November 17, 2017

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

Re: K173365
Trade/Device Name: Bausch + Lomb Boston® Scleral Lens Case
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (Hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LRX
Dated: October 25, 2017
Received: October 26, 2017

Dear Nancy Fehrman:

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)*
K173365

Device Name
Bausch + Lomb Boston® Scleral Lens Case

Indications for Use *(Describe)*
Bausch + Lomb Boston® Scleral Lens Case is indicated for storage of gas permeable (fluoro silicone acrylate and silicone acrylate) contact lenses, including large diameter (scleral) lenses, during chemical disinfection.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

Bausch + Lomb Boston® Scleral Lens Case

1. Submitter Information

Primary	Alternate
Nancy Fehrman Senior Manager, Regulatory Affairs 1400 North Goodman Street Rochester, NY 14609 Tel. (585) 338-5310 Fax (585) 338-0702 Email: Nancy.Fehrman@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: October 25, 2017

2. Device Name

Common Name: Contact Lens Case

Trade Name: Bausch + Lomb Boston® Scleral Lens Case

Classification: Case, Contact Lens

Device classification: Class II (21 CFR §886.5928)

Product Code: LRX

3. Predicate Device

CyberCases™ by Bausch & Lomb® (K013232)

4. Description of the Device

Bausch + Lomb Boston® Scleral Lens Case consists of a polypropylene cap and polypropylene body for storage of gas permeable (fluoro silicone acrylate and silicone acrylate) contact lenses, including large diameter (scleral) lenses, during chemical disinfection.

5. Intended Use

Bausch + Lomb Boston® Scleral Lens Case is indicated for storage of gas permeable (fluoro silicone acrylate and silicone acrylate) contact lenses, including large diameter (scleral) lenses, during chemical disinfection.

6. Description of Safety and Substantial Equivalence

A series of preclinical testing was performed to demonstrate the safety and effectiveness of Bausch + Lomb Boston® Scleral Lens Case 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

Microbiology issues pertaining to contact lens cases are covered by the warning included in the labelling which states:
Contact lens cases can be a significant source of microbial contamination. To help prevent eye infections, contact lens cases should be cleaned, rinsed and air dried every day, and replaced at least every three months.

Toxicology

Systemic toxicity, cytotoxicity, and ocular irritation studies were completed for Bausch + Lomb Boston® Scleral Lens Case The test results demonstrated the biocompatibility of the Bausch + Lomb Boston® Scleral Lens Case.

Clinical Data

Clinical studies involving the Bausch + Lomb Boston® Scleral Lens Case were unnecessary for this application. The Bausch + Lomb Boston® Scleral Lens Case is similar in design, materials and intended use to the predicate device, which has been commercially available in the market for over 15 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 Bausch + Lomb Boston® Scleral Lens Case are substantially equivalent to the CyberCases™ by Bausch & Lomb® (K013232).

SUBSTANTIAL EQUIVALENCE SUMMARY TABLE

Feature	CyberCases™ by Bausch & Lomb® (K013232)	Bausch + Lomb Boston® Scleral Lens Case (Subject of this 510(k))
Product Code	LRX	LRX
Regulation Number	21 CFR 886.5928	21 CFR 886.5928
Indications For Use	Indicated for use in the storage of hard, rigid gas permeable (fluoro silicone acrylate and silicone acrylate) and soft (hydrophilic) contact lenses during chemical disinfection	Indicated for use in the storage of gas permeable (fluoro silicone acrylate and silicone acrylate) contact lenses during chemical disinfection
Technology Features	Differentiate between the right and left wells for lens storage using right lens cap colors	Differentiate between the right and left wells for lens storage using right lens cap colors
Materials	Polypropylene cap and body	Polypropylene cap and body
Colorants	Orange, 2% Magenta (pink), 1% Teal, 1% Green, 2% Purple, 1%	Orange, up to 3% Magenta, up to 3% Teal, up to 3% Green, up to 4% Purple, up to 6% White, up to 3% Blue, up to 4% Bright Green, up to 3% Lime Green, up to 3%
Volume	3.3mL fill volume Sufficient volume to assure that the lens remains completely immersed under conditions of use	6.5mL fill volume Sufficient volume to assure that the lens remains completely immersed under conditions of use
Right cap embossment	“R”	None
Left cap embossment	“L”	“L”
Biocompatibility	Met the Requirements for: ISO 10993-5 Biological evaluation of medical devices, Part 5: Tests for in vitro cytotoxicity; ISO 10993-10 Biological evaluation of medical devices, Part 10: Tests for irritation and skin sensitization	Met the Requirements for: ISO 10993-5 Biological evaluation of medical devices, Part 5: Tests for in vitro cytotoxicity; ISO 10993-10 Biological evaluation of medical devices, Part 10: Tests for irritation and skin sensitization

	ISO 10993-11 Biological evaluation of medical devices, Part 11: Tests for systemic toxicity.	ISO 10993-11 Biological evaluation of medical devices, Part 11: Tests for systemic toxicity.