NOV 25 1998

K983291

510(k) SUMMARY – K983291

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**

BOSTON Simplicity Multi-action Solution (P950010, June 9, 1995) has been selected as the predicate devices for SOLO-Care™ Brand MULTI-PURPOSE SOLUTION.

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, 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, rinsing, chemical (not heat) disinfecting, protein removal and storing of soft (hydrophilic) or rigid gas permeable (fluoro silicone acrylate and silicone acrylate) lenses as recommended by your eye care practitioner.

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

A series of preclinical and clinical studies have been conducted to assess and demonstrate the safety and effectiveness of SOLO-Care Brand Multi-Purpose Solution for soft (hydrophilic), contact lenses (P940042, April 25, 1996). In addition, SOLO-Care Brand Multi-Purpose Solution has been approved for a daily protein removal indication for soft contact lenses under K982168. Soft contact lenses represent worst case in terms of cleaning, protein removal, rinsing, disinfecting and storing of contact lenses. In addition, lens solution compatibility tests were conducted under the recommended care regimen, compared with the predicate device (Boston Simplicity) indicating that SOLO-Care Brand Multi-Purpose Solution is compatible with rigid gas permeable (flourosilicone and silicon acrylate) lenses. An addition compatibility study was also successfully conducted to determine the compatibility of SOLO-Care Brand Multipurpose Solution when used in conjunction with Focus Lens Drops. Focus Lens Drops was previously approved for use with rigid gas permeable lenses under P860060/S02 on March 28, 1990.

7. **Substantial Equivalence**

SOLO-Care Brand Multi-Purpose Solution is substantially equivalent to BOSTON Simplicity Multi-Action Solution for daily cleaning, rinsing, disinfecting and storing rigid gas permeable (fluoro silicone acrylate and silicone acrylate) lenses. In addition, SOLO-Care Brand Multi-Purpose Solution has been approved for a daily protein removal indication for soft contact lenses under K982168.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 1998

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

Re: K983291
Trade Name: SOLO-Care ™ Brand Multi-Purpose Solution
(labeling change to allow for use with Soft and RGP Lenses)
Regulatory Class: II
Product Code: 86 MRC
Dated: September 18, 1998
Received: September 21, 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

510(k) Number: K983291

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

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ☐ or Over-the-Counter: ☑

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K983291