July 31, 2019

Alcon Laboratories, Inc.
Dr. Ralf Finke
Senior Regulatory Specialist
Alcon Vision Care
Industriering 1
Grosswallstadt, DE 63868 Bavaria

Re: K191795
Trade/Device Name: 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: LRX, LPN
Dated: July 2, 2019
Received: July 3, 2019

Dear Dr. 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. 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.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

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/cdrh-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, 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

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)*

K191795

Device Name

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.

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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:	June 24, 2019

II. Devices Subject to this 510(k)

Trade Names:	AOCup Lens Case with AODisc (part of the Clear Care Cleaning & Disinfecting Solution system and the Clear Care Plus Cleaning & Disinfecting Solution system)
Common Name:	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:	LRX (lens case) LPN (Solution)

III. Predicate Device

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

510(k) Number	Device
Previously approved in PMA P820040, Supplement S032, 23-Oct-1995 (Reclassified to Class II in 1997) Special 510k K162597, 19-Oct-2016 Special 510k K173538, 04-Oct-2017	AOCup Lens Case with AODisc
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)
K142284, 26-Jan-2015	Clear Care Plus Cleaning & Disinfecting Solution (contains the AOCup Lens Case with AODisc as part of the system)

IV. Device Description

The AOCup Lens Case with AODisc is equivalent to the predicate device except change to the silicone material of a 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 does 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 of an o-ring gasket in the screw cap of predicate device AOCup Lens Case cleared in 510k K162597 and K173538 has been changed to a different silicone material. 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.

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.