August 10, 2018

Bausch + Lomb Incorporated
Melissa Thomas
Senior Manager Regulatory Affairs
1400 North Goodman Street
Rochester, NY 14609

Re: K181627
Trade/Device Name: Bausch + Lomb Boston SIMPLUS Multi-Action Solution,
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: June 13, 2018
Received: June 20, 2018

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/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,

Scott E. Steffen -S

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)*
K181627

Device Name
Bausch + Lomb Boston SIMPLUS Multi-Action Solution
Bausch + Lomb Boston One Step Liquid Enzymatic Cleaner

Indications for Use *(Describe)*
Bausch + Lomb Boston Simplus Multi-Action Solution is indicated for cleaning, removing protein, rinsing, disinfecting, conditioning, storing and cushioning fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses.

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.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) SUMMARY

## Boston SIMPLUS Multi-Action Solution and Boston One Step Liquid Enzymatic Cleaner

## 1. Submitter Information


| Primary | Alternate |
|---|---|
| Melissa Thomas<br>Senior Manager, Regulatory Affairs<br>1400 North Goodman Street<br>Rochester, NY 14609<br>Tel. (585) 338-6045<br>Fax (585) 338-0702<br>Email: Melissa.Thomas@bausch.com | Glenn Davies, O.D.<br>Sr. Director Regulatory Affairs,<br>1400 North Goodman Street<br>Rochester, NY 14609<br>Tel. (585) 338-8215<br>Email: Glenn.Davies@bausch.com |


Summary Prepared: **June 13, 2018**

## 2. Device Name

Trade Name: Bausch + Lomb Boston SIMPLUS Multi-Action Solution
Bausch + Lomb Boston One Step Liquid Enzymatic Cleaner

Classification: Accessories, Contact Lens Care Products

Device classification: Class II

Regulation Number: 886.5918 Rigid Gas Permeable Contact Lens Care Products

Product Code: MRC

## 3. Predicate Device

Bausch + Lomb Boston Simplus Multi-Action Solution (K024289)
Bausch + Lomb Boston One Step Liquid Enzymatic Cleaner (K973217)

## 4. Description of the Device

Bausch + Lomb Boston Simplus Multi-Action Solution is a sterile, aqueous, buffered solution that contains poloxamine, hydroxyalkylphosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, Glucam and preserved with chlorhexidine gluconate (0.003%), polyaminopropyl biguanide (0.0005%).

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 Simplus Multi-Action Solution is indicated for cleaning, removing protein, rinsing, disinfecting, conditioning, storing and cushioning fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses.

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 is submitting this 510(k) to update the warnings related to use of water, and modify the lens case care regimen to rinse with a disinfecting solution as a substitute for the tap water rinse as recommended in the *August 15, 2010 Contact Lens Care Product Labeling Guidance*. This continues Bausch + Lomb's commitment to to remove all water from the gas permeable regimens and labeling.

There are no proposed changes to the formulation, or care regimen. The only change proposed in this 510(k) is related to removing water from the lens case regimen, and enhancing the warnings related to the use of water.

## 7. Substantial Equivalence

The proposed changes to the labeling reflect the changes Bausch + Lomb committed to the agency recommendations from the *August 15, 2010 Contact Lens Care Product Labeling Guidance* in addition to FDA current thinking. The modification to remove water from the lens case rinse in addition to adding warnings related to the use of water do not have an impact on the safety or efficacy of the product and the products remain substantially equivalent to the current commercialized product as there is no change in formulation or regimen.