December 06, 2022

Bausch & Lomb Incorporated
Melissa Thomas
Director, Regulatory Affairs
1400 N Goodman Street
Rochester, NY 14609

Re: K222541
Trade/Device Name: Bausch + Lomb Preservative Free Lubricating and Rewetting Drops
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (Hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LPN, MRC
Dated: November 4, 2022
Received: November 7, 2022

Dear Melissa Thomas:

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 -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)*

K222541

Device Name

Bausch + Lomb Preservative Free Lubricating and Rewetting Drops

Indications for Use *(Describe)*

Bausch + Lomb Preservative Free Lubricating and Rewetting Drops are indicated for use to lubricate and rewet soft (hydrophilic) contact lenses, including silicone hydrogel as well as silicone acrylate (SA) and fluorosilicone acrylate (FSA) rigid gas permeable (RGP) contact lenses during wear. The product may be used with daily or extended wear, and disposable lenses.

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
Bausch + Lomb
Preservative Free Lubricating and Rewetting Drops

1. General Information

Submitter:	**Contact Person:**
Bausch & Lomb Incorporated 1400 North Goodman Street Rochester, NY 14609 General Telephone: 585-338-5800	Melissa Thomas 1400 North Goodman Street Rochester, NY 14609 585-338-6045 (phone) 585-338-0702 (fax) Melissa.Thomas@bausch.com

Premarket Notification Number: K222541

Preparation Date: November 4, 2022

2. Device Identification

Device Name: Bausch + Lomb Preservative Free Lubricating and Rewetting Drops

Classification Name: Soft hydrophilic contact lens care product (21 CFR §886.5928),
Rigid gas permeable contact lens care product (21 CFR §886.5918)

Common Name: Soft (hydrophilic) contact lens care solution
Rigid gas permeable contact lens care products

Product Codes: LPN, MRC

Device Classification: Class II

3. Predicate Device

P830034/S016 OPTI-FREE Replenish Rewetting Drops approved on November 21, 1990 is a sterile, buffered, isotonic, aqueous solution that contains a citrate/borate buffer and sodium chloride with edetate disodium 0.05% and POLYQUAD* (polyquaternium-1) 0.001% as preservatives and RLM-100 (PEG-11 lauryl ether carboxylic acid) and TETRONIC®1 1304.

4. Product Description

The subject of this 510(k) submission is for the new product, Bausch + Lomb Preservative Free Lubricating and Rewetting Drops, which is substantially equivalent to the currently commercialized OPTI-FREE Replenish Rewetting Drops.

Bausch + Lomb Preservative Free Lubricating and Rewetting Drops is a sterile, preservative free, buffered, isotonic, aqueous solution that contains boric acid, sodium borate, potassium chloride, erythritol, poloxamine, glycerol and hyaluronan for lubricating and rewetting soft (hydrophilic)

contact lenses including silicone hydrogel contact lenses and rigid gas permeable contact lenses during wear.

When used 4 times a day, Bausch + Lomb Preservative Free Lubricating and Rewetting Drops helps prevent deposit build-up on lenses.

Bausch + Lomb Preservative Free Lubricating and Rewetting Drops may be supplied in a foil pouch containing sterile Single Use Dispensers or in Multi-Dose bottles. The dispenser, foil pouch, bottles and cartons are marked with a lot number and expiration date.

5. Indications for Use

Bausch + Lomb Preservative Free Lubricating and Rewetting Drops are indicated for use to lubricate and rewet soft (hydrophilic) contact lenses, including silicone hydrogel as well as silicone acrylate (SA) and fluorosilicone acrylate (FSA) rigid gas permeable (RGP) contact lenses during wear. The product may be used with daily or extended wear, and disposable lenses.

6. Summary of Technological Characteristics

The technological characteristics of Bausch + Lomb Preservative Free Lubricating and Rewetting Drops are substantially equivalent to those of the predicate device.

Table 1: Comparison of Characteristics

Features	**Predicate Device OPTI-FREE Replenish Rewetting Drops**	**Subject Device Bausch + Lomb Preservative Free Lubricating and Rewetting Drops**
510(k) Number	P830034/S016	To be assigned
Classification		
Classification	Class II	Class II
Product Code	LPN	LPN, MRC
Indication		
Indicated for Soft Contact Lenses	Yes	Yes
Indicated for Silicone Hydrogel Lenses	Yes	Yes
Indicated for Rigid Gas Permeable Lenses	Yes	Yes
Intended Use	Indicated to lubricate and rewet daily, extended wear and disposable soft (hydrophilic) contact lenses and fluorosilicone acrylate and silicone acrylate, gas permeable and silicone hydrogel contact lenses as follows: • Moisturizing lenses as needed during the day to reduce discomfort.	Bausch + Lomb Preservative Free Lubricating and Rewetting Drops are indicated for use to lubricate and rewet soft (hydrophilic) contact lenses, including silicone hydrogel as well as silicone acrylate (SA) and fluorosilicone acrylate (FSA) rigid gas permeable (RGP) contact lenses

	• Moisturizing extended wear lenses prior to retiring at night and upon awakening.	during wear. The product may be used with daily or extended wear, and disposable lenses.
Formulation / Regimen		
Deposit buildup prevention	Place 2 drops in each eye and blink 2-3 times, 4 times a day.	To help prevent deposit buildup: Place 2 drops in each eye and blink 2-3 times, 4 times a day.
Preservatives	POLYQUAD*	None
Surfactant	Tetronic 1304	Poloxamine 1107
Storage	Store at room Temperature	Store at room Temperature
Discard Date	None noted in labeling	90 days (Multi-Dose Unit) Immediately after use (Single Dose Unit)
Primary Container	White Plastic Bottle, white cap	Natural LDPE** Bottle, natural cap or Natural LDPE dispenser
Tamper Resistant	Yes	Yes, Tamper Evident Pull Strip (Multi-Dose Unit)

*Polyquaternium-1

**Low Density Polyethylene

7. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that Bausch + Lomb Preservative Free Lubricating and Rewetting Drops is substantially equivalent to the predicate device.

8. Performance Data

A series of preclinical and clinical testing was performed to demonstrate the safety and effectiveness of Bausch + Lomb Preservative Free Lubricating and Rewetting Drops as described in Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products, May 1, 1997. A brief summary of the test results is provided below:

Biocompatibility

Bausch + Lomb performed a series of studies to assess the biocompatibility of Bausch + Lomb Preservative Free Lubricating and Rewetting Drops, the primary packaging, and the biological safety of the formulation over shelf life in accordance with FDA Guidance Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products.

Biocompatibility testing was conducted on product packaged in both configurations under various conditions. Testing was performed on the formulation alone, the formulation in conjunction with marketed contact lenses, and the primary packaging components including the formulation-

contacting components of the multi-dose dispenser. In addition, testing was conducted at end of shelf life.

Biological testing was previously conducted on the formulation-contacting components of the Multi-Dose Unit, including *in vitro* cytotoxicity and *in vivo* acute systemic toxicity, intracutaneous irritation, muscle implantation and sensitization. Additionally, Bausch + Lomb conducted Ocular Irritation testing.

Bausch + Lomb evaluated the biocompatibility of the Multi-Dose Unit LDPE bottles in *in vitro* cytotoxicity, *in vivo* systemic toxicity and acute ocular irritation studies.

Bausch + Lomb Preservative Free Lubricating and Rewetting Drops Single Dose Unit Dispensers uses identical packaging materials previously cleared under K200416. Therefore, testing previously conducted on the Single Dose Unit dispensers was leveraged to support biocompatibility.

The Bausch + Lomb Preservative Free Lubricating and Rewetting Drops formulation alone has been assessed for biocompatibility in *in vitro* cytotoxicity, and *in vivo* acute and repeated dose ocular irritation studies.

In vitro cytotoxicity testing was conducted on the Bausch + Lomb Preservative Free Lubricating and Rewetting Drops formulation in conjunction with marketed traditional soft contact lenses, silicone hydrogel contact lenses, silicone acrylate and fluorosilicone acrylate rigid gas permeable contact lenses. Additionally, *in vivo* ocular irritation studies were conducted with representative silicone acrylate and fluorosilicone acrylate rigid gas permeable lenses and soft contact lenses, which evaluated the formulation in both packaging configurations with and without contact lens wear following repeated topical ocular administration.

The passing results of the testing demonstrate the Biocompatibility and Biological Safety over shelf life of Bausch + Lomb Preservative Free Lubricating and Rewetting Drops.

<u>Microbiology</u>
Single Dose Unit (SDU) testing was conducted in accordance with FDA Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products May 1997 requirements Section III.E, “Product Specific Guidance In-Eye Contact Lens Solutions (e.g., Lubricating and/or Rewetting Drops)”.

The package integrity and tip seal effectiveness of the Multi-Dose Unit configuration was evaluated using Tip Seal, Tip Contamination and Aerosol Challenge Testing. All testing demonstrated a robust tip seal barrier as no microbial ingress was apparent as evidenced by testing of the container contents for microbial growth. Tip Seal and Aerosol Challenge testing after simulated in use over a minimum of 90 days demonstrated an integrous robust tip seal barrier.

<u>Lens Compatibility</u>
The results of lens compatibility studies demonstrate Bausch + Lomb Preservative Free Lubricating and Rewetting Drops is compatible with soft contact lenses including silicone hydrogel contact lenses, rigid gas permeable, silicone acrylate ((SA), and fluorosilicone acrylate (FSA)) lenses.

Clinical Study

Bausch + Lomb conducted a controlled clinical study with soft (hydrophilic) contact lenses, including silicone hydrogel lenses, silicone acrylate (SA), and fluorosilicone acrylate (FSA) lenses, comparing the safety and effectiveness of Bausch + Lomb Preservative Free Lubricating and Rewetting Drops to OPTI-FREE Replenish Rewetting Drops. The results of the study support a substantial equivalence determination.

A total of 369 subjects were enrolled in a one month multicenter, randomized, masked, parallel, bilateral study conducted in the USA. Subjects were randomized to receive investigational Bausch + Lomb Preservative Free Lubricating and Rewetting Drops (Test), or OPTI-FREE Replenish Rewetting Drops (Control). Eligible subjects were enrolled into one of eight lens groups based on their habitual contact lenses. In total, 365 of the 369 subjects enrolled completed the study.

Subject Demographics

Of the 188 subjects in the Bausch + Lomb Preservative Free Lubricating and Rewetting Drops group, 60 (31.9%) were male and 128 (68.1%) were female, with a mean (SD) age of 35.6 (9.56) years (range: 18 - 63 years). Of the 181 subjects in the OPTI-FREE Replenish Rewetting Drops group, 57 (31.5%) were male and 124 (68.5%) were female, with a mean (SD) age of 33.7 (8.57) years (range: 18 - 65 years).

With regard to race, in the Bausch + Lomb Preservative Free Lubricating and Rewetting Drops group 144 (76.6%) subjects were White, 18 (9.6%) were Black/African American, 24 (12.8%) were Asian, and 2 (1.1%) was Multiple. In the OPTI-FREE Replenish Rewetting Drops group 130 (71.8%) subjects were White, 21 (11.6 %) were Black/African American, 27 (14.9%) were Asian, 1 (0.6%) was Native Hawaiian or Other Pacific Islander and 2 (1.1 %) was Multiple.

Safety Results

The primary endpoint of interest for slit lamp findings was achieved. The Bausch + Lomb Preservative Free Lubricating and Rewetting Drops group demonstrated noninferiority to the OPTI-FREE Replenish Rewetting Drops group Over All Follow-up Visits for slit lamp findings greater than Grade 2.

In the test device Bausch + Lomb Preservative Free Lubricating and Rewetting Drops there were five ocular treatment-emergent adverse events (TEAEs) reported in three eyes of two subjects. The five ocular TEAEs were eye irritation (2), eye pruritus (2) and eye complication associated with ocular discomfort with device (contact lens) (1). Four eye irritation and eye pruritus adverse events occurred simultaneously in a single subject. All five ocular TEAEs resolved with no action required, and there were no eyes discontinued from the study due to an adverse event (AE). In the control group using OPTI-FREE Replenish Rewetting Drops there were no TEAEs.

There were no corneal infiltrates reported and no changes to pre-existing corneal scars. There were no notable differences between the Bausch + Lomb Preservative Free Lubricating and Rewetting Drops and OPTI-FREE Replenish Rewetting Drops groups for any of the lens wear or lens performance parameters at any of the study visits. Visual acuities were similar between eyes of both groups.

In conclusion, graded slit lamp findings, the comparison of AEs, and the comparison of visual acuities indicate that the Bausch + Lomb Preservative Free Lubricating and Rewetting Drops is safe for use with soft contact lenses, including silicone hydrogel lenses as well as silicone acrylate (SA) and fluorosilicone acrylate (FSA) rigid gas permeable (RGP) contact lenses.

Effectiveness Results

For each of the three primary effectiveness endpoints (overall comfort averaged over all follow-up visits; dryness averaged over all follow-up visits; and optimal [none or light] lens deposits at all follow-up visits), the treatment differences indicated that the Bausch + Lomb Preservative Free Lubricating and Rewetting Drops is non-inferior to the OPTI-FREE Replenish Rewetting Drops solution. There were no notable differences between the two treatment groups with regard to the additional effectiveness assessments of symptoms/complaints, worn lens characteristics, and dispensed lens characteristics. In conclusion, the three primary effectiveness endpoints indicate that the Bausch + Lomb Preservative Free Lubricating and Rewetting Drops is effective for use with soft contact lenses, including silicone hydrogel lenses as well as silicone acrylate (SA) and fluorosilicone acrylate (FSA) rigid gas permeable (RGP) contact lens.

Substantial Equivalence

The cumulative results of laboratory, *in vitro, in vivo,* and clinical testing sponsored by Bausch + Lomb demonstrate that the safety, effectiveness and performance of Bausch + Lomb Preservative Free Lubricating and Rewetting Drops are substantially equivalent to OPTI-FREE Replenish Rewetting Drops for soft contact lenses, including silicone hydrogel contact lenses as well as silicone acrylate (SA) and fluorosilicone acrylate (FSA) rigid gas permeable (RGP) contact lens.