November 25, 2016

Bausch & Lomb Incorporated
Glenn Davies, O.D.
Senior Director Regulatory Affairs
1400 North Goodman Street
Rochester, NY 14609

Re: K161819
Trade/Device Name: NNR06 Multi-purpose Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (Hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LPN
Dated: October 19, 2016
Received: October 20, 2016

Dear Dr. Davies:

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 yours,

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
Indications for Use

Bausch + Lomb® NNR06 Multi-Purpose Solution is indicated for use in the daily conditioning, cleaning, removal of protein deposits, rinsing, chemical (not heat) disinfection, and storage of soft (hydrophilic) contact lenses, including silicone hydrogel contact lenses, as recommended by your eye care practitioner.

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.”
1. **Submitter Information**

Bausch & Lomb Incorporated  
1400 North Goodman Street  
Rochester, NY 14609  

**Contact Person**  
Glenn A. Davies, O.D.  
Senior Director Regulatory Affairs  

**Telephone Number**  
(585) 338-8215  

Summary Prepared: November 2016

2. **Device Name**

**Common Name:** Soft (hydrophilic) Contact Lens Care Solution  
**Trade Name:** NNR06 Multi-Purpose Solution  
**Classification:** Accessories, Soft Lens Products  
**Device classification:** Class II (21 CFR §886.5928)  
**Product Code:** LPN

3. **Predicate Device**

COMPLETE Multi-Purpose Solution Easy Rub Formula (K030092)

4. **Description of the Device**

Bausch + Lomb NNR06 Multi-Purpose Solution is a sterile, isotonic solution containing a triple disinfection system (polyaminopropyl biguanide 0.00005%, polyquaternium 0.00015% and alexidine 0.0002%), dual surfactants, poloxamine, poloxamer 181, and a novel buffering system consisting of edetate disodium, sodium citrate, and diglycine. The formulation also contains boric acid, sodium borate, sodium chloride and purified water. 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 NNR06 Multi-Purpose Solution is indicated for use in the daily cleaning, conditioning, removing protein deposits, rinsing, chemical (not heat) disinfection, and storage of soft (hydrophilic) contact lenses, including silicone hydrogel contact lenses, as recommended by your eye care practitioner.

6. **Description of Safety and Substantial Equivalence**

A series of preclinical and clinical testing was performed to demonstrate the safety and effectiveness of Bausch + Lomb NNR06 Multi-Purpose 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:

**Biocompatibility**

Cytotoxicity, ocular irritation, oral toxicity, sensitization and *in vivo* ocular biocompatibility studies were completed for Bausch + Lomb NNR06 Multi-Purpose Solution. The test results demonstrated the biocompatibility of NNR06 Multi-Purpose Solution.

Testing was conducted according to *Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products*, May 1, 1997 and ISO Standard 10993-1 *Biological evaluation of medical devices and related biocompatibility standards* (ISO 9394, ISO 10993-5, ISO 10993-10, ISO 10993-11).

**Microbiology**

The sponsor conducted a series of studies according to EN ISO 14729:2001 *Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses*, including Amendment 1 (2010), and EN ISO 14730:2014 *Antimicrobial preservative efficacy testing and guidance on determining discard date*, ISO18259 *Method to assess contact lens care products with contact lenses in a lens case*, and ISO 19045 *Method for evaluating Acanthamoeba encystment by contact lens care products* and demonstrate Bausch + Lomb NNR06 Multi-Purpose Solution exceeds the criteria for disinfection and preservative efficacy.

In addition, ISO 17665-1 *Sterilization of Health Care Products – Moist Heat* and ISO 11137 *Sterilization of Health Care Products – Radiation* were used to assess the sterilization method for production.

**Lens Compatibility**

The results of lens compatibility studies demonstrate Bausch + Lomb NNR06 Multi-Purpose Solution is compatible with soft contact lenses including silicone hydrogel contact lenses.

Testing was conducted according to *Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products*, May 1, 1997 and ISO Standard 11981.
Determination of physical compatibility of contact lens care products with contact lenses, ISO 11986 Determination of preservative uptake and release.

Cleaning Efficacy
The cleaning efficacy of the solution was evaluated through the determination of the Critical Micelle Concentration. The surfactant concentrations are well above the CMC for the individual surfactants. In vitro laboratory studies demonstrated the cleaning properties of NNR06 Multi-Purpose Solution with contact lenses artificially deposited with protein.

Clinical Study
Bausch + Lomb conducted a controlled clinical study with soft (hydrophilic) contact lenses, including silicone hydrogel lenses, comparing the safety and effectiveness of Bausch + Lomb NNR06 Multi-Purpose Solution to Complete Multi-Purpose Solution Easy Rub Formula. The study was a three-month, active control, parallel group, masked randomized study of habitual contact lens wearers.

Testing was conducted according to Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products, May 1, 1997 and ISO Standard 11980 Guidance for clinical investigations.

Safety
The primary endpoint of interest for slit lamp findings was achieved. There were no reported adverse events in either treatment group during the study. Visual acuities were similar between eyes of both groups.

Graded slit lamp findings; the incidence and type of slit lamp findings and symptoms requiring medical treatment; the comparison of visual acuities; and the absence of adverse events indicate that the NNR06 Solution is safe for use with soft contact lenses, including silicone hydrogel lenses.

Effectiveness
Comfort-related symptoms/complaints, Investigator-assessed lens wettability, and Investigator-assessed lens deposits indicate that the NNR06 Multi-Purpose Solution is effective for use with soft contact lenses including silicone hydrogel lenses.

The results of the study demonstrated similar safety and effectiveness profiles and support a substantial equivalence determination.

7. Substantial Equivalence
Bausch + Lomb NNR06 Multi-Purpose Solution has the same technological characteristics, sterile, isotonic, aqueous chemical disinfecting solution, as the predicate device. Bausch + Lomb NNR06 Multi-Purpose Solution does not raise new questions of safety and effectiveness.
The cumulative results of laboratory, \textit{in vitro}, \textit{in vivo}, and clinical testing sponsored by Bausch + Lomb demonstrate that the safety, effectiveness and performance of Bausch + Lomb NNR06 Multi-Purpose Solution are substantially equivalent to AMO Complete Multi-Purpose Solution Easy Rub Formula for soft contact lenses, including silicone hydrogel contact lenses.

The similarities and differences between Bausch + Lomb NNR06 Multi-Purpose Solution and the predicate device, AMO Complete Multi-Purpose Solution Easy Rub Formula, are described in the following table.

**SUBSTANTIAL EQUIVALENCE SUMMARY TABLE**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Bausch + Lomb NNR06 Multi-Purpose Solution</th>
<th>AMO Complete Multi-Purpose Solution Easy Rub Formula</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicated for Soft Lenses</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Indicated for Silicone Hydrogel Lenses</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Indicated for use in conditioning, cleaning, removal of protein rinsing, disinfection and storage of contact lenses</td>
<td>Yes</td>
<td>Yes (Except Conditioning)</td>
</tr>
<tr>
<td>Rub Regimen</td>
<td>3 Drops 20 Seconds</td>
<td>3 Or More Drops 20 Seconds</td>
</tr>
<tr>
<td>Optional No-Rub Regimen</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Rinse Required for Cleaning</td>
<td>Thoroughly Rinse 5 Seconds Each Side</td>
<td>Rinse 5 Seconds Each Side</td>
</tr>
<tr>
<td>Minimum Disinfection Time</td>
<td>4 hours</td>
<td>6 hours</td>
</tr>
<tr>
<td>Triple Disinfection System</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Preservatives / Disinfectants</td>
<td>Polyaminopropyl Biguanide 0.5ppm</td>
<td>Polyhexamethylene Biguanide 1ppm</td>
</tr>
<tr>
<td></td>
<td>Polyquaternium 1.5ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Alexidine 2.0ppm</td>
<td></td>
</tr>
</tbody>
</table>
### SUBSTANTIAL EQUIVALENCE SUMMARY TABLE (CONTINUED)

<table>
<thead>
<tr>
<th>Feature</th>
<th>Bausch + Lomb NNR06 Multi-Purpose Solution</th>
<th>AMO Complete Multi-Purpose Solution Easy Rub Formula</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dual Surfactants</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Surfactants</td>
<td>Poloxamer 181 Poloxamine</td>
<td>Poloxamer 237</td>
</tr>
<tr>
<td>Lens Storage Period</td>
<td>30 Days</td>
<td>30 Days</td>
</tr>
<tr>
<td>Discard After Opening</td>
<td>90 Days</td>
<td>No Use Before Expiration Date</td>
</tr>
<tr>
<td>Primary Container</td>
<td>Clear Plastic Bottle Multiple Sizes</td>
<td>White Plastic Bottle Multiple Sizes</td>
</tr>
</tbody>
</table>