510(k) SUMMARY K023455 FEB 2 8 2003

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.

510 (k) SUMMARY
FOR
AOSEPT Clear Care Cleaning and Disinfecting Solution

Submitter Information

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

Device Name

Classification Name: Rigid gas permeable contact lens solution
Proprietary Name: AOSEPT Clear Care Cleaning and Disinfecting Solution

Predicate Devices

SOLO-Care™Brand Hard Solution

Description

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.

Indications for Use

AOSept Clear Care Cleaning and Disinfecting Solution is indicated for use in cleaning, daily protein removal, disinfecting, and storing of soft (hydrophilic) or rigid gas permeable (fluoro silicone acrylate and silicone acrylate) contact lenses as recommended by your eye care practitioner.

Description of Safety and Substantial Equivalence

A series of preclinical studies were previously conducted and reviewed by FDA to assess and demonstrate the safety and effectiveness of AOSept Clear Care with soft hydrophilic lenses. These studies were previously reviewed under two 510(k), K013512 and K003345. All toxicology and microbiological tests were conducted in accordance with GLP regulations. All other testing was conducted in accordance with and in conformance to applicable device regulations. The results further demonstrated that the solution is non-toxic and biocompatible.

The results sumerized below demonstrate that AOSept Clear Care is substantially equivalent to SOLO-Care Hard for cleaning, rinsing, disinfecting and storing rigid permeable (fluoro silicone acrylate and silicone acrylate lenses.

Compatibility

A study was conducted to verify the optical and physical parameters of Paraperm EW (Group II) and Fluoroperm 30 (Group III) hydrophobic contact lenses remain within specifications when used with AOSept Clear Care after 30 cycles. Paraperm EW (Group II) and Fluoroperm 30 (Group III) hydrophobic contact lenses were shown to be

compatible with AOSept Clear Care in terms of optical (power, base curve and diameter) and physical (visual appearance, % transmittance and microscope) properties.

In addition, a compatibility study was successfully conducted to demonstrate the compatibility of AOSept Clear Care when used in conjunction with Focus Lens Drops and Aquify Lens Drops.

Microbiology

The antimicrobial activity of AOSept Clear Care was previously evaluated by the ISO 14729 (FDA 510(k)) Stand Alone Test and Regimen Test procedure for disinfection of contact lenses. The results, as previously reviewed under K013512 and K003345, demonstrated that AOSept Clear Care provides effective disinfection of contact lenses based on ISO 14729 and the FDA 510(k) performance criteria for contact lens disinfecting solutions.

Biocompatibility

AOSept Clear Care meets the guidelines set forth in the FDA's May1, 1997 Guidance for Industry; Premarket Notification 510(k) Guidance for Contact Lens Care Products. In addition, compatibility was demonstrated with AOSept Clear Care and two currently marketed lubricating/rewetting drops (Focus Lens Drops and Aquify Comfort Drops).

Clinical

A one-month prospective randomized, trial consisting of a baseline visit and two follow-up visits were conducted with AOSept Clear Care. Subjects were randomized into two treatment groups according to which were to use the test and which were to use the control solution. Two thirds of subjects used the AOSept Clear Care, while and one-third used the control solution.

The data supports that AOSept Clear Care is an effective lens care system for rigid gas permeable lenses. The data also support that lenses treated AOSept Clear Care were clean after 1-month wear: 91% none or slightly deposited and 7% reporting lens needs cleaning at follow-up 2 visit. In addition, only 29% of the AOSept Clear Care users used lubricating drops prior to insertion every day and comfort was graded high (>8.5 [0-10 scale] at Follow-up 2). Subjects using the Aquify lubricating system showed higher comfort, fewer lens deposits and better lens wettability than those subjects using Focus Clerz.

In conclusion, the data supports that AOSept Clear Care is clinically acceptable as a care system for RGP lenses and is substantially equivalent to SOLO-Care Hard.

Substantial Equivalence

AOSept Clear Care Cleaning and Disinfection Solution is substantially equivalent to the SOLO-Care Hard Solution in cleaning, disinfecting, daily protein removal and storing of rigid gas permeable (fluoro silicone acrylate and silicone acrylate) contact lenses as recommended by your eye care practitioner.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2003

CIBA VisionCorporation
C/O Steven Dowdley, RAC
11460 Johns Creek Parkway
Duluth, GA 30097-1556

Re: K023455
Trade/Device Name: AOSEPT Clear Care Cleaning and Disinfecting Solution
Regulation Number: 21 CFR 886.5928, 21 CFR 886.5918
Regulation Name: Soft contact lens care products, Rigid gas permeable contact lens care products
Regulatory Class: Class II
Product Code: LPN, MRC
Dated: January 22, 2003
Received: January 29, 2003

Dear Mr. Dowdley:

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) 594-4613. 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 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

Enclosure

PART III. INDICATIONS FOR USE STATEMENT

K023455

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 cleaning, daily protein removal, disinfecting, and storing of soft (hydrophilic) or rigid gas permeable (fluoro silicone acrylate and silicone acrylate) contact lenses as recommended by your eye care practitioner.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Karen Waibant

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

510(k) Number K023455