K013512 DEC 2 0 2001

510(k) SUMMARY

In response to the requirements addressed by the Safe Medical Devices Act (SMDA) of 1990, a summary follows with the safety and effectiveness information upon which the substantial equivalence determination is based.

SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
AOSEPT Clear Care Cleaning and Disinfecting Solution

1. **Submitter Information**
CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia 30097
Contact Person: Steven Dowdley
Telephone No: 678-415-3897

2. **Device Name**
Classification Name: Soft (hydrophilic) Contact Lens Solution
Proprietary Name: AOSEPT Clear Care Cleaning and Disinfecting Solution

3. **Predicate Devices**
Bausch & Lomb ReNu MultiPlus Mulit-Purpose Solution

4. **Description of the Devices**
The AOSept Clear Care Cleaning and Disinfecting Solution is an aqueous solution contains hydrogen peroxide 3% (stabilized with phosphonic acid), sodium chloride, a phosphate buffer system and a non-ionic surfactant. The solution is indicated for use in simultaneous cleaning and disinfecting, daily protein removal, and storing of soft (hydrophilic) contact lenses as recommended by your eye care practitioner.

5. **Indications for Use**
AOSeptClear Care Cleaning and Disinfecting Solution is indicated for use in simultaneous cleaning, daily protein removal, disinfecting, and storing of soft (hydrophilic) contact lenses as recommended by your eye care practitioner.

6. **Description of Safety and Substantial Equivalence**

Cleaning Studies
Previous studies have demonstrated the cleaning capacity of AOSEPT Clear Care Cleaning and Disinfecting Solution (K003345) with soft contact lenses. The study previously submitted and reviewed demonstrated that AOSept Clear Care was substantially equivalent to the ReNu Multiplus and OptiFree Express in terms of daily protein removal.

Microbiology
A series of studies were completed to demonstrate the microbiological efficacy of AOSEPT Clear Care. These studies were previously submitted under 510(k) K003345. These studies demonstrate that AOSEPT Clear Care meets the stand-alone criteria of

the disinfection efficacy test of the FDA May 1, 1997 Guidance for Industry; Premarket Notification 510(k) Guidance Document for Contact Lens Care Products.

Clinical Evaluation Summary:

Overview

A three-month prospective, randomized, single masked, contralateral trial was preformed. Study participants were all randomized for which eye used the test and which eye used the control product. The control used in the study was Bausch & Lomb ReNu Multi-Plus Multi-Purpose solution. The regimen followed by the participants was the manufacturer's instructions for the eye using the control product (including rub and rinse) and the instructions provided for the eye using the test product (no rub/no rinse). The contra-lateral design and inclusion criteria optimize sensitivity in comparing the products.

Statistically significant differences in favor of AOSept Clear Care were found for insertion comfort and overall dryness. Statistically significant preference differences in those who expressed a preference in favor of AOSept Clear Care were also found for insertion comfort, dryness and lens cleanliness. Statistically significant differences (at the 0.01 or greater level) in favor of AOSept Clear Care were also found for all subjective ratings. Statistically significant differences (0.01 or greater) in favor of AOSept Clear Care were found for all subjective preference rankings.

Front surface wetting of the lenses was observed by the investigators and was found to be similar between the two lens groups. In addition, there were no statistically significant differences in investigator appraisal of lens deposits, front surface wetting and objective dark-field image analysis of lenses worn for 90 days. Both the test and control product provided clinically acceptable lens cleanliness when used according to their directions for use as measured by dark filed image analysis of the returned lenses.

The safety of AOSept Clear Care used without a rub (for lenses worn greater than one-month), is clinically acceptable and similar to the Bausch & Lomb ReNu Multi-Purpose Solution used according to its approval labeling, which requires a digital rubbing step.

7. **Substantial Equivalence**

AOSept Clear Care Cleaning and Disinfection Solution is substantially equivalent to the Bausch & Lomb ReNu Multi-Purpose Solution in cleaning, disinfecting, daily protein removal and storing of soft (hydrophilic) contact lenses as recommended by your eye care practitioner. The system was also shown to be substantially equivalent to the ReNu Multiplus Solution in daily removal of protein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2001

Mr. Steven Dowdley, RAC
Regulatory Specialist
Global Regulatory Affairs
CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, GA 30097

Re: K013512
Trade/Device Name: AOSEPT Clear Cleaning and Disinfecting Solution
(No Rub Regimen for soft contact lenses worn more than 30 days)
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LPN
Dated: October 16, 2001
Received: October 22, 2001

Dear Mr. Dowdley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

PART III. INDICATIONS FOR USE STATEMENT

510(k) Number: *This is a new 510 (k) Notification. (Number to be assigned)*

Device Name: AOSEPT Clear Care Cleaning and Disinfecting Solution

Indications for Use:
AOSEPT Clear Care Cleaning and Disinfecting Solution is indicated for use in simultaneous cleaning, daily protein removal, disinfecting, and storing of soft (hydrophilic) contact lenses as recommended by your eye care practitioner.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ☐ or over-the-counter: ☑

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

510(k) Number K013572