DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2004

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

Re: K042176
Trade/Device Name: AQuify Lens Comfort Drops
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LPN
Dated: July 28, 2004
Received: August 23, 2004

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

- **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
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**
AMO Blink-N-Clean

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**

- **Comparison of Technological Characteristics:** The action section has been expanded. No changes have been made to the current product formulation.
- **Non- clinical:** No new studies performed. Non-clinical data from K013204 should be referenced.
- **Discussion of Clinical Data:** Clinical data

7. **Conclusions Drawn form Data Supporting Equivalence Determination**

The purpose of this application is to provide a more descriptive "action" section to the package insert for AQuify Lens Comfort Drops. There were no changes to the product formulation. Application, K013204 has already established the substantial equivalence of the product. The clinical data provide in the application supports that AQuify Lens Comfort Drops is substantially equivalent to Complete Blink-N-Clean.

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: ☒

David W.C. Brown, Ph.D.

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

510(k) Number K042176