September 23, 2020

Bausch & Lomb Incorporated
Pinal Shah
Manager Regulatory Affairs
400 Somerset Corporate Boulevard
Bridgewater, NJ 08807

Re: K200416
Trade/Device Name: Bausch + Lomb Boston One Step Liquid Enzymatic Cleaner
Regulation Number: 21 CFR 886.5918
Regulation Name: Rigid Gas Permeable Contact Lens Care Products
Regulatory Class: Class II
Product Code: MRC
Dated: August 20, 2020
Received: August 21, 2020

Dear Pinal Shah:

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)*
K200416

Device Name
Bausch + Lomb Boston One Step Liquid Enzymatic Cleaner

Indications for Use *(Describe)*
Bausch + Lomb Boston One Step Liquid Enzymatic Cleaner is indicated for weekly enzymatic cleaning of fluorosilicone acrylate and silicone acrylate rigid gas permeable contact lenses during conditioning (wetting, soaking, and disinfecting) with Boston Conditioning Solution or Boston ADVANCE Comfort Formula Conditioning Solution.

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 Boston One Step Liquid Enzymatic Cleaner

1. Submitter Information

Primary	Alternate
Pinal Shah Manager, Regulatory Affairs 400 Somerset Corporate Boulevard Bridgewater, New Jersey 08807 Tel: (908)927-0535 Fax: (908)927-1856 Email: pinal.shah@bauschhealth.com	Susan Pate Sr Manager Regulatory Affairs 1400 North Goodman Street Rochester, NY 14609 Tel. (585) 338-5708 Email: Susan.Pate@bausch.com

Summary Prepared: **February 18, 2020**

2. Device Name

Trade Name: Bausch + Lomb Boston One Step Liquid Enzymatic Cleaner

Classification: Products, Contact Lens Care, Rigid Gas Permeable

Device classification: Class II

Regulation Number: 886.5918 Rigid Gas Permeable Contact Lens Care Product

Product Code: MRC

3. Predicate Device

Bausch + Lomb Boston One Step Liquid Enzymatic Cleaner (K181627).

4. Description of the Device

Bausch + Lomb Boston One Step Liquid Enzymatic Cleaner is a preservative free sterile, aqueous solution containing proteolytic enzyme (subtilisin) as the active ingredient, and glycerol.

5. Intended Use

Bausch + Lomb Boston One Step Liquid Enzymatic Cleaner is indicated for weekly enzymatic cleaning of fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses during conditioning (wetting, soaking, and disinfecting) with Boston Conditioning Solution or Boston ADVANCE Comfort Formula Conditioning Solution.

6. Description of Safety and Substantial Equivalence

Bausch + Lomb submitted this 510(k) to add an alternative manufacturing site located at Unither Pharmaceuticals in Coutances, France for Boston One Step Liquid Enzymatic Cleaner packaged as a Single-Use Dispenser (SUD). Preclinical testing was completed to support the additional manufacturing site change, in addition to changing the SUD packaging resin, and raw material supplier sources. There are not any changes to the product formulation, specifications or care regimen.

Preclinical testing was completed 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 and ocular irritation studies were completed for the Boston One Step Liquid Enzymatic Cleaner and its primary packaging components. Systemic toxicity was conducted on the primary packaging components. The test results demonstrated the biocompatibility of the Boston One Step Liquid Enzymatic Cleaner and its primary packaging components.

7. Substantial Equivalence

The preclinical testing results demonstrate that the safety, effectiveness and performance of Boston One Step Liquid Enzymatic Cleaner are substantially equivalent to the currently commercialized Boston One Step Liquid Enzymatic Cleaner.