December 4, 2017

Alcon Laboratories, Inc.
Ralf Finke
Senior Regulatory Specialist
Ciba Vision GmbH
Industriering 1
Grosswallstadt, Bavaria 63868, Germany

Re: K173538
Trade/Device Name: Clear Care Cleaning & Disinfecting Solution, AOCup Lens Case with AODisc
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (Hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LPN, LRX
Dated: November 10, 2017
Received: November 15, 2017

Dear Ralf Finke:

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)*
K173538

Device Name
Clear Care Cleaning & Disinfecting Solution, AOCup Lens Case with AODisc

Indications for Use *(Describe)*
For storage of soft (hydrophilic), and rigid gas permeable (RGP) hard contact lenses during disinfection with buffered 3% hydrogen peroxide contact lens solution.

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.

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510(k) Summary

This 510(k) summary document has been prepared in accordance with section 21 CFR 807.92.

I. Submitter of the 510(k)

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Date Prepared:	November 10, 2017

II. Devices Subject to this 510(k)

Trade Names:	Clear Care Cleaning & Disinfecting Solution, AOCup Lens Case with AODisc
Common Name:	Cleaning and Disinfecting Solution, Contact lens case
Classification Name:	Ophthalmic
Device Classification:	Class II (21 CFR 886.5928) Soft (hydrophilic) contact lens care products; (21 CFR 886.5918) Rigid gas permeable contact lens care products
Product Code:	LPN (Solution), LRX (lens case)

III. Predicate Device

The legally marketed device(s) to which we are claiming substantial equivalence are:

510(k) Number	Device
K003345, 26-Mar-2001; K013512, 20-Dec-2001; K022687, 19-Nov-2002; K023455, 28-Feb-2003; K030522, 12-Sep-2003; K031521, 27-Jun-2003	Clear Care Cleaning & Disinfecting Solution (contains the AOCup Lens Case with AODisc as part of the system)
Previously approved in PMA P820040, Supplement S032, 23-Oct-1995 (Reclassified to Class II in 1997) Special 510k K162597, 19-Oct-2016	AOCup Lens Case with AODisc

IV. Device Description

The AOCup Lens Case with AODisc is equivalent to the predicate device except change to the silicone material of a gasket and the coating of this silicone gasket. The gasket has O-ring form and is included in the screw cap assembly of the lens case.

The device is a specialized lens case consisting of a transparent cup with a connected unit of screw cap, lens holders (baskets) and platinum-coated neutralization disc. The platinum catalyst coating and shape of the plastic disc are designed to effectively neutralize hydrogen peroxide in the lens care system to harmless water and oxygen gas.

The modifications of gasket material and coating do not change any indications for use nor the basic technical principle of the device functions.

V. Indications for Use

For storage of soft (hydrophilic), and rigid gas permeable (RGP) hard contact lenses during disinfection with buffered 3% hydrogen peroxide contact lens solution.

VI. Comparison to Technological Characteristics with the Predicate Device

The silicone material and its coating of an o-ring gasket in the screw cap of predicate device AOCup Lens Case cleared in 510k K162597 has been changed to a different silicone material and different coating. Dimensions and technical function of the gasket are unchanged.

VII. Performance Data

The AOCup Lens Case with AODisc and the changed gasket was evaluated in biocompatibility, physicochemical and design functionality tests.

Toxicological safety has been tested and confirmed in a battery of tests of the new silicone as well as the new coating material in accordance with the subparts of standard ISO 10993. Furthermore, extractable and leachable testing of the coated and uncoated gaskets has been conducted in accordance with USP and EP requirements.

Design functionality tests were conducted to confirm that the coating adheres reliably to the silicone material and does not affect negatively any functionality characteristics of the gasket in the lens case assembly.

VIII. Conclusions

Successful results of all nonclinical testing supported the substantial equivalence and therefore safety and efficacy of the modified AOCup Lens Case with AODisc to the existing product for its intended use.