

JAN 21 1999



K984046

510(k) Summary

SUBMITTER:

Submitted on behalf of:

Company Name: Ocular Sciences, Inc.
Address: 475 Eccles Av.
South San Francisco, CA 95014
Phone: (415) 583-1400
Fax: (415) 583-1108

CONTACT PERSON: Richard E. Lippman, O.D., F.A.A.O.
Official Representative and Correspondent
C.L. McIntosh & Associates, Inc.
12300 Twinbrook Parkway Suite 625
Rockville, MD 20852

DATE SUMMARY PREPARED: October 1, 1998

TRADE NAME: BIOMEDICS[®] 55 (ocufilcon D) UV Blocking Daily Wear
soft (Hydrophilic) Contact Lens

COMMON NAME: contact lens

SUBSTANTIALLY EQUIVALENT TO:

The BIOMEDICS[®] 55 (ocufilcon D) UV Blocking Daily Wear Contact Lens with In-Monomer Tint is equivalent to the daily wear lens of the same material as cleared in K942214, P890023/S26, P890023/S4, and K972303 in-monomer visibility tint cast molded ocufilcon D for daily wear currently marketed by Ocular Sciences, Inc.

The BIOMEDICS[®] 55 (ocufilcon D) UV Blocking Daily Wear contact lens is substantially equivalent to the indication for use of the BIOMEDICS[®] 55 (ocufilcon D) In Monomer Tint ocufilcon D cast molded contact lens marketed for use in the U.S. by Ocular Sciences, Inc. cleared under K972303. Additionally, the subject contact lens is equivalent and has the same characteristics and properties as the clear BIOMEDICS[®] 55 (ocufilcon D) cast molded contact lens, cleared under K942214, and P890023/S26. The cast molding process was approved under P890023/S4. This lens is in the Lens Group IV high water ionic group as established by the FDA and located in the Guidance

000032

Corporate Offices:
475 Eccles Avenue
South San Francisco,
California 94080
800-628-5367
Ph: 650-583-1400

Canada:
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Puerto Rico:
P.O. Box 2801
Highway 538 km. 0.7
Santa Isabel Industrial Park
Santa Isabel,
Puerto Rico 00757

Document for Daily Wear Contact Lenses, Revised Edition May 1994. The physical, optical, and chemical properties of the BIOMEDICS^R 55 (ocufilcon D) UV visibility tint cast molded Ocular Sciences, Inc. contact lens are substantially equivalent to both the clear and tinted versions of the BIOMEDICS^R 55 (ocufilcon D) ocufilcon D cast molded contact lenses.

DESCRIPTION of the DEVICE:

Soft contact lenses are hemispherical shells manufactured of polymerized material of HEMA and other monomeric ingredients including a proprietary ultraviolet absorber, 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), hyperopia (farsightedness) and astigmatism (multiple foci). Each lens provides corrective power which is to correspond 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 6mm. 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 BIOMEDICS^R 55 (ocufilcon D) soft (hydrophilic) contact lens is indicated for daily wear in normal eyes whose eyes are either myopic, hyperopic, or astigmatic in powers from -20.00 to +20.00 Diopters and astigmatic corrections from -0.25 to -10.00 Diopters. Spherical lenses may mask astigmatism of up to 2.00 Diopters that does not interfere with visual acuity. The lens may be dispensed in a daily disposable or frequent replacement scheduled program. The lenses may be prescribed for daily wear for disposal after removal in the Disposable Lens Program or for cleaning and disinfection in the Frequent Replacement Program, as recommended by the eyecare practitioner. The lens may be disinfected only with a chemical disinfection regimen.

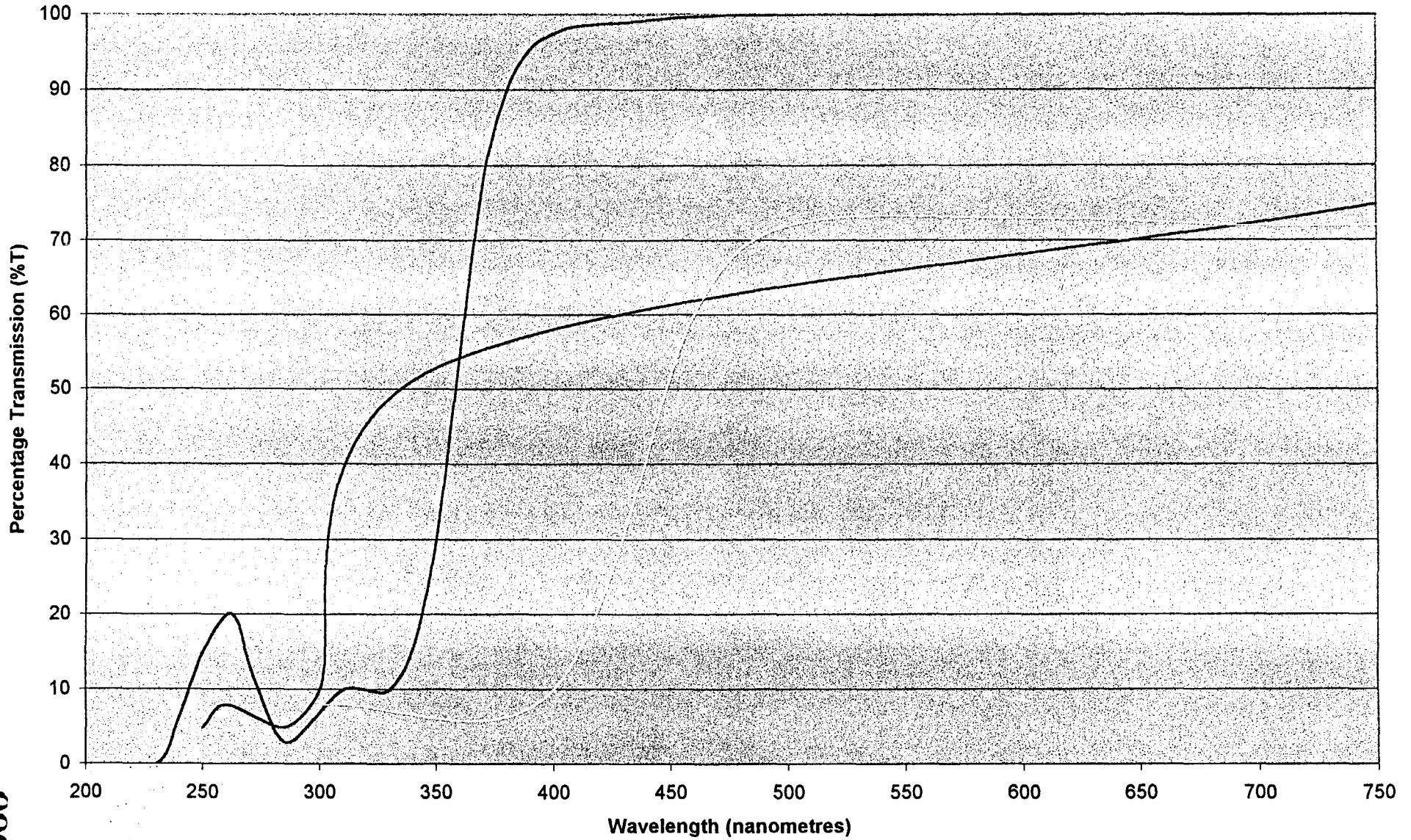
PARAMETERS AVAILABLE:

Base Curves: 6.50 mm to 10.8 mm
Diameters: 12.5 mm to 18.0 mm
Powers: -20.00 to +20.00 Diopters sphere
Cylinder Power: -00.25 to -10.00 Diopters
Center Thickness: 0.025 mm to 0.27 mm depending on power
Tint: Blue Visibility tint

ULTRAVIOLET TRANSMITTANCE CURVES

The following graph represents the transmittance of ultraviolet light in the UVA and UVB range as well as light transmittance through the visual spectrum, as compared to the human cornea and crystalline lens:

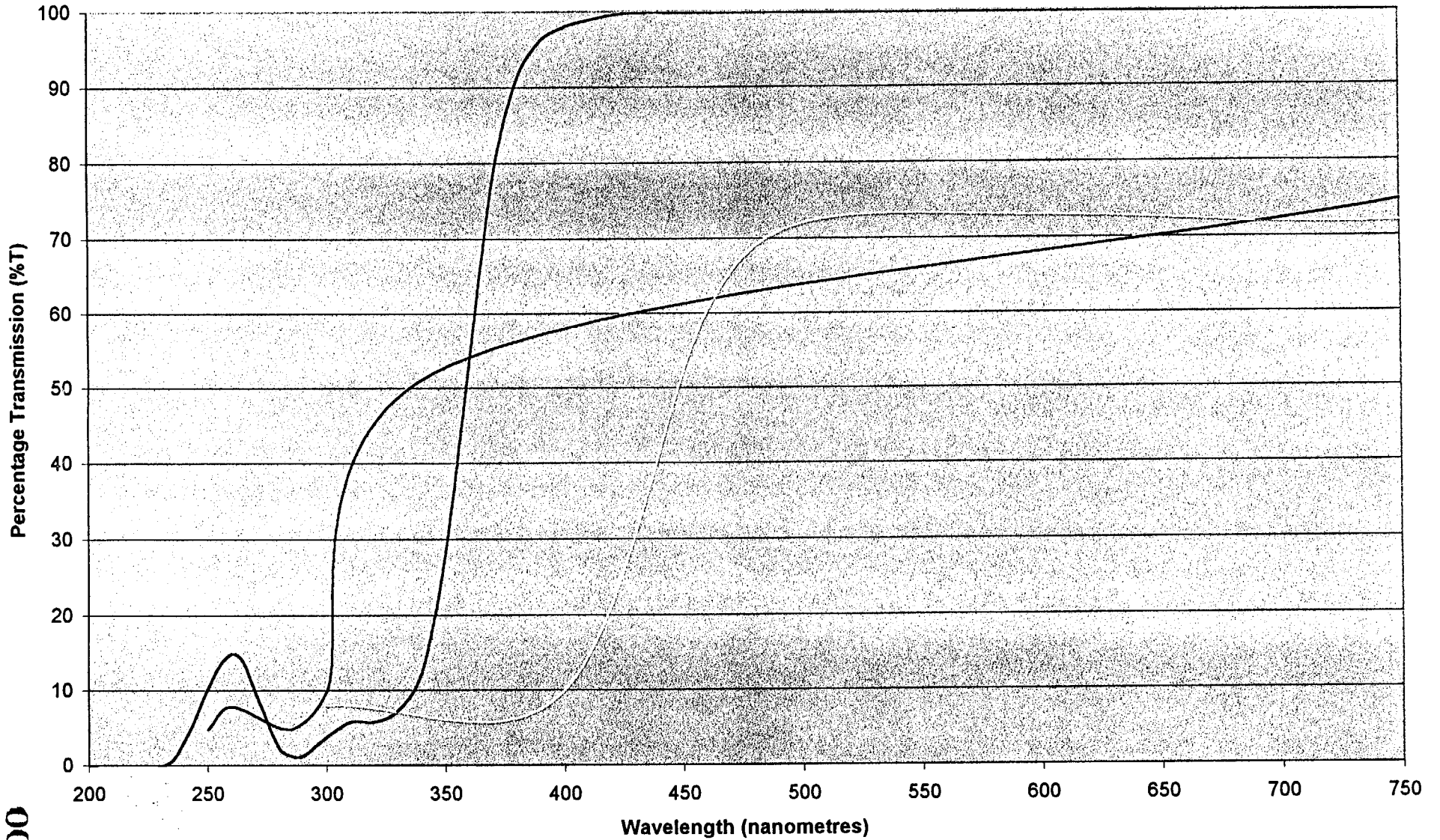
Typical Transmittance Profile of Ocufilecon D Hydrophilic Contact Lens with UV [redacted] versus a Human Cornea and a Human Lens







— Ocufilecon D contact lens with UV [redacted] -8.0D, nominal centre thickness 0.06 mm
 — Human Cornea (24 year old person)
 — Human Crystalline Lens (25 year old person)

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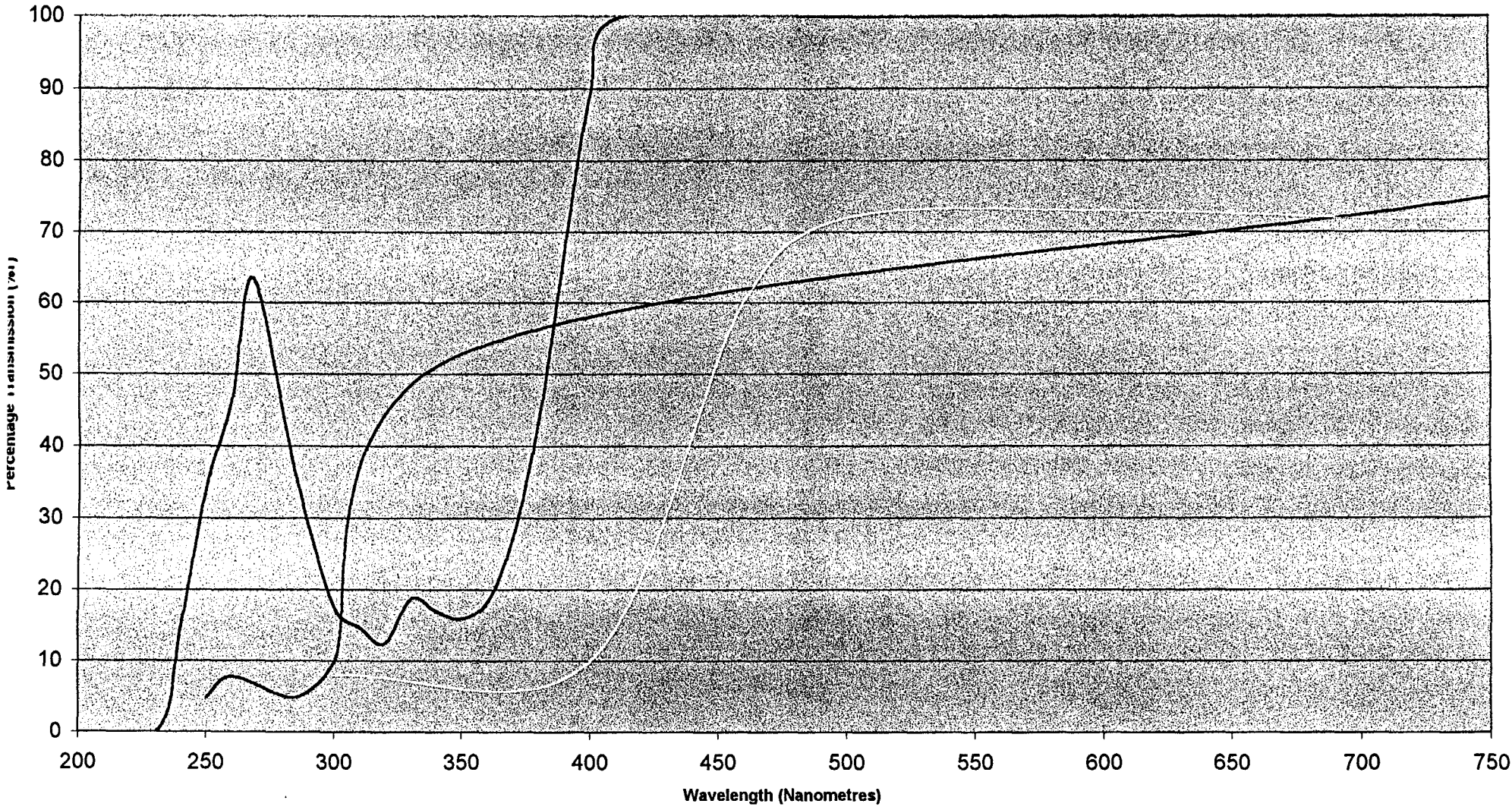
Typical Transmittance Profile of -2.50 D Ocufilecon D Hydrophilic Contact Lens with UV  versus a Human Cornea and a Human Lens



 Ocufilecon D contact lens with UV  -2.50D, nominal centre thickness 0.07 mm
 Human Cornea (24 year old person)
 Human Crystalline Lens (25 year old person)

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Typical Transmittance Profile of Ocufilcon D Hydrophilic Contact Lens with UVAM versus a Human Cornea and a Human Lens



— Ocufilcon D contact lens with UVAM, -6.0D, nominal centre thickness 0.06 mm
 — Human Cornea (24 year-old person)
 Human crystalline lens (25 year old person)

000037



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 1999

Ocular Sciences, American Hydron, Inc.
c/o Richard E. Lippman, O.D., F.A.A.O.
C.L. McIntosh & Associates, Inc.
12300 Twinbrook Parkway
Rockville, Maryland 20852

Re: K984046

Trade Name: Biomedics ® 55 (ocufilcon D) UV Blocking Soft Contact Lens for Daily Wear

Regulatory Class: II

Product Code: 86 LPL

Dated: November 6, 1998

Received: November 13, 1998

Dear Dr. Lippman:

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 (Pre-market 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

510(k) Number (if known) K984046

Device Name: Biomedics 55 (ocufilcon D) UV Blocking Daily Wear Contact Lens

Indications for Use:

The BIOMEDICS^R 55 (ocufilcon D) UV Blocking soft (hydrophilic) contact lens is indicated for daily wear in not-aphakic, normal eyes which manifest myopia, hyperopia, or astigmatism in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters. Spherical lenses may mask astigmatism in patients with up to 2.00 diopters that does not interfere with visual acuity. The lens may be dispensed in a daily disposable or frequent replacement scheduled program. The lenses may be prescribed for daily wear for disposal after removal in the Disposable Lens Program or for cleaning and disinfection in the Frequent Replacement Program, as recommended by the eyecare practitioner. The lens may be disinfected only with a chemical disinfection regimen.

Additional Claims:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

Daniel W. Brown, M.D.

(Division Sign-Off)
Division of Ophthalmic Devices

Over-The-Counter Use

(Optional Format 1-2-96)

510(k) Number K984046

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