K972303

## 510(k) Summary

AUG 20 1997

**SUBMITTER:**

**Submitted on behalf of:**


| | |
|---|---|
| Company Name: | Ocular Sciences/American Hydron Inc |
| Address: | 475 Eccles Avenue<br>South San Francisco, CA 95014 |
| Phone: | (415) 583-1400 |
| Fax: | (415) 583-1108 |


**CONTACT PERSON:** David Marcus Ph.D.

**DATE SUMMARY PREPARED:** August 7, 1977

**TRADE NAME:** Hydron Biomedics 55 (ocufilcon D) visibility tint molded daily wear soft contact lens

**COMMON NAME:** contact lens

**SUBSTANTIALLY EQUIVALENT TO:**

The Hydron Biomedics 55 (ocufilcon D) visibility tint Ocular Sciences/ American Hydron contact lens with in-monomer tint is equivalent to the tinted daily wear lens of the same material cleared in K942214 for daily wear and is identical to the in-monomer tinted ocufilcon D contact lens approved in PMA P890023/S4 for extended wear currently marketed by Ocular Sciences/ American Hydron, Inc. in the U.S.

The Hydron Biomedics 55 (ocufilcon D) visibility tinted Ocular Sciences/ American Hydron contact lens for daily wear is identical to the Hydron Biomedics 55 in-monomer tinted contact lens marketed for use in the U.S. by Ocular Sciences/American Hydron approved in PMA P890023/S4 on August 28, 1996; it is manufactured by the same manufacturing process. Additionally, the subject contact lens is substantially equivalent to the tinted Hydron Biomedics 55 contact lens cleared under K942214. This lens is in the Lens Group IV high water ionic group as established by the FDA and located in the Guidance Document for Daily Wear Contact Lenses, Revised Edition May 1994. The physical, optical, and chemical properties of the Hydron Biomedics 55 (ocufilcon D) visibility tinted cast molded contact lens are equivalent to the clear and identical to the tinted versions of the Hydron Biomedics 55 (ocufilcon D cast molded contact lens.

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## DESCRIPTION OF THE DEVICE:

Soft contact lenses are hemispherical shells manufactured of polymerized material of HEMA and other monomeric ingredients crosslinked with EGDMA and other components which yield the appearance of lenses which are designed to fit over the corneal surface of the eye. These lenses are designed with varying base curves which conform to the shape of the radius of the cornea and center over the apex of the cornea to provide corrective refraction for functional conditions of the eye including myopia (nearsightedness) and hyperopia (farsightedness). Each lens provides corrective power which corresponds to the refractive power of the eye to which it is being treated. Each lens is designed with a base curve on the internal side of the lens and an optical zone in the center of the lens which is generally of a diameter greater than 6 mm. Secondary and tertiary curves as well as beveled edge configurations are built into the lens for the purpose of aiding in lens centration and comfort.

## INDICATIONS FOR USE:

The Hydron Biomedics 55 (ocufilcon D) visibility tint soft (hydrophilic) contact lens is indicated for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic or hyperopic and may exhibit astigmatism of 2.00 D or less that does not interfere with visual acuity; it is available in powers from -10 to + 10 diopters.

Eyecare practitioners may prescribe the lens for either single-use disposable wear or for frequent/planned replacement wear, with cleaning, disinfection, and scheduled replacement (see WEARING SCHEDULE). When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfection system.

## PARAMETERS AVAILABLE:

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|---|---|
| Base Curves: | 6.50 mm to 10.8 mm |
| Diameters: | 12.5 mm to 18.0 mm |
| Powers: | -10.00 to + 10.00 Diopters sphere |
| Center Thickness: | 0.025 mm to 0.27 mm depending on power |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ocular Sciences/American Hydron, Inc.
c/o David Marcus, Ph.D.
22210 Quinterno Court
Cupertino, CA 95014

AUG 20 1997

Re: K972303
Trade Name: HYDRON BIOMEDICS 55 (Ocufilcon D) Soft (Hydrophilic) Daily Wear Contact Lens (In Monomer Visibility Tint, Cast Molded)
Regulatory Class: II
Product Code: 86 LPL
Dated: June 17, 1997
Received: June 19, 1997

Dear Dr. Marcus:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) 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 current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications Statement

AUG 20 1997

510(k) Number (if known): K972303

Device Name: Hydron Biomedics 55 (ocufilcon D) Visibility Tint Daily Wear Contact Lens

Indications For Use:

The Hydron Biomedics 55 (ocufilcon D) visibility tint soft (hydrophilic) contact lens is indicated for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic or hyperopic and may exhibit astigmatism of 2.00 D or less that does not interfere with visual acuity; it is available in powers from -10 to + 10 diopters.

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(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 _____

(Optional Format 1-2-96)

08/07/97



Myra Smith 8/11/97

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K972303