SEP 14 2005

K050729

510(k) SUMMARY

Submitted by:

Kim B. Kracke

Senior Manager, Regulatory Affairs

Alcon Research, Ltd.

6201 South Freeway

Fort Worth, Texas 76134-2099

(817) 551-8338 (Phone)

(817) 551-4630 (Fax)

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) contact lens care products, this solution is classified as a Class II – Special Controls Product.

Indications for Use:

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

ALCON® Multi-Purpose Disinfecting Solution can also be used with OPTI-FREE® SUPRACLENS® Daily Protein Remover.

Description:

ALCON® Multi-Purpose Disinfecting Solution is a sterile, buffered, isotonic, aqueous solution containing sodium citrate, sodium chloride, sodium borate, propylene glycol, a proprietary dual action conditioning system (Tetronic® 1304†, nonanoyl

ethylenediaminetriacetic acid) with POLYQUAD® (polyquaternium-1) 0.001% and ALDOX® (myristamidopropyl dimethylamine) 0.0005% as preservatives.

† Tetronic® is a trademark of BASF.

Substantial Equivalence:

ALCON® Multi-Purpose Disinfecting Solution is substantially equivalent in terms of its actions and indications for use to Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution.

ALCON® Multi-Purpose Disinfecting Solution 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.*

Safety and Effectiveness:

Cleaning Effectiveness Studies

Laboratory studies were conducted with ALCON® Multi-Purpose Disinfecting Solution. The purpose of these studies was to evaluate passive cleaning using a no rub regimen with silicone hydrogel and soft contact lenses and the ability to clean laboratory deposited lenses. The results indicate that ALCON® Multi-Purpose Disinfecting Solution is effective at passively cleaning all soft contact lenses including silicone hydrogel lenses. This data is supported by results of clinical evaluations.

Additional laboratory studies conducted with OPTI-FREE® SUPRACLENS® Daily Protein Remover in combination with ALCON® Multi-Purpose Disinfecting Solution indicate improved cleaning efficacy on soft contact lenses.

The cleaning efficacy of the solution has been evaluated through the determination of the Critical Micelle Concentration (CMC). The surfactant concentration is well above the CMC, which ensures the effective cleaning function of the product.

Compatibility Studies

Lens compatibility studies performed with silicone hydrogel and FDA Groups I and IV contact lenses show that ALCON® Multi-Purpose Disinfecting Solution is compatible with all soft contact lenses including silicone hydrogels.

Wettability Studies

In vitro and *ex vivo* wettability studies were carried out on ALCON® Multi-Purpose Disinfecting Solution versus Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution marketed disinfection product. The *in vitro* study results correlated with the *ex vivo* study data where the ALCON® Multi-Purpose Disinfecting Solution formulation showed significantly lower wetting angles indicating excellent wettability. Comparatively, the Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution product showed high contact angles in the plateau region of the *in vitro* wetting data and this correlated with the *ex vivo* data where high wetting angles were observed. All of the *ex vivo* wetting angles were observed after eight hours of contact lens wear.

Microbiology Studies

A series of studies based on the FDA's May 1, 1997 *Guidance for Industry; Premarket Notification 510(k) Guidance Document for Contact Lens Care Products*, 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, the ANSI Contact Lens Care Products Standard, and EN ISO 14730:2000 Ophthalmic optics – Contact lens care products – Antimicrobial preservative efficacy testing and guidance on determining discard date were completed to demonstrate the microbiological efficacy of ALCON® Multi-Purpose Disinfecting Solution.

The product meets the Stand Alone Antimicrobial Activity of the above standards both in the presence and absence of organic soil. The product passes the Regimen Criteria in the presence of soil when tested according to the directions for use. In addition, results showed that the combination of ALCON® Multi-Purpose Disinfecting Solution with OPTI-FREE® SUPRACLENS® Daily Protein Remover meets the primary criteria of the Stand Alone test.

Biocompatibility

ALCON® Multi-Purpose Disinfecting Solution 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*. Based on the results of the comprehensive preclinical evaluations, ALCON® Multi-Purpose Disinfecting Solution is safe for the consumer under the recommended use conditions, as well as under conditions of reasonably foreseeable misuse.

Clinical Studies

A series of clinical studies was conducted using ALCON® Multi-Purpose Disinfecting Solution. A three-month clinical study with asymptomatic soft (hydrophilic) lens wearers, a one-month study with silicone hydrogel lens wearers and a one-month study with symptomatic soft (hydrophilic) lens wearers were conducted to demonstrate the safety and efficacy of the ALCON® Multi-Purpose Disinfecting Solution regimen with silicone hydrogel and soft (hydrophilic) contact lenses. The control products were the Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution regimen and the Advanced Medical Optics Complete MoisturePLUS Multi-Purpose Solution regimen used according to the current approved label. The safety and efficacy of the ALCON® Multi-Purpose Disinfecting Solution regimen were clinically acceptable and similar to the marketed comparator regimens when used according to the approved label. Lenses cared for with the ALCON® Multi-Purpose Disinfecting Solution regimen had statistically lower levels of lens deposits than the control regimens. In at least one of the three studies, subjects assigned to the ALCON® Multi-Purpose Disinfecting Solution regimen had statistically lower corneal staining and significantly improved comfort (on some measures of comfort) compared to one of the predicate product regimens. An additional clinical study was conducted to evaluate the effect of the ALCON® Multi-Purpose Disinfecting Solution regimen on the wetting characteristics of soft (hydrophilic) contact lenses. (This study is also cited above in the Wettability Studies section.) The control product was Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution regimen used according to the current approved label. Lenses were rinsed and disinfected overnight in the assigned multi-purpose solution. The differences in lens wettability after wear between ALCON® Multi-Purpose Disinfecting Solution and Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution were statistically significant ($p \leq 0.0001$) in favor of ALCON® Multi-Purpose Disinfecting Solution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 2005

Ms. Kim B. Kracke
Senior Manager, Regulatory Affairs
Alcon Research, Ltd.
6201 South Freeway
Fort Worth, TX 76134

Re: K050729
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: September 12, 2005
Received: September 13, 2005

Dear Ms. Kracke:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K050729

Device Name: Alcon Multi-Purpose Disinfecting Solution

Indications for Use:

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

Alcon Multi-Purpose Disinfecting Solution can also be used with OPTI-FREE® SUPRACLENS® Daily Protein Remover.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **OR** **Over-The-Counter Use** X
(Per 21 CFR 801.109)

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

510(k) Number K050729