Contact Lens for Presbyopia for daily wear is indicated for the correction of refractive ametropia (myopia or hyperopia) and presbyopia in aphakic and not aphakic persons with non-diseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of 1.50 diopters or less where the astigmatism does not interfere with visual acuity.

Samfilcon B Contact Lens for Astigmatism
Bausch + Lomb Samfilcon B Contact Lens for Astigmatism for daily wear is indicated for the correction of refractive ametropia (myopia, hyperopia, and/or astigmatism) in aphakic and not aphakic persons with non-diseased eyes with refractive astigmatism not exceeding 10.00 diopters.

Samfilcon B Contact Lens Multifocal for Astigmatism
Bausch + Lomb Samfilcon B Contact Lens Multifocal for Astigmatism for daily wear is indicated for the correction of refractive ametropia (myopia, hyperopia, and/or astigmatism) and presbyopia in aphakic and not aphakic persons with non-diseased eyes with refractive astigmatism not exceeding 10.00 diopters.

When prescribed for frequent planned replacement wear, the contact lens is to be cleaned, rinsed, and disinfected each time it is removed from the patient's eye and discarded after the recommended wearing period prescribed by the eye care practitioner. The lens may be disinfected using a chemical disinfection system.

Samfilcon B Contact Lenses for daily wear are available for a frequent/planned replacement modality.

Technological comparison to predicate devices

Indication Statements	**Predicate Device** Alden HP Contact Lenses, **K091327**	**Subject Device** Bausch + Lomb Samfilcon B Contact Lens
Spherical	Indicated for the correction of refractive ametropia (myopia or hyperopia) in aphakic and not aphakic persons with non-diseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of 1.50 diopters or less where the astigmatism does not interfere with visual acuity.	Same as predicate
Multifocal	Indicated for the correction of refractive ametropia (myopia or hyperopia) and presbyopia in aphakic and not aphakic persons with non-diseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of 1.50 diopters or less where the astigmatism does not interfere with visual acuity.	Same as predicate
Toric	Indicated for the correction of refractive ametropia (myopia, hyperopia, and/or astigmatism) in aphakic and not aphakic persons with non-diseased eyes with refractive astigmatism not exceeding 10.00 diopters.	Same as predicate
Multifocal Toric	Indicated for the correction of refractive ametropia (myopia, hyperopia, and/or astigmatism) and presbyopia in aphakic and not aphakic persons with non-diseased eyes.	Same as predicate
Property	**Predicate Device** Bausch + Lomb Ultra (samfilcon A) Contact Lens, **K131208**	**Subject Device** Bausch + Lomb Samfilcon B Contact Lens
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	Custom made, Lathed
Material Group	Silicone hydrogel	Same as predicate
USAN Name	samfilcon A	samfilcon B
Water Content	46%	41%
Oxygen Permeability[1] (edge corrected)	114	126
Specific Gravity	1.048	1.052

[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 samfilcon B 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, and ISO 10993-1 and completed the following tests of the Samfilcon B Contact Lens:

- In-Vitro Cytotoxicity
    - Direct Contact per ISO 10993-5 and ISO 18189
    - Agarose Overlay per ISO 10993-5
    - Elution Method per ISO 10993-5
- Guinea pig maximization skin sensitization per ISO 10993-10
- Ocular Irritation Study
    - Acute Ocular Irritation per ISO 10993-10
    - 5-Day study in rabbits per ISO 9394 (modified)
    - 22-Day study in rabbits per ISO 9394
- Systemic Toxicity
    - Acute systemic toxicity per ISO 10993-11

The following tests were performed according to GLP on the silicone vial stopper:

- Cytotoxicity
    - Elution Method per ISO 10993-5
- Ocular Irritation Study per ISO 10993-10
- Systemic Toxicity
    - Acute systemic toxicity per ISO 10993-11

Performance Testing was conducted on the Bausch + Lomb Samfilcon B Contact Lens which included:

- Physical, Chemical and Spectral Properties
- Leachable Monomer and Additives

Summary of Clinical Performance Data

Bausch + Lomb conducted an active-controlled, randomized, double-masked, multicenter, clinical study in the US, evaluating the safety and effectiveness of the Bausch + Lomb Samfilcon B Contact Lens. Subjects were adapted soft contact lens wearers between the ages of 18 and 40 years old.

Both the primary safety and primary effectiveness endpoints of the study were met. The primary safety endpoint was statistical non-inferiority with respect to the proportion of eyes with slit lamp findings Grade >2 at any follow-up visit between the test and control lenses. And the primary effectiveness endpoint was statistical non-inferiority with respect to mean distance high-contrast logMAR lens visual acuity for each eye between the test and control lenses. These

results demonstrate that the Samfilcon B Contact Lens is noninferior to the control lens with respect to the incidence of moderate/severe slit lamp findings and distance lens visual acuity.

There were no reports of serious adverse events related to the test or control lens.

Patient Accountability (number of patients reported at each stage)

Stage	Investigational Device Total	Control Device Total	Total
Enrolment	56	28	84
Treatment	46	21	67
Primary Safety Endpoint Analysis	56	28	84
Primary Effectiveness Endpoint Analysis	46	21	67

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 Samfilcon B Contact Lens are substantially equivalent to the Bausch + Lomb (Samfilcon A) Contact Lens.