K051430

JUL 18 2005

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:

Applicant information:

Date Prepared:	May 31, 2005
Name:	Hydrogel Vision Corporation
Address:	7575 Commerce Court Sarasota, FL 34243
Contact Person:	Donna Hovanec Manager, Quality Systems Hydrogel Vision Corporation
Phone number:	941-739-1382
Fax number:	941-758-6887

Device information:

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Lens, Soft Contact, Daily Wear
Trade Name:	Extreme $H_2O^{®}$ 54%(hioxifilcon D) 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 manufacture and market the Extreme $H_2O^{®}$ 54% soft contact lens.

Equivalent Device:

The Extreme $H_2O^{®}$ 54% (hioxifilcon D) soft contact lens is substantially equivalent to our 59% Extreme $H_2O^{®}$ (hioxifilcon A) soft contact lens already cleared under 510(k) K992692.

Device Description:

Extreme $H_2O^{®}$ 54% (hioxifilcon D) soft contact lenses are hemispherical shells and are available as spherical (G54 13.6 and G54 14.2) or toric (G54 Toric) lens designs. The Extreme $H_2O^{®}$ 54% (hioxifilcon D) soft contact lens is fabricated from hioxifilcon D, 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 46% hioxifilcon D and 54% water by weight when immersed in normal saline solution buffered with either sodium bicarbonate or sodium borate. The lens is available with a blue visibility handling tint, phthalocyanato (2) - (copper).

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a colorless, transparent optical surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped. However, it will return to its proper configuration when completely rehydrated in the proper storage solution.

Intended Use (Indications):

The Extreme $H_2O^{®}$ 54% (hioxifilcon D) 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 spherical lens may be worn by persons who exhibit astigmatism of 0.75 Diopters or less that does not interfere with visual acuity. The toric lens may be worn by persons who exhibit astigmatism of up to 10.00 Diopters.

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: Comparison to Predicate Device

PROPERTY	Extreme $H_2O^{®}$ 54% BENZ-G 4X	59% Extreme $H_2O^{®}$ BENZ-G 5X
Lens Material	hioxifilcon D	hioxifilcon A
Material Classification	Hydrophilic Lens Group II	Hydrophilic Lens Group II
Method of Manufacture	Cast Molded	Cast Molded
Indications for Use	The Extreme $H_2O^{®}$ 54% (hioxifilcon D) 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 spherical lens may be worn by persons who exhibit astigmatism of 0.75 Diopters or less that does not interfere with visual acuity. The toric lens may be worn by persons who exhibit astigmatism of up to 10.00 Diopters. 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.	The 59% Extreme $H_2O^{®}$ (hioxifilcon A) 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 spherical lens may be worn by persons who exhibit astigmatism of 0.75 Diopters or less that does not interfere with visual acuity. The toric lens may be worn by persons who exhibit astigmatism of up to 10.00 Diopters. 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.
Water Content	54% ± 2%	59% ± 2%
Refractive Index	1.414 hydrated	1.404 hydrated
Light Transmission	>95%	> 95%
Specific Gravity	1.300 (dry)	1.308 (dry)
Tint	Blue Phthalocyanato (2) – (copper)	Blue Phthalocyanato (2) – (copper)
Packaging	Blister pack	Blister Pack
Oxygen Permeability - (ANSI Z80:2004 Upgraded polarographic method)* in Fatt Dk units	21	28

Toxicology:

The following toxicology (ISO) tests were performed on the Extreme $H_2O^{®}$ 54%:

- Systemic Injection Test - No biological reaction within mice
- Agar Diffusion Test – Non-cytotoxic
- Primary Ocular Irritation – Non-irritant to rabbits

Clinical Data:

It was determined that clinical studies were not necessary to establish the safety and effectiveness of the Extreme $H_2O^{®}$ 54% soft contact lens. Extreme $H_2O^{®}$ 54% lenses are made from Benz-G 4X material (hioxifilcon D). This material is formulated from the same components as the previously cleared materials Benz-G 3X (hioxifilcon B) and Benz-G 5X (hioxifilcon A), but with different ratios of components that bracket the new material between these two cleared materials. The physical/chemical/toxicological results for the Extreme $H_2O^{®}$ 54% soft contact lens made from hioxifilcon D indicate that this material falls between the previously cleared 59% Extreme $H_2O^{®}$ soft contact lens (hixofilcon A) and the previously cleared Benz-G 3X (hioxifilcon B) in all respects. The Extreme $H_2O^{®}$ 54% lens is manufactured using the same cast molding process as our currently marketed 59% Extreme $H_2O^{®}$ (See K952620, K992692, and K964528). Therefore, there are no new issues of safety and effectiveness which would require clinical data.

Conclusion:

The information provided in this 510(k) establishes that the Extreme $H_2O^{®}$ 54% (hioxifilcon D) soft contact lens is substantially equivalent in terms of the physical/chemical/optical and toxicological performance characteristics, the method of manufacture, packaging, and intended use to the predicate device 59% Extreme $H_2O^{®}$ (hioxifilcon A) soft contact lens.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2005

Hydrogel Vision Corporation
c/o Donna Hovanec
Manager, Quality Systems
7575 Commerce Court
Sarasota, FL 34243

Re: K051430
Trade/Device Name: Extreme H_2O® 54% (hioxifilcon D) Soft Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: May 31, 2005
Received: June 1, 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,

David M. Whipple
Acting 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

INDICATIONS FOR USE STATEMENT

Device Name: Extreme $H_2O^{®}$ 54% (hioxifilcon D) soft contact lens

INDICATIONS FOR USE:

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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)

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

510(k) Number K051430

Prescription Use ✓ / **(Per 21 CFR 801.109)**

Prescription Use _____ or Over-The-Counter Use _____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)