

**VII. 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  
SOLO-CARE™ HARD SOLUTION**

1. **Submitter Information**  
CIBA Vision Corporation  
11460 Johns Creek Parkway  
Duluth, Georgia 30097  
Contact Person: Steven Dowdley (Senior Regulatory Affairs Associate)  
Telephone No. 678-415-3897
2. **Device Name**  
Classification Name: Rigid Gas Permeable Contact Lens Solution  
Proprietary Name: SOLO-CARE™ HARD SOLUTION
3. **Predicate Devices**  
The predicate devices selected for this submission was BOSTON Advanced Conditioning Solution, BOSTON Classic and Boston Simplicity Solution. These products were selected because of similarities in the indication and formulation of this product and the proposed device.
4. **Description of the Devices**  
SOLO-Care™ HARD Solution is a sterile aqueous solution containing hydroxyethylcellulose, tris amino, sodium chloride, disodium edetate, poloxamer 407, polyoxyethylene polyoxpropylene block copolymer, and is preserved polyhexanide 0.0002%. SOLO-Care™ HARD Solution contains multiple active ingredients in sufficient concentration to perform the function of daily cleaning, rinsing, disinfecting and conditioning rigid gas permeable and hard contact lenses as recommended by an 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™ Hard Solution is indicated for use in daily cleaning, rinsing, chemical (not heat) disinfecting and conditioning fluoro silicone acrylate, silicone acrylate and hard (PMMA) contact lenses as recommended by your 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 Hard 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 that the solution is non-toxic and biocompatible, and is comparable to other currently marketed contact lens solutions.

**Preclinical Testing****Cleaning Effectiveness – Critical Micelle**

Results demonstrated that the surfactant concentration is formulated in SOLOCare Hard Solution at sufficiently high levels to maintain its activity for cleaning and detergency.

Contact Wetting Angle

Dynamic contact angle analysis indicated that the SOLO-care Hard Solution is statistically equivalent to predicate solution Boston Simplicity in terms of surface wettability of the lens.

Solution Compatibility

Compatibility testing of SOLO-care HARD with CAB, silicon acrylate and fluorsilicone acrylate lens materials was conducted to demonstrate compatible with various material types. The study showed that after 30 cycles all parameters were still within the ANSI/ISO reference range for rigid gas permeable lenses for both solutions. In addition, there was no change in the cosmetic appearance of the lenses.

Stability (chemical and microbiological)

Shelf life for SOLO-Care HARD Solution has been demonstrated on 3 lots of product filled in white polypropylene bottles. Chemical stability testing was conducted at 4°C, 25°C, 30°C and 40°C on pH, osmolarity, viscosity, appearance and active ingredients. Based on the data collected, the trends observed and the estimated calculations of the accelerated test samples the shelf life for SOLO-care HARD Solution is 24 months.

Preservative Effectiveness

Studies were performed to evaluate the preservative effectiveness of SOLOCare HARD Solution. The results demonstrate that SOLO-Care Hard meets the requirements of the ISO/DIS 14730 Preservative Effectiveness Test against the panel organisms tested.

Disinfection Efficacy

The ISO Regimen Test was performed in accordance with ISO/CD 14729 to determine the antimicrobial effectiveness of the SOLO-Care Hard regimen. The results demonstrated that the solution meets the requirements of the standard.

Toxicology Results

L929 Direct Contact Material Assay, L929 Agar Overlay Diffusion Assay, Growth Inhibition Test, and Ocular Irritation Test were conducted in accordance with and in conformance to applicable regulations. Results demonstrated that the solution and lenses treated with the solution did not cause a toxic response or increase ocular irritation.

Clinical Testing

Three clinical studies were used to evaluate SOLO-care Hard Solution. Overall 166 contact lens wearers were enrolled and were exposed to the test and control solution from a wearing period of 1 month to 6 months.

The data from the studies were examined using descriptive statistics, tests for normality, analysis of variance and/or t-tests where appropriate. Analysis of all data from the studies showed no that the test and control solutions were substantially equivalent. In addition, no additional safety concerns were raised regarding the test solution.

7. Substantial Equivalence

SOLO-Care Hard Solution is substantially equivalent to BOSTON Advanced Conditioning Solution, BOSTON Classic and Boston Simplicity Solution in terms of usage, formulation similarities, and indications for use in daily cleaning (Boston Simplicity only), rinsing, chemical (not heat) disinfecting, storing and wetting of fluoro silicone acrylate, silicone acrylate and hard (PMMA) contact lenses as recommended by your eye care practitioner.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K993949  
Trade Name: SOLO-Care™ Hard Solution (RGP multipurpose solution)  
Regulatory Class: II  
Product Code: 86 MRC  
Dated: October 12, 1999  
Received: November 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**

K993949

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

**Device Name:** SOLO-Care™ Hard Solution

**Indications for Use:**

SOLO-Care™ Hard Solution is indicated for use in daily cleaning, rinsing, chemical (not heat) disinfecting and conditioning of fluoro silicone acrylate, silicone acrylate and hard (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:

*Lonnie W. C. Brown, M.D.*

(Division Sign-Off)  
Division of Ophthalmic Devices

510(k) Number K993949

Confidential