DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 11, 2017

Bausch & Lomb Incorporated
Ms. Melissa Thomas
Senior Manager, Regulatory Affairs
1400 North Goodman Street
Rochester, New York 14609

Re: K170483
Trade/Device Name: Bausch + Lomb Sensitive Eyes Plus Saline Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (Hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LPN, MRC
Dated: February 14, 2017
Received: February 16, 2017

Dear Ms. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Denise L. Hampton -S

for Malvina 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170483

Device Name
Bausch + Lomb Sensitive Eyes Plus Saline

Indications for Use *(Describe)*

Bausch + Lomb Sensitive Eyes Plus Saline Solution is a sterile, preserved solution for rinsing soft (hydrophilic) and gas permeable contact lenses after cleaning and before lens insertion with chemical (not heat) and hydrogen peroxide systems.

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

K170483

Bausch + Lomb Sensitive Eyes Plus Saline Solution

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: April 2017

2. Device Name

Trade Name: Bausch + Lomb Sensitive Eyes Plus Saline Solution

Classification: Accessories, Contact Lens Care Products

Device classification: Class II

Regulation Number:
886.5928 Soft Contact Lens Care Products
886.5918 Rigid Gas Permeable Contact Lens Care Products

Product Code: LPN, MRC

3. Predicate Device

Bausch + Lomb Sensitive Eyes Plus Saline Solution (P800024/S16)
Menicon Saline Rinse Solution (K151768)

4. Description of the Device

Bausch + Lomb Sensitive Eyes Plus Saline Solution is a sterile, isotonic, buffered solution that contains boric acid, sodium borate, potassium chloride, sodium chloride, preserved with polyaminopropyl biguanide (0.00003%) and edetate disodium (0.025%). The sterile solution is packaged in a plastic bottle with a tamper evident seal and labeled with a lot number and expiration date.

5. Intended Use

Bausch + Lomb Sensitive Eyes Plus Saline Solution is a sterile, preserved solution for rinsing soft (hydrophilic) and gas permeable contact lenses after cleaning and before lens insertion with chemical (not heat) and hydrogen peroxide systems.

6. Description of Safety and Substantial Equivalence

A series of preclinical testing was performed to demonstrate the safety and effectiveness of 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 performed to establish discard dating of 90 days for Sensitive Eyes Plus Saline Solution. The test articles were evaluated initially and again following simulated use for the proposed discard date of 90 days.

The results of these evaluations demonstrate that Sensitive Eyes Plus Saline Solution meets the requirements of ISO 14730, Annex C Procedure II, Ophthalmic optics - Contact lens care products - Antimicrobial preservative efficacy testing and guidance on determining discard for the designation of a 90 day discard date.

Additionally a modified regimen procedure allowing for a rinse with Sensitive Eyes Plus Saline Solution In Place of Tap Water was conducted for both Boston Conditioning Solution and Boston Advance Conditioning Solution. The results of both evaluations 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.

Biocompatibility

Biocompatibility tests were unnecessary for this application. The Sensitive Eyes Plus Saline Solution was previously cleared for use and expansion of the indication did not prompt the need for new testing.

Lens Compatibility

The results of lens compatibility studies per ISO 11981 demonstrate Bausch + Lomb Sensitive Eyes Plus Saline Solution is compatible with rigid gas permeable contact lenses.

Clinical Data

Clinical studies involving Sensitive Eyes Plus Saline Solution were unnecessary for this application. The Sensitive Eyes Plus Saline Solution has been commercially available in the market for over 25 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 Sensitive Eyes Plus Saline Solution when used with gas permeable contact lenses are substantially equivalent to the current product which is indicated for use with soft contact lenses.

SUBSTANTIAL EQUIVALENCE SUMMARY TABLE

Feature	Menicon Saline Rinse Solution (K151768)	Sensitive Eyes Plus Saline Solution (P800024/S16)	Sensitive Eyes Plus Saline Solution (K170483)
Product Code	LPN, MRC	LPN	LPN, MRC
Regulation Number	21 CFR 886.5918 21 CFR 886.5928	21 CFR 886.5928	21 CFR 886.5918 21 CFR 886.5928
Indicated for Soft Lenses	Yes	Yes	Yes
Indicated for Rigid Gas Permeable Lenses	Yes	No	Yes
Rinse Required for Cleaning	Unknown	Thoroughly Rinse 5 Seconds Each Side	Thoroughly Rinse 5 Seconds Each Side
Discard After Opening	Unknown	NA	90 day Discard Date
Primary Container	Plastic resin container with twist off cap	Plastic Bottle Multiple Sizes	Plastic Bottle Multiple Sizes
Container Usage	Single Use	Multi Use	Multi Use
Preserved	No	Yes	Yes
Sterile	Yes	Yes	Yes
Technology Features	Isotonic Aqueous Solution	Isotonic Aqueous Solution	Isotonic Aqueous Solution
Materials	Plastic Resin Container With Twist Off Cap	Plastic Resin Container With Cap	Plastic Resin Container With Cap
Principles of Operation	Mechanical Rinsing	Mechanical Rinsing	Mechanical Rinsing
Directions for Use	Unknown	Rinse After Cleaning (5 sec. per side) Rinse After Disinfection (20 seconds) Carton Onsert Bausch.com	Rinse After Cleaning (5 sec. per side) Rinse After Disinfection (20 seconds) Carton Onsert Bausch.com