NOV 17 1998

K 952168

SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
SOLO-CARE™ Brand MULTI-PURPOSE SOLUTION

1. **Submitter Information**

CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia 30097
Contact Person: Steven Dowdley (Senior Regulatory Affairs Associate)
Telephone No. 770-418-3897

2. **Device Name**

Classification Name: Soft (hydrophilic) Contact Lens Solution
Proprietary Name: SOLO-CARE™ Brand MULTI-PURPOSE SOLUTION

3. **Predicate Devices**

Bausch & Lomb ReNu® Multi-Purpose Solution and Bausch & Lomb ReNu® 1 Step Enzymatic Cleaner have been selected as the predicate devices for SOLO-Care™ Brand MULTI-PURPOSE SOLUTION. This combination of products was selected becuase when used as a system it is indicated for removing protein from soft contact lenses.

4. **Description of the Devices**

SOLO-Care™ Brand Multi-Purpose Solution is a sterile aqueous solution containing sodium chloride, polyoxyethylene polyoxypropylene block copolymer, sodium phosphate dibasic, sodium phosphate monobasic, and preserved with edetate disodium dihydrate 0.025% and polyhexanide 0.0001%. SOLO-Care™ Brand Multi-Purpose Solution contains multiple active ingredients in sufficient concentration to perform the function of daily cleaning, daily protein removal, rinsing, disinfecting, and storing soft (hydrophilic) contact lenses as recommended by your eye care practitioner. The sterile solution is contained in a plastic bottle and is labeled with a lot number and expiration date.

5. **Indications for Use**

SOLO-Care Brand Multi-Purpose Solution is indicated for use in daily cleaning, daily protein removal, rinsing, disinfecting, and storing of soft (hydrophilic) contact lenses as recommended by an eye care practitioner.

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

A series of preclinical and clinical studies were completed to demonstrated the safety and effectiveness of SOLO-Care Brand Multi-Purpose Solution, and to establish substantial equivalence to currently marketed, predicate solutions. All testing was conducted in accordance with and in conformance to applicable device regulations. Results demonstrate the solution is non-toxic and biocompatible, and is comparable to other currently marketed soft contact lens solutions. Results from all tests demonstrate the substantial equivalence to previously FDA approved, and currently marketed predicate devices.

Preclinical Testing:

A series of preclinical tests were performed to asses the safety and effectiveness of the solution. All preclinical toxicology and microbiology tests were conducted in accordance with GLP regulation (21 CFR Part 58). Results of the testing demonstrated that SOLO-Care Brand Multi-Purpose Solution is safe and effective as a multi-purpose soft (hydrophilic) contact lenses solution.

Clinical Testing:

A one month clinical evaluation was conducted in accordance with current Good Clinical Practices and published regulations (21 CFR Parts 50, 56, 312, 812). The clinical results provide valid scientific evidence that SOLO-care™ Multi-Purpose Solution is substantially equivalent to ReNu® Multi-Purpose Solution / ReNu® 1 Step™ Enzymatic Cleaner for the removal of visible protein. There were also no safety or efficacy issues raised with SOLO-care™ Multi-Purpose Solution used without a rinse prior to insertion.

7. **Substantial Equivalence**

SOLO-Care Brand Multi-Purpose Solution is substantially equivalent to Bausch & Lomb ReNu Multi-Purpose Solution used with Bausch & Lomb ReNu 1 Step Enzymatic Cleaner in that both SOLO-Care Brand Multi-Purpose Solution and ReNu Multi-Purpose Solution with Bausch & Lomb ReNu 1 Step Enzymatic Cleaner are indicated for use in daily cleaning, daily protein removal, rinsing, disinfecting, and storing of soft (hydrophilic) 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

NOV 17 1998

Mr. Steven Dowdley
Senior Associate, Regulatory Affairs
CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, GA 30097-1556

Re: K982168
Trade Name: SOLO-Care ™ Brand Multi-Purpose Solution
(Daily Protein Removal Claim for use with Soft Lenses)
Regulatory Class: II
Product Code: 86 LPN
Dated: September 22, 1998
Received: September 24, 1998

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 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

INDICATIONS FOR USE STATEMENT

Device Name: SOLO-Care ™ Brand Multi-Purpose Solution

Indications for Use:

SOLO-Care ™ Brand Multi-Purpose Solution is indicated for use in daily cleaning, rinsing, chemical (not heat) disinfecting, protein removal 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 Devices
510(k) Number K982168