K031957

AUG 14 2003

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
KARATS Multi-purpose 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: KARATS Multi-purpose Solution

3. **Predicate Device(s)**

KARATS Multi-purpose Solution

4. **Description of the Device**

Karats Multi-Purpose Solution is a sterile aqueous solution containing sorbitol, tromethamine, pluronic F127, sodium phosphate dihydrogren, dexpanthnol, edetate disodium dihydrate and preserved with polyhexanide 0.0001

5. **Indications for Use**

Karats Multi-Purpose Solution is indicated for cleaning, rinsing, chemical (not heat) disinfecting, protein removal and storing soft (hydrophilic) lenses (including silicone hydrogel lenses) as recommended by your eye care practitioner.

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

A series of preclinical and clinical studies have been completed on this product and were previously submitted under submission K021635. The non-clinical and clinical studies were completed to demonstrate the substantial equivalence of KARATS to other currently marketed 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.

Silicone Hydrogel Lens Compatibility Data

A study was conducted to verify that Lotrafilcon A (silicone hydrogel) lenses are compatible with KARATS Multi-purpose Solution. The study showed there was no significant difference between KARATS and the saline control solution, with respect to optical and physical changes in the measured properties of the lenses. KARATS Multi-purpose Solution 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.

Surface Analysis by XPS

X-Ray Photoelectron Spectroscopy (XPS) was used to analysis the surface of the lenses to determine if the surface coating was compromised by the solution. Following cycling in the solution, lens samples were processed and analyzed. The kinetic energy of the photoelectrons

was measured and the binding energy of the photoelectron was calculated. The results showed that there were no significant changes to the surface of the Focus NIGHT & DAY lens as analyzed by XPS testing.

In Vitro Cleaning Efficacy
Results of the study showed that KARATS is substantially equivalent to currently marketed products in terms of daily protein removal. This data was previously submitted and reviewed in original 510(k) submission - K021635.

Cytotoxicity
A series of cytotoxicity studies were previously conducted to demonstrate the safety of KARATS. Results of the testing demonstrated that KARATS is non-cytotoxic and is a non-irritant. This data was previously submitted and reviewed in original 510(k) submission - K021635.

Microbiology
A series studies were previously completed to demonstrate the microbiological efficacy of KARATS. These studies were previously submitted under 510(k) K021635. These studies demonstrate that KARATS meets the stand-alone criteria of the disinfection efficacy test of the FDA May 1, 1997 Guidance for Industry; Premarket Notification 510(k) Guidance Document for Contact Lens Care Products.

Clinical Testing
A series of clinical studies have been conducted, submitted and reviewed in 510(k) submission K021635. Data from the clinical studies supported the substantial equivalence of KARATS.

7. **Substantial Equivalence**
The data provided in this 510(k) submission concludes that Karats Multi-Purpose Solution is substantially equivalent to Karats Multi-Purpose Solution for cleaning, rinsing, chemical (not heat) disinfecting, protein removal and storing soft (hydrophilic) 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

AUG 14 2003

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

Re: K031957
Trade/Device Name: Karats Multi-Purpose Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LPN
Dated: June 23, 2003
Received: July 21, 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

PART III. INDICATIONS FOR USE STATEMENT

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

Device Name: KARATS Multi-purpose Solution

Indications for Use:
Karats Multi-Purpose Solution is indicated for cleaning, rinsing, chemical (not heat) disinfecting, protein removal and storing soft (hydrophilic) 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 K031957