K102860

MAY 10 2011

**510(k) SUMMARY**

**Submitted by:**

Beth L. Schultz

Manager II, Regulatory Affairs

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**Device Name:**

Proprietary Name: Alcon Multi-Purpose Disinfecting Solution

Common Name: Soft (Hydrophilic) Contact Lens Care Solution

Classification Name: Under 21 CFR §886.5928 titled Soft (hydrophilic) contct lens care products, this solution is classified as a Class II – Special Controls Product.

**Indications for Use:**

For use in the daily cleaning, reconditioning, rinsing, removing protein deposits, and reducing lipid deposition, chemical (not heat) disinfection, and storage of silicone hydrogel and soft (hydrophilic) contact lenses as recommended by your eye care practitioner.

**Description:**

Alcon Multi-Purpose Disinfecting Solution (MPDS) is a sterile, buffered, aqueous solution containing sodium citrate, sodium chloride, boric acid, sorbitol, aminomethylpropanol, disodium EDTA, two wetting agents (TETRONIC® 1304† and HydraGlyde™ Moisture Matrix) with POLYQUAD® (polyquaternium-1) 0.001% and ALDOX® (myristamidopropyl dimethylamine) 0.0006% preservatives. HydraGlyde™ Moisture Matrix is a proprietary synthetic block copolymer that is primarily designed for wetting and lubricating silicone hydrogel lenses.

†Tetronic® is a trademark of BASF.

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**Substantial Equivalence:**

Alcon MPDS meets the guidelines set forth in FDA's May 1, 1997 *Guidance for Industry; Premarket Notification 510(k) Guidance Document for Contact Lens Care Products.*

Alcon MPDS is substantially equivalent in terms of its actions and intended use to Bausch & Lomb™ renu® fresh™ multi-purpose solution (K974723), Bausch & Lomb™ BioTrue™ multi-purpose solution (K083757), Alcon OPTI-FREE® Replenish® Multi-Purpose Disinfecting Solution (K050729) and Alcon Multi-Purpose Solution (K071236). A summary of the test results is provided below:

**Safety and Effectiveness:**

Cleaning:

The cleaning efficacy of Alcon MPDS was evaluated through the determination of the Critical Micelle Concentration. The surfactant concentrations are well above the CMC for the individual surfactants. Cleaning efficacy studies conducted with Alcon MPDS indicate that it is effective at removing protein deposits and reducing lipid deposition from silicone hydrogel and soft (hydrophilic) lenses. Studies also demonstrated cleaning activity when lenses were soaked in Alcon MPDS.

Compatibility:

The results of lens compatibility studies show that Alcon MPDS is compatible with soft (hydrophilic) and silicone hydrogel lenses.

Microbiology:

Alcon conducted a series of studies based on FDA's May 1, 1997 *Guidance for Industry; Premarket Notification 510(k) Guidance Document for Contact Lens Care Products.*, ANSI Z80, EN ISO 14729:2001 *Ophthalmic optics- Contact lens care products- Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses* and EN ISO 14730:2000 Opthalmic optics- *Contact lens care products- Antimicrobial preservative efficacy testing and guidance on determining discard date* to demonstrate the

microbiological efficacy of Alcon MPDS. Alcon MPDS exceeds the criteria for disinfection and preservative efficacy.

Biocompatibility:

Alcon MPDS was tested in compliance with the guidelines set forth in FDA's May 1, 1997 *Guidance for Industry; Premarket Notification 510(k) Guidance Document for Contact Lens Care Products.* Based on the results of the comprehensive preclinical evaluations, Alcon MPDS is safe for the consumer under the recommended use conditions, as well as under conditions of reasonably foreseeable misuse.

Clinical:

A clinical study was conducted to evaluate the safety and efficacy of the Alcon® MPDS in silicone hydrogel and soft (hydrophilic) contact lens wearers. The control product was Bausch & Lomb™ renu® fresh™ Multi-Purpose Solution. The safety and efficacy of Alcon MPDS was clinically acceptable and similar to or better than the control. Alcon MPDS is substantially equivalent to the control. The results indicate that Alcon MPDS provides comfort and moisture from insertion to removal.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Re: K102860
Trade/Device Name: Alcon Multi-Purpose Disinfecting Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LPN
Dated: April 28, 2011
Received: April 29, 2011

Dear Dr. Schultz:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K102860

# Indications for Use

510(k) Number (if known): K102860

Device Name: Alcon Multi-Purpose Disinfecting Solution

Indications for Use:
For use in the daily cleaning, reconditioning, rinsing, removing protein deposits, and reducing lipid deposition, chemical (not heat) disinfection, and storage of silicone hydrogel and soft (hydrophilic) contact lenses as recommended by your eye care practitioner.

| Prescription Use (Part 21 CFR 801 Subpart D) | | AND/OR | Over-The-Counter Use (21 CFR 801 Subpart C) | X |
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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