FEB - 2 2005

HYDROGEL VISION CORPORATION
510(K) Premarket Notification – Supplement 2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K040303

Applicant information:

Date Prepared:	January 27, 2005
Name:	Hydrogel Vision Corporation
Address:	6447 Parkland Drive Sarasota, FL 34243
Contact Person:	Donna Hovanec Quality System Coordinator Hydrogel Vision Corporation
Phone number:	941-739-1382

Device information:

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Lens, Soft Contact, Daily Wear
Trade Name:	59% Extreme H_2O (hioxifilcon A) Soft Contact Lens for Daily Wear (cast-molded, with a visibility tint)

Purpose of 510(k) Submission:

Hydrogel Vision Corporation is requesting clearance from the FDA to expand the Indications for Use for the 59% Extreme H2O soft contact lens. The lens was originally approved on October 18, 1999, under 510(k) K992692, for the indication of daily wear correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes that are myopic or hyperopic with astigmatism of 0.75 Diopters or less that does not interfere with visual acuity. We are submitting this 510(k) to expand the indication to include toric lenses. The 59% Extreme H_2O (hioxifilcon A) toric soft contact lens for daily wear is indicated for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lens may be worn by persons who exhibit astigmatism of 10.00 Diopters or less. Eye care practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning disinfection and

scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfection system.

Equivalent Device:

The 59% Extreme H_2O (hioxifilcon A) toric soft contact lens is substantially equivalent to our already cleared 59% Extreme H_2O (hioxifilcon A) spherical lens under 510(k) K992692.

Device Description:

59% Extreme H2O (hioxifilcon A) soft contact lenses are hemispherical shells and are available as spherical (G59 S-Thin and G59 S-Xtra) or toric (G59 Toric) lens designs. The 59% Extreme H2O (hioxifilcon A) soft contact lens is fabricated from hioxifilcon A, which is a non-ionic, copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydroxypropyl Methacrylate (Glycerol Methacrylate, GMA) and cross-linked with ethylene glycol dimethacrylate (EGDMA). It consists of 41% hioxifilcon A and 59% water by weight when immersed in normal saline solution buffered with either sodium bicarbonate or sodium perforate. The lens is available with a blue visibility handling tint, phthalocyanato (2) - (copper).

Intended Use (Indications):

The 59% Extreme H_2O (hioxifilcon A) toric soft contact lens for daily wear is indicated for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lens may be worn by persons who exhibit astigmatism of 10.00 Diopters or less.

Eye care practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfection system.

Substantial Equivalence:

The information provided in this 510(k) establishes that the 59% Extreme H2O (hioxifilcon A) toric soft contact lens differs only in design to the 59% Extreme H2O (hioxifilcon A) spherical soft contact lens and meets the requirements per section 510(k) of the act regarding substantial equivalence and *does not raise* different questions of safety and effectiveness than the predicate device identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 2 2005

Hydrogel Vision Corporation
c/o Donna Hovanec
Quality System Coordinator
6447 Parkland Drive
Sarasota, FL 34243

Re: K040303
Trade/Device Name: 59% Extreme H_2O (hioxifilcon A) Contact Lens for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: January 13, 2005
Received: January 14, 2005

Dear Ms. Hovanec:

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) 827-8910. 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/industry/support/index.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

Enclosure

HYDROGEL VISION CORPORATION
510(K) Premarket Notification – Supplement 2

INDICATIONS FOR USE STATEMENT

Device Name: 59% Extreme H_2O® (hioxifilcon A) toric soft contact lens

INDICATIONS FOR USE:

The 59% Extreme H_2O (hioxifilcon A) toric soft contact lens for daily wear is indicated for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lens may be worn by persons who exhibit astigmatism of 10.00 Diopters or less.

Eye care practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfection system.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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

510(k) Number K040303