May 28, 2021

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

Re: K202932
Trade/Device Name: ABT12 multi-purpose solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (Hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LPN
Dated: April 27, 2021
Received: April 28, 2021

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, 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)*
K202932

Device Name
ABT12 multi-purpose solution

Indications for Use *(Describe)*
Bausch + Lomb ABT12 multi-purpose solution is indicated for use in the daily cleaning, conditioning, removing protein deposits, rinsing, chemical (not heat) disinfection, and storage of soft (hydrophilic) contact lenses, including silicone hydrogel contact lenses, as recommended by your eye care practitioner.

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

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: K202932

Preparation Date: May 27, 2021

1. Names

Device Name:	Bausch + Lomb ABT12 multi-purpose solution
Classification Name:	Accessories, Soft Lens Products
Common Name:	Soft (hydrophilic) Contact Lens Care Solution
Product Codes:	LPN
Device Classification:	Class II (21 CFR §886.5928)

2. Predicate Devices

K014202 COMPLETE multi-purpose solution Easy Rub Formula cleared on February 20, 2002.

3. Product Description

The subject of this 510(k) submission is for the new product Bausch + Lomb ABT12 multi-purpose solution which is substantially equivalent to the COMPLETE multi-purpose solution Easy Rub Formula which is currently commercialized.

Bausch + Lomb ABT12 multi-purpose solution is a sterile isotonic aqueous solution [containing polyaminopropyl biguanide (0.00005%), polyquaternium (0.00015%), and alexidine (0.00025%)] for disinfecting, cleaning, conditioning, rinsing, protein removal, and storing soft (hydrophilic) and silicone hydrogel contact lenses. The sterile solution is packaged in a plastic bottle with a tamper evident seal and labeled with a lot number and expiration date.

4. Indications for Use

Bausch + Lomb ABT12 multi-purpose solution is indicated for use in the daily cleaning, conditioning, removing protein deposits, rinsing, chemical (not heat) disinfection, and storage of soft (hydrophilic) contact lenses, including silicone hydrogel contact lenses, as recommended by your eye care practitioner.

5. Summary of Technological Characteristics

The technological characteristics of Bausch + Lomb ABT12 multi-purpose solution are substantially equivalent to those of the predicate devices.

Table 1: Comparison of Characteristics

Features	Predicate Device COMPLETE multi-purpose solution Easy Rub Formula	Subject Device ABT12 multi-purpose solution
510(k) Number	K014202	K202932
Classification		
Classification	Class II	Class II
Product Code	LPN	LPN
Indication		
Indicated for Soft Contact Lenses	Yes	Yes
Indicated for Silicone Hydrogel Lenses	No	Yes
Intended Use	Indicated for the care of soft (hydrophilic) contact lenses. Use this product, as recommended by your eye care professional, to: • Chemically (NOT HEAT) Disinfect • Clean • Rinse • Store • Remove Protein	Indicated for use in the daily cleaning, conditioning, removing protein deposits, rinsing, chemical (not heat) disinfection, and storage of soft (hydrophilic) contact lenses, including silicone hydrogel contact lenses, as recommended by your eye care practitioner.
Formulation / Regimen		
Rub Regimen	3 Or More Drops for 20 seconds	3 Drops for 20 seconds
Optional No-Rub Regimen	No	No
Rinse Required for Cleaning	Rinse for 5 seconds on each side	Thoroughly rinse for 5 seconds on each side
Minimum Disinfection Time	6 hours	4 hours
Triple Disinfection System	No	Yes
Preservatives / Disinfectants	Polyhexamethylene biguanide	Polyaminopropyl Biguanide Polyquaternium Alexidine
Dural Surfactants	No	Yes
Surfactants	Poloxamer 237	Poloxamer 181 Poloxamine 1107
Lens Storage Period	30 Days	30 Days
Discard After Opening	90 Days	90 Days
Primary Container	White Plastic Bottle, Multiple Sizes	Clear Plastic Bottle, Multiple Sizes
Tamper Resistant	Yes	Yes, includes a tamper evident seal

6. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that Bausch + Lomb ABT12 multi-purpose solution is substantially equivalent to the predicate devices.

Performance Data

A series of preclinical and clinical testing was performed to demonstrate the safety and effectiveness of Bausch + Lomb ABT12 multi-purpose solution 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

Cytotoxicity, ocular irritation, oral toxicity, sensitization and *in-vivo* ocular biocompatibility studies were completed for Bausch + Lomb ABT12 multi-purpose solution in accordance with FDA Guidance Premarket Notification (510(K)) Guidance Document for Contact Lens Care Products. Testing was conducted under various conditions including on ABT12 multi-purpose solution itself, the ABT12 solution manufactured with the maximum preservative concentrations, and testing with extracts of eight different lenses (USAN materials) cycled 30 times in ABT12 multi-purpose solution. In relevant studies the predicate device K014202 was used for side by side comparison. ABT12 multi-purpose solution uses identical packaging materials previously cleared under K083757, testing previously conducted on the packaging components was leveraged to support biocompatibility. The test results demonstrated the biocompatibility of Bausch + Lomb ABT12 multi-purpose solution.

Microbiology

The sponsor conducted a series of studies according to EN ISO 14729:2001 Ophthalmic optics – Contact lens care products – Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses, including Amendment 1 (2010) and EN ISO 14730:2014 Ophthalmic optics – Contact lens care products – Antimicrobial preservative efficacy testing and guidance on determining discard date and demonstrate Bausch + Lomb ABT12 multi-purpose solution exceeds the criteria for disinfection and preservative efficacy.

Lens Compatibility

The results of lens compatibility studies demonstrate Bausch + Lomb ABT12 multi-purpose solution is compatible with soft contact lenses including silicone hydrogel contact lenses.

Cleaning Efficacy

The cleaning efficacy of the solution was evaluated through the determination of the Critical Micelle Concentration (CMC). The surfactant concentrations are well above the CMC for the individual surfactants. *In-vitro* laboratory studies demonstrated the cleaning properties of Bausch + Lomb ABT12 multi-purpose solution with contact lenses artificially deposited with protein.

Clinical Study

Bausch + Lomb conducted a controlled clinical study with soft (hydrophilic) contact lenses, including silicone hydrogel lenses, comparing the safety and effectiveness of Bausch + Lomb ABT12 multi-purpose solution to COMPLETE multi-purpose solution Easy Rub Formula. The results of the study support a substantial equivalence determination.

A total of 252 subjects were enrolled in a three-month multicenter, randomized, masked, parallel, bilateral study conducted in the USA. Subjects were randomized to receive Bausch + Lomb investigational

ABT12 multi-purpose solution (Test), or COMPLETE® Multi-Purpose Solution (Control). Eligible subjects were enrolled into one of five lens groups based on their habitual contact lenses. In total, 240 of the 252 subjects enrolled completed the study.

Subject Demographics:
Of the 127 subjects in the ABT12 group, 39 (30.7%) were male and 88 (69.3%) were female, with a mean (SD) age of 34.4 (9.72) years (range: 18 - 67 years). Of the 125 subjects in the COMPLETE group, 34 (27.2%) were male and 91 (72.8%) were female, with a mean (SD) age of 34.1 (9.79) years (range: 18 - 65 years).

With regard to race, in the ABT12 group 101 (80.2%) subjects were White, 13 (10.3%) were Black/African American, 11 (8.7%) were Asian, and 1 (0.8%) was Multiple. In the COMPLETE group 103 (82.4%) subjects were White, 11 (8.8 %) were Black/African American, 10 (8.0%) were Asian, and 1 (0.8 %) was Multiple.

Safety results:
The primary endpoint of interest for slit lamp findings was achieved. The ABT12 group demonstrated non-inferiority to the COMPLETE group Over All Follow-up Visits for slit lamp findings greater than Grade 2.

In the test device ABT12 multi-purpose solution there were no eyes with serious adverse events, adverse device effects, or significant non-serious adverse events, and there were no eyes discontinued from the study due to an AE. None of the AEs in either treatment group were considered related to the study solution.

There were no corneal infiltrates reported and no changes to pre-existing corneal scars. There were no notable differences between the ABT12 and COMPLETE 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 ABT12 multi-purpose solution is safe for use with soft contact lenses, including silicone hydrogel 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 ABT12 solution is non-inferior to the COMPLETE 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 ABT12 multi-purpose solution is effective for use with soft contact lenses, including silicone hydrogel lenses.

<u>Substantial Equivalence</u>
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 ABT12 multi-purpose solution are substantially equivalent to COMPLETE multi-purpose solution Easy Rub Formula for soft contact lenses, including silicone hydrogel contact lenses.