

JAN 24 2012

510(k) SUMMARY**BAUSCH + LOMB EZS05
3% Hydrogen Peroxide
Disinfecting Solution****1. Submitter Information**

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609

Contact Person
Heather Michaels
Specialist Global Regulatory Affairs

Telephone Number
(585) 338-8493

2. Device Name

Common Name: Contact Lens Disinfection Solution
Trade Name: TBD
Classification: Soft (hydrophilic) contact lens care products
Device classification: Class II (21 CFR §886.5928)
Product Code: LPN

3. Predicate Devices

Ciba AOSEPT Disinfecting Solution (K003345, K013512)
Ciba Clear Care Cleaning and Disinfecting Solution (K022687)

4. Description of the Device

BAUSCH + LOMB EZS05 Disinfecting Solution is a sterile, buffered 3% hydrogen peroxide solution with a phosphonic acid stabilizer, sodium chloride and phosphate buffers. A special lens case containing a platinum coated neutralizing disc is provided with the EZS05 Disinfecting Solution. The sterile solution is packaged in a plastic bottle with a tamper evident seal and labelled with a lot number and expiration date

5. Intended Use

BAUSCH + LOMB EZS05 Disinfecting Solution is indicated for disinfecting, protein removal, and storage of soft (hydrophilic) contact lenses, as recommended by your eye care practitioner.

6. Description of Safety and Substantial Equivalence

A series of preclinical testing was performed to demonstrate the safety and effectiveness of BAUSCH + LOMB EZS05 Disinfecting Solution. A summary of the test results is provided below:

Biocompatibility

EZS05 Disinfecting Solution was evaluated for non-clinical safety in accordance with FDA Guidance for Contact Lens Solutions and Accessory Products, May 1997, as well as referencing several recognized testing Standards which were performed under Good Laboratory Practice regulations. Cytotoxicity, ocular irritation, and sensitization studies were completed for BAUSCH + LOMB EZS05 Disinfecting Solution. The test results demonstrated that BAUSCH + LOMB EZS05 Disinfecting Solution is non-cytotoxic, and not an ocular irritant or sensitizing agent.

Microbiology

A series of studies were conducted according to 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 *Ophthalmic optics – Contact lens care products – Antimicrobial preservative efficacy testing and guidance on determining discard date*. The testing demonstrated BAUSCH + LOMB EZS05 Disinfecting Solution meets the criteria for disinfection and preservative efficacy.

Lens Compatibility

The results of lens compatibility studies demonstrate BAUSCH + LOMB EZS05 Disinfecting Solution is compatible with soft contact lenses including silicone hydrogel contact lenses.

Protein Removal

The protein removal ability of EZS05 and predicate device Ciba Clear Care was evaluated with Polymacon (38.6% water), Etafilcon A (55% water), Galyfilcon A (47% water), and Balafilcon A (36% water) Soft Contact Lenses. The study evaluated the efficacy of the test products on lenses deposited *in vitro* with lysozyme and subjected to a single cleaning / disinfection regimen. The amount of lysozyme remaining on the lenses was quantitated by extraction and HPLC assay for total protein. The results demonstrated that EZS05 was statistically equivalent to the predicate device, Ciba Clear Care Cleaning and Disinfecting Solution.

Clinical Study

EZS05 Disinfecting Solution contains 3% hydrogen peroxide as the active ingredient, which is the same active ingredient within marketed concentrations of peroxide disinfecting solutions currently marketed in the U.S. Bausch & Lomb assessed the market history of peroxides, the ingredients compared to marketed product and, the applicability of the US FDA's "Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products" and determined that further Clinical Studies are not warranted.

Substantial Equivalence

The cumulative results of laboratory, *in vitro* and *in vivo* testing sponsored by Bausch & Lomb demonstrate that the safety, efficacy and performance of BAUSCH + LOMB EZS05 Disinfecting Solution are substantially equivalent to Ciba AOSEPT Disinfecting Solution, and Ciba Clear Care Cleaning and Disinfecting Solution for soft contact lenses.

SUBSTANTIAL EQUIVALENCE SUMMARY TABLE

Feature	BAUSCH + LOMB EZS05 Disinfecting Solution	Ciba Clear Care Cleaning and Disinfecting Solution K022687	Ciba AOSEPT Disinfecting Solution K003345, K013512
Indicated for soft lenses	Yes	Yes	Yes
Indicated for the removal of Protein	Yes	Yes	No
Rub Regimen	No	Yes, only for Rigid Gas Permeable Lenses	No
Lens Case	Designed for system	Designed for system	Designed for system
Minimum Disinfection Time	6 hours	6 hours	6 hours
Post disinfection saline rinse prior to wear	Optional	Optional	Yes
Hydrogen Peroxide Content	3%	3%	3%
Buffer System	Phosphate Buffer	Phosphate Buffer	Phosphate Buffer
Stabilizer	Phosphonic Acid	Phosphonic Acid	Phosphonic Acid
Lens Storage Period	7 days	7 days	24 hours



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

Bausch & Lomb, Inc.
c/o Ms. Heather Michaels
Specialist Global Regulatory Affairs
1400 North Goodman Street
Rochester, NY 14609

JAN 24 2012

Re: K111877
Trade/Device Name: Bausch & Lomb EZS05 Disinfecting Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LPN
Dated: January 17, 2012
Received: January 18, 2012

Dear Ms. Michaels:

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/CDRHOices/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
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

Indications for Use

510(k) Number (if known): K111877

Device Name: BAUSCH + LOMB EZS05 Disinfecting Solution

Indications for Use:

BAUSCH + LOMB EZS05 Disinfecting Solution is indicated for disinfecting, protein removal, and storage of 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 X
(Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K111877