



Food and Drug Administration
10903 New Hampshire Avenue
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October 19, 2016

Alcon Laboratories, Inc.
% Mr. Ralf Finke
Senior Regulatory Specialist, Alcon Vision Care
CIBA Vision GmbH
Industriering 1
Grosswallstadt, Bavaria, DE 63868

Re: K162597

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

Dated: September 16, 2016

Received: September 19, 2016

Dear Mr. 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.

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,

 Kesia Alexander

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

510(k) Number (if known)

K162597

Device Name

AOSEPT Clear Care Cleaning and Disinfecting Solution (AOCup Lens Case with AODisc)

Indications for Use (Describe)

For use in simultaneous cleaning, daily protein removal, disinfecting, and storage of soft (hydrophilic) contact lenses (including silicone hydrogel lenses) or rigid gas permeable (fluoro silicone acrylate and silicone acrylate) 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.

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8 510(K) SUMMARY

This summary document is being prepared in accordance with section 21 CFR 807.92(c).

A. Submitter Information:

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Date Prepared: September 2016

B. Device Name:

Trade Names: AOSEPT Clear Care Cleaning and Disinfecting Solution
(AOCup Lens Case with AODisc)

Common Name: Contact Lens Accessory

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)

C. Predicate Devices:

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)	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)

D. Device Description:

The two color AOCup Lens Case with AODisc is equivalent to the predicate device except modifications of colorants and minor modifications to basket geometry.

It 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 the strong oxidizing agent hydrogen peroxide to harmless water and oxygen gas.

The modifications of colorants and basket geometry do not change any indications for use nor the basic technical principle of the device functions.

E. Indications for Use:

For use in simultaneous cleaning, daily protein removal, disinfecting, and storage of soft (hydrophilic) contact lenses (including silicone hydrogel lenses) or rigid gas permeable (fluoro silicone acrylate and silicone acrylate) contact lenses as recommended by your eye care practitioner.

F. Brief Summary of Nonclinical Test and Results:

The two color AOCup Lens Case with AODisc was evaluated in biocompatibility, physicochemical, design functionality and microbiological tests. 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.