November 27, 2017

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

Re: K173089
Trade/Device Name: Bausch + Lomb Boston Original Cleaner, Bausch + Lomb Boston Original Conditioning Solutions
Regulation Number: 21 CFR 886.5918
Regulation Name: Rigid Gas Permeable Contact Lens Care Products
Regulatory Class: Class II
Product Code: MRC
Dated: October 1, 2017
Received: October 5, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Denise L. Hampton -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)*
K173089

Device Name
Bausch + Lomb Boston Original Cleaner
Bausch + Lomb Boston Original Conditioning Solutions

Indications for Use *(Describe)*
Boston Original Cleaner is indicated for use to clean silicone acrylate and fluoro silicone acrylate gas permeable contact lenses after each removal and before conditioning (wetting, soaking, disinfecting).

Boston Original Conditioning Solutions is indicated for wetting, disinfecting and soaking (after cleaning and rinsing) of fluoro silicone acrylate and silicone acrylate gas permeable contact 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Bausch + Lomb Boston Original Cleaner & Boston Original Conditioning Solutions

1. Submitter Information

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

Summary Prepared: September 27, 2017

2. Device Name

Trade Name: Bausch + Lomb Boston Original Cleaner
Bausch + Lomb Original Conditioning Solutions

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 Original Cleaner (P820069)
Bausch + Lomb Boston Original Conditioning Solutions (K980133)
Bausch + Lomb Sensitive Eyes Plus Saline Solution (K170483)

4. Description of the Device

Boston Original Cleaner is a sterile, concentrated, homogeneous surfactant solution containing alkyl ether sulfate and silica gel as cleaning agents, titanium dioxide and fragrance.

Boston Original Conditioning Solutions is a sterile, aqueous buffered, solution containing a cellulosic viscosifier, cationic cellulose derivative polymer and

polyvinyl alcohol as wetting and cushioning agents; preserved with chlorhexidine gluconate (0.006%) and edetate disodium (EDTA) (0.05%).

5. Intended Use

Boston Original Cleaner is indicated for use to clean silicone acrylate and fluoro silicone acrylate gas permeable contact lenses after each removal and before conditioning (wetting, soaking, disinfecting).

Boston Original Conditioning Solutions is indicated for wetting, disinfecting and soaking (after cleaning and rinsing) of fluoro silicone acrylate and silicone acrylate gas permeable contact lenses.

6. Description of Safety and Substantial Equivalence

A series of preclinical testing was performed to demonstrate the safety and effectiveness of the modified regimen which replaces the water rinse with Bausch + Lomb Sensitive Eyes Plus Saline 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:

Microbiology

Studies were previously performed to establish discard dating for both Boston Original Cleaner and Boston Original Conditioning Solutions. The test articles were evaluated initially and again following simulated use for the proposed 90 day discard dates.

The results of these evaluations demonstrate that both solutions meet the requirements of ISO 14730, Annex C, Ophthalmic optics - Contact lens care products - Antimicrobial preservative efficacy testing and guidance on determining discard date.

Additionally a modified regimen procedure allowing for a rinse with Sensitive Eyes Plus Saline Solution in place of tap water was conducted. The results demonstrate that modified regimen with Sensitive Eyes Plus Saline Solution meets the FDA performance criteria for regimen evaluation as described in the *May 1, 1997 Guidance for Industry, Pre-market Notification (510(k)) Guidance Document for Contact Lens Care Products* when used in a 10 second rub, 5 second rinse (per lens side) regimen. The products used in this regimen also meet the performance criteria established in ISO Standard 14729: 2001/Amd. 1:2010: (E) for regimen testing. Regimen testing was previously reviewed as part of K170483.

Biocompatibility

Biocompatibility tests were unnecessary for this application. Previous data submitted is still applicable, please reference K980133 for Boston Original Conditioning Solutions, and P820069 for Boston Original Cleaner.

Lens Compatibility

The results of lens compatibility studies per ISO 11981 demonstrate that replacing water with Bausch + Lomb Sensitive Eyes Plus Saline Solution as part of the regimen is compatible with gas permeable contact lenses.

Clinical Data

Clinical studies involving the modified regimen for Boston Original Cleaner and Conditioning Solutions were unnecessary for this application. This Cleaner – Conditioning System has been commercially available in the market for almost 20 years with well demonstrated safety and efficacy.

7. Substantial Equivalence

The cumulative results of laboratory testing sponsored by Bausch + Lomb demonstrate that the safety, effectiveness and performance of the modified regimen for Boston Original Cleaner and Conditioning Solutions to include Bausch + Lomb Sensitive Eyes Plus Saline Solution when used with gas permeable contact lenses are substantially equivalent to the current regimen with a water rinse.