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K031522

PART IX. 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.

510(k) SUMMARY
FOR
SOLOCare Plus Multipurpose Solution

1. **Submitter Information**

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

2. **Device Name**

Classification Name: Soft (hydrophilic) Contact Lens Solution
Proprietary Name: SOLO-Care Plus Multipurpose Solution

3. **Predicate Device(s)**

SOLO-Care Plus Multipurpose Solution

4. **Description of the Device**

SOLO-Care Plus Multi-Purpose Solution is a sterile aqueous solution containing sodium chloride, bis-tris propane, pluronic F127, cremephor and preserved with edetate disodium dihydrate 0.025% and polyhexanide 0.0001%.

5. **Indications for Use**

SOLO-CARE PLUS Multipurpose Solution is indicated for cleaning, rinsing, chemical (not heat)disinfecting, daily protein removal, and storing of soft (hydrophilic) contact lenses (including silicone hydrogel lenses) as recommended by your eye care practitioner.

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

SOLO-Care Plus Multipurpose solution is substantially equivalent in terms of its actions and indications for use, to SOLO-Care Plus Multipurpose Solution, cleared for marketing under 510(k) K012731.. SOLO-Care Plus meets the guidelines set forth in FDA's May 1, 1997 Guidance for Industry, Premarket Notification 510(k) Guidance Document for Contact Lens Care products.

Silicone Hydrogel Lens Compatibility Data:

A study was conducted to verify that Lotrafilcon A (silicone hydrogel) lenses are compatible with SOLO-Care Plus. The study showed there was no significant difference between SOLO-Care™ Plus Multi-Purpose Solution and the saline control solution, with respect to optical and physical changes in the measured properties of the lenses. SOLO-Care Plus meets the guidelines set forth in FDA's May 1, 1997 Guidance for

Industry, Premarket Notification 510(k) Guidance Document for Contact Lens Care products.

In Vitro Cleaning Efficacy
This study was conducted to compare the protein cleaning efficacy of SOLO-Care™ Plus Multi-Purpose Solution to currently marketed SOLO-Care Multipurpose Solution. Results of the study showed that SOLO-Care Plus is substantially equivalent to SOLO-Care Multipurpose Solution in terms of daily protein removal. This data was previously submitted and reviewed in original 510(k) submission - K012731.

Cytotoxicity
A series of cytotoxicity studies were conducted to demonstrate the safety of SOLO-Care Multipurpose Solution. Results of the testing demonstrated that SOLO-Care Multipurpose Solution is non-cytotoxic and is a non-irritant. This data was previously submitted and reviewed in original 510(k) submission - K012731.

Microbiological
A two series of microbiological studies were conducted to demonstrate the microbial efficacy SOLO-Care Multipurpose Solution. The first series evaluated the product under a rub/rinse regimen, while the second regimen evaluated the performance of the product under a pre-rinse/ no rub regimen. In the studies, both regimen demonstrated that SOLO-Care Multipurpose Solution met the stand-alone criteria with organic load for disinfection. Additionally, the regimen test criteria was also meet for both regimen for SOLO-Care Plus. This data was previously submitted and reviewed in original 510(k) submission - K012731.

Clinical Testing
A series of clinical studies have been conducted, submitted and reviewed in original 510(k) submission - K012731 to support the substantial equivalency of SOLO-Care Plus.

7. **Substantial Equivalence**
The data provided in this 510(k) submission concludes that SOLO-Care Plus Multipurpose Solution is substantially equivalent to SOLO-CARE PLUS Multipurpose Solution is indicated for cleaning, rinsing, chemical (not heat)disinfecting, daily protein removal, and storing of soft (hydrophilic) contact lenses (including silicone hydrogel 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

JUN 27 2003

CIBAVision Corporation
c/o Steven Dowdley, RAC
CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, GA 30097

Re: K031522
Trade/Device Name: SOLO-Care Plus Multipurpose Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LPN
Dated: May 12, 2003
Received: May 28, 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 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, 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

510(k) Number: *(Number to be assigned)*

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

Indications for Use:
SOLO-CARE PLUS Multipurpose Solution is indicated for cleaning, rinsing, chemical (not heat)disinfecting, daily protein removal, and storing of soft (hydrophilic) contact lenses (including silicone hydrogel 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 Ear, Nose and Throat Devises

510(k) Number K031522