K0132 04

APR 0 3 2002

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
AQuify Lens Comfort Drops

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: AQuify Lens Comfort Drops

3. **Predicate Devices**

Bausch and Lomb - ReNu Multiplus Lubricating and Rewetting Drops
Pfizer - Visine for Contacts
Biomatrix - Hylashield CL Lubricating Eye Drops

4. **Description of the Devices**

AQuify Lens Comfort Drops is a sterile solution containing sodium hyaluronate, sodium chloride, sodium phosphate and sodium perborate stabilized with phosphoric acid as a preservative.

5. **Indications for Use**

Use AQuify Lens Comfort Drops to moisten, cushion, refresh, and provide temporary relief from dryness and irritation associated with contact lens wearing.

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

A series of preclinical and clinical studies were completed to demonstrate the substantial equivalence of AQuify Lens Comfort Drops to the predicate device(s). 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. Results from all tests demonstrate the substantial equivalence to previously FDA approved predicate device.

Lens Compatibility Data:

There was no significant difference between AQuify Lens Comfort Drops and the control solution with respect to optical (power, base curve and diameter) and physical (visual appearance and % transmittance) changes in the measured properties of lenses. The results further showed that the changes observed in lens power and diameter were within ANSI specifications. The proposed solution was found to be substantially equivalent to the control solution

Cytotoxicity
A series of comprehensive cytotoxicity studies were conducted to evaluate the safety of AQuify Lens Comfort Drops. Results of the testing demonstrated that AQuify Lens Comfort Drops is non-cytotoxic and is a non-irritant.

Microbiological
AQuify Lens Comfort Drops tested for microbiological safety and effectiveness using the FDA guidelines for contact lens solution. The solution met the acceptance criteria for the ISO/FDA Preservative Effectiveness Test.

Clinical Testing
A one month clinical study was conducted to evaluate the substantial equivalence of AQuify Lens Comfort Drops to B&L ReNu Multi-purpose Lubricating and Rewetting Drops. The results of the study demonstrated no differences in biomicroscopy findings, symptoms, or vision safety measures between AQuify Lens Comfort Drops (HAM) and the control treatment groups. In addition, there were no adverse differences for shown in the test cell for lens surface characteristics, wearing times or subjective ratings. The findings of this study demonstrate the substantial equivalence of AQuify Lens Comfort Drops.

7. **Substantial Equivalence**

The data provided in this 510(k) submission concludes that AQuify Lens Comfort Drops is substantially equivalent to the predicate devices selected for this submission (ReNu Multiplus Lubricating and Rewetting Drops, Visine for Contacts, and Hylashield CL Lubricating Eye Drops).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Steven Dowdley
CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia 30097

APR 0 3 2002

Re: K013204
Trade/Device Name: AQuify Lens Comfort Drops
Regulation Number: 886.5928
Regulatory Class: Soft (hydrophilic) contact lens care products
Product Code: LPN
Regulation Number: 886.5918
Regulatory Class: Rigid gas permeable contact lens care products
Product Code: MRC
Dated: January 24, 2002
Received: January 30, 2002

Dear Mr. Dowdley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and have determined the device is substantially equivalent 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

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

K013204

PART III: INDICATIONS FOR USE STATEMENT

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

Device Name: AQuify Lens Comfort Drops

Indications for Use:

Use AQuify Lens Comfort Drops to moisten, cushion, refresh, and provide temporary relief from dryness and irritation associated with contact lens wearing.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ☐ or over-the-counter: ☑ JS

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K013204