JUL 16 1999

K991403

# 510(K) 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**

Currently marketed SOLO-Care™ Brand MULTI-PURPOSE SOLUTION was selected as the predicate devices for this submission. This product was selected because the formulation and indications for use are identical to the device proposed in this submission.

4. **Description of the Devices**

SOLO-Care™ Brand Multi-Purpose Solution is a sterile aqueous solution used in the care contact lenses and is indicated for cleaning, rinsing, chemical (not heat) disinfecting and protein removal, storing soft (hydrophilic), rigid gas permeable (fluoro silicon acrylate and silicon acrylate) and PMMA contact lenses as recommended by your eye care practitioner. It may also be uses as a diluent for enzymatic cleaning tablets, which are to be used in conformance to the established labeling directions of the enzymatic cleaning tablet. The solution is contains in a plastic bottle and consists of a sterile isotonic solution containing sodium chloride, polyoxyethylene polyoxypropylene block copolymer, sodium phosphate dibasic, sodium phosphate monobasic, and preserved with edetate disodium dihydrate and polyhexanide 0.0001%. Each bottle is supplied sterile and is labeled with a lot number and expiration date.

5. **Indications for Use**

SOLO-Care™ Brand Multi-Purpose Solution is indicated for cleaning, rinsing, chemical (not heat) disinfecting and protein removal, storing soft (hydrophilic), rigid gas permeable (fluoro silicon acrylate and silicon acrylate) and PMMA contact lenses as recommended by your eye care practitioner.

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

A series of pre-clinical studies have been completed to demonstrate the safety and effectiveness of SOLO-Care Brand Multi-Purpose Solution; all studies have previously been submitted under P940042, K 982168, and under K983291. To support the claim of 10-minute disinfection, a series of microbiological testing has been completed at time periods ranging from 10 minutes to 4 hours. A compatibility study was also successfully completed to demonstrate compatibility with PMMA lenses. All results were satisfactory.

7. **Substantial Equivalence**

SOLO-Care Brand Multi-Purpose Solution is substantially equivalent to the predicate device. SOLO-Care Brand Multi-Purpose Solution in a 10-minute disinfection cycle time is substantially equivalent to a 4-hour disinfection cycle time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 1999

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

Re: K991403
Trade Name: SOLO-Care ™ Brand Multi-Purpose Solution
Regulatory Class: II
Product Code: 86 LPN
Dated: April 20, 1999
Received: April 22, 1999

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

**PART III. INDICATIONS FOR USE STATEMENT**

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

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

**Indications for Use:**
SOLO-Care™ Brand Multi-Purpose Solution is indicated for cleaning, rinsing, chemical (not heat) disinfecting and protein removal, storing soft (hydrophilic), rigid gas permeable (fluoro silicon acrylate and silicon acrylate)and PMMA contact lenses as recommended by your eye care practitioner.

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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 K991403