November 30, 2018

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

Re: K182249
Trade/Device Name: Bausch + Lomb Ultra (samfilcon A) Multifocal for Astigmatism Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: November 1, 2018
Received: November 2, 2018

Dear Ms. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

J. Angelo Green

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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)*
K182249

Device Name
Bausch + Lomb Ultra (samfilcon A) Multifocal for Astigmatism Contact Lens

Indications for Use *(Describe)*
The Bausch + Lomb Ultra (samfilcon A) Multifocal for Astigmatism Contact Lens is 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 up to 5.00 diopters and require an add power ranging from +0.75D to +5.00D.

The lens may be prescribed for Frequent/Planned Replacement Wear or Disposable Wear in a power range of +20.00 to -20.00 diopters.

FREQUENT/PLANNED REPLACEMENT WEAR
When prescribed for Frequent/Planned Replacement Wear, the Bausch + Lomb Ultra (samfilcon A) Multifocal for Astigmatism 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.

DISPOSABLE WEAR
When prescribed for Disposable Wear, the Bausch + Lomb Ultra (samfilcon A) Multifocal for Astigmatism Contact Lens, 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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510(k) SUMMARY

Submitter Information:

Date Prepared:	August 16, 2018
Name:	Bausch & Lomb Incorporated
Address:	1400 North Goodman Street Rochester, NY 14609
Contact Person:	Barbara Klube-Falso Associate Director, Regulatory Affairs
Phone Number:	(585) 338-8503 (585) 338-0702 (fax)
Email:	Barbara.Klube-Falso@bausch.com

Device Information:

Trade Name:	Bausch + Lomb Ultra (samfilcon A) Multifocal for Astigmatism Contact Lens
Common Name:	Soft contact lens, daily wear
Device Classification:	Class II (21 CFR 886.5925)
Classification Name:	Daily Wear Soft (Hydrophilic) Contact Lens
Product Code:	MVN, LPL

Predicate Device:

The predicate devices are

- Bausch + Lomb Ultra (samfilcon A) Visibility Tinted Soft (hydrophilic) Contact Lenses cleared under K131208, and
- Coopervision, Inc., Avaira Vitality (fanfilcon A) Multifocal Toric Soft (hydrophilic) Contact Lens cleared under K160803.

Device Description:

The Bausch + Lomb (samfilcon A) Multifocal for Astigmatism Contact Lens is 46% water and 54% samfilcon A material (a siloxane copolymer with N-vinyl pyrrolidone). This lens is tinted blue with Reactive Blue Dye 246 to make them easier to see when handling.

The packaging material consists of a polypropylene blister, borate buffered saline with poloxamine 1107 and a plastic coated aluminium lid stock. The disposable blister container and the lidstock are used in the predicate device. The packaged lenses are steam sterilized in a validated autoclave. Each lens is labelled with the lens parameters, lot number and expiration date.

Lenses have the following physical properties:

Refractive Index:	1.411
Light Transmittance:	97.3%
Water Content:	46%
Specific Gravity:	1.048
Oxygen Permeability:	114 x 10^{-11}[cm^3O_2(STP) x cm]/(sec x cm^2 x mmHg)@35°C (polarographic method)

The lens design includes the following parameter ranges:

Diameter	13.5mm to 15.0mm
Center Thickness	0.05mm to 0.75mm (varies with power)
Base Curve	7.8mm to 9.5mm
Power Range	+20.00D to -20.00D
Cylinder Power (Toric)	-0.75D to -5.00D
Cylinder Axis (Toric)	0^o to 180^0
Add Power (Multi-Focal)	+0.75D to +5.00D

Indications for Use:

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The lens may be prescribed for Frequent/Planned Replacement Wear or Disposable Wear in a power range of +20.00 to -20.00 diopters.

FREQUENT/PLANNED REPLACEMENT WEAR
When prescribed for Frequent/Planned Replacement Wear, the Bausch + Lomb Ultra (samfilcon A) Multifocal for Astigmatism 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.

DISPOSABLE WEAR
When prescribed for Disposable Wear, the Bausch + Lomb Ultra (samfilcon A) Multifocal for Astigmatism Contact Lens, is to be discarded after each removal.

Technological Characteristics:

The table below shows a side-by-side comparison of technological characteristics evaluated to determine substantial equivalence of the new device to the predicate device. Differences were evaluated during the design and development of the new device. Performance testing was completed and demonstrated the proposed device and predicate device are substantially equivalent, and the differences do not negatively impact the safety and efficacy of the device.

Property	**Predicate Device** Bausch + Lomb (samfilcon A) *K131208*	**Predicate Device** Coopervision Multifocal Toric (fanfilcon A) *K160803*	**New Device** Bausch + Lomb (samfilcon A) Multifocal for Astigmatism Lens
Intended Use	Daily Wear, Daily Disposable	Daily Wear, Daily Disposable	Same
Lens Material Group	Silicone Hydrogel	Silicone Hydrogel	Same
Visibility Tint	Reactive Blue 246	Reactive Blue 246	Same
Manufacturing Method	Cast Molded	Cast molded	Same
Lens Designs	Spherical, Toric, Multifocal	Multifocal Toric	Multifocal Toric
Sterilization Method	Moist Heat	Moist Heat	Same
Packaging	Polypropylene Blister	blister	Polypropylene Blister
Packaging Solution	Borate Buffered Saline with Poloxamine	Buffered saline solution	Borate buffered saline with Poloxamine
USAN Name	samfilcon A	fanfilcon A	samfilcon A
Water Content	46%	55%	46%

Summary of Non-Clinical Performance Data:

A series of *in vitro* and *in vivo* preclinical toxicology and biocompatibility testing was performed to assess the safety and effectiveness of the contact lens material, samfilcon A. Testing was performed in accordance with the FDA guidance titled *Premarket Notification (510(k)) Guidance document for Daily Wear Contact Lenses*, May 1994 and GLP regulation 21 CFR part 58 and included the following:

- Leachable
- Ocular Irritation – Lens device, Packaging
- Sensitization
- Systemic Toxicity – Lens device, Packaging

Performance testing included conformance to predetermined specifications and functional testing to verify that the device performs as expected without creating additional risk to the user.

Stability testing, real-time, was performed on the samfilcon A contact lens and demonstrates that the product is stable for five years.

The testing performed on the predicate device, Bausch + Lomb Ultra (samfilcon A) Contact Lens, 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 Bausch + Lomb Ultra (samfilcon A) Contact Lens. Therefore the previous testing is fully applicable.

Summary of Clinical Performance Data

Clinical performance data to confirm safety and effectiveness of the samfilcon A lens material in the daily disposable modality was obtained via a clinical study of the Bausch + Lomb Ultra (samfilcon A) Contact Lens. Due to the similarities between the subject device and the predicate device, the clinical study performed on the predicate device is applicable to the subject device and no additional clinical study was performed.

Substantial Equivalence Conclusion:

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