August 8, 2019

Allergan, Inc.
Emily Huang, MS
Senior Manager, Global Regulatory Affairs
2525 Dupont Drive
Irvine, CA 92623-9534

Re: K190674
Trade/Device Name: REFRESH® RELIEVA™ For CONTACTS
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (Hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LPN, MRC
Dated: July 3, 2019
Received: July 5, 2019

Dear Ms. Huang:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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.


For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdhr-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

J Angelo Green

J. Angelo Green, Ph.D.
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality Center for Devices and Radiological Health

Enclosure
Indications for Use

REFRESH® RELIEVA™ FOR CONTACTS is indicated to lubricate and rewet soft and rigid gas permeable contact lenses, to help relieve dryness, discomfort and irritation that may be associated with lens wear and to cushion lenses by placing a drop on the lens prior to the application on the eye.

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

Applicant Information

Preparation Date: 07 August 2019
Applicant: Allergan
2525 Dupont Drive
Irvine, CA 92623-9534
Contact Person: Emily Huang, Senior Manager, Global Regulatory Affairs
Telephone Number: (714) 246-2294
Fax Number: (714) 796-3015
Email: emily.huang@allergan.com

Device Information

Trade Name: REFRESH® RELIEVA™ FOR CONTACTS
Common Name: Soft (hydrophilic) Contact Lens Care Products and Rigid Gas Permeable Contact Lens Care Products
Classification Name: Soft (hydrophilic) Contact Lens Care Products (21 CFR 886.5928) and Rigid Gas Permeable Contact Lens Care Products (21 CFR 886.5918)
Device Classification: Class II
Product Code: LPN and MRC

Predicate Device

The predicate devices are:
- REFRESH® Contacts Lubricating and Rewetting Drops (K992028)
- REFRESH OPTIVE CONTACTS Lubricating and Rewetting Drops (K083812)

Description of Device

REFRESH® RELIEVA™ FOR CONTACTS is a sterile, buffered, isotonic, preserved solution. This aqueous formulation includes carboxymethylcellulose sodium, glycerin, boric acid, calcium chloride dihydrate, erythritol, magnesium chloride hexahydrate, potassium chloride, purified water, sodium borate decahydrate, sodium citrate dihydrate, sodium hyaluronate and the preservative PURITE® (stabilized oxychloro complex 0.01%). The solution may also contain hydrochloric acid and/or sodium hydroxide to adjust pH.

All ingredients except for Purite are compendial grade (USP/NF/Ph Eur). The product is supplied in a teal colored, low density polyethylene (LDPE) multi-dose bottle and tip with a teal colored high impact polystyrene (HIPS) cap. The bottles are further packaged in paper cartons with a patient information insert.

Indications for Use

REFRESH® RELIEVA™ FOR CONTACTS is indicated to lubricate and rewet soft and rigid gas permeable contact lenses, to help relieve dryness, discomfort and irritation that may be
associated with lens wear and to cushion lenses by placing a drop on the lens prior to the application on the eye.

The indication for REFRESH® RELIEVA™ FOR CONTACTS is identical to the predicate devices. The modifications to the predicate devices do not change the intended use and the changes do not raise any additional significant safety or effectiveness concerns.

**Comparison of Technological Characteristics with the Predicate Device**

The intended use of REFRESH® RELIEVA™ FOR CONTACTS is identical to its predicate devices: For use with soft (hydrophilic) contact lenses and for use with rigid gas permeable (RGP) contact lenses. The components of the device are not novel and are included in already cleared contact lens lubrication and rewetting solutions with similar concentrations. The components of REFRESH® RELIEVA™ FOR CONTACTS and the predicate devices are provided in Table 1.

**Table 1**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Predicate 1: REFRESH CONTACTS (9329X)</th>
<th>Predicate 2: REFRESH OPTIVE CONTACTS (9689X)</th>
<th>Proposed Device: REFRESH RELIEVA FOR CONTACTS (10077X)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carboxymethylcellulose Sodium</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Glycerin</td>
<td>-</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Sodium Hyaluronate</td>
<td>-</td>
<td>-</td>
<td>X</td>
</tr>
<tr>
<td>Erythritol</td>
<td>-</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Boric Acid</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Sodium Borate Decahydrate</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Sodium Citrate Dihydrate</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Potassium Chloride</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Calcium Chloride Dihydrate</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Levothiamine</td>
<td>-</td>
<td>X</td>
<td>-</td>
</tr>
<tr>
<td>Magnesium Chloride Hexahydrate</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>PURITE®, a stabilized oxychloro complex</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>X</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sodium Hydroxide / Hydrochloric Acid</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Purified Water</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
Allergan performed stability, biocompatibility and performance testing (bench, nonclinical, and clinical studies with this formulation to support the claim of substantial equivalence). A summary of the testing and studies is provided below.

**Stability**
The product demonstrated chemical and physical stability to support a 24-month shelf-life. Microbiology testing demonstrated the product’s ability to maintain sterility and preservative effectiveness throughout the shelf-life.

**Biocompatibility**
*In-vitro* and *in-vivo* studies were performed to assess the safety and effectiveness of REFRESH® RELIEVA™ FOR CONTACTS. The tests were designed in accordance to FDA’s Guidance for Industry - Premarket Notification [510(k)] Guidance Document for Contact Lens Care Products dated 1 May 1997. The results of these studies indicate that the physical, chemical and microbiological properties of REFRESH® RELIEVA™ FOR CONTACTS are substantially equivalent to the predicate devices REFRESH CONTACTS and REFRESH OPTIVE CONTACTS.

**Clinical Studies**
A 3-month clinical study was conducted to evaluate the safety and efficacy of REFRESH® RELIEVA™ FOR CONTACTS to the marketed contact lens comfort drop, REFRESH CONTACTS® in contact lens wearers. The objective of this study was to provide evidence to support the claim that the performance of REFRESH® RELIEVA™ FOR CONTACTS is substantially equivalent to REFRESH CONTACTS for lubricating and rewetting during lens wear, and cushioning upon lens insertion. Results of the clinical study demonstrated substantial equivalence to REFRESH CONTACTS®.

**Conclusion**
Based on the stability, biocompatibility and performance testing (bench, nonclinical, and clinical studies) summarized above, the safety and effectiveness profile for REFRESH® RELIEVA™ FOR CONTACTS was substantially equivalent to the predicate devices for the same intended use.