

Ocular Sciences <i>(ocufilcon D) soft (hydrophilic) contact lens</i>	510(K) Premarket Notification SUMMARY OF SAFETY AND SUBSTANTIAL EQUIVALENCE	Reference : OCDA55 Section : 3 Version : 1 Page : 1 / 5
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K020193

FEB 28 2002

1. APPLICANT'S NAME AND ADDRESS

Ocular Sciences Inc.
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Concord, CA 94520
USA

Contact Person

Richard Lippman, OD FAAO
Senior Consultant
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2. IDENTIFICATION OF DEVICE

Common Name:	Hydrophilic Soft Contact Lens
Trade Name:	BIOMEDICS® UV ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lens
Classification:	Daily Wear Soft (hydrophilic) Contact Lens
Device classification:	Class II (21 CFR 886.5925)

3. DESCRIPTION OF DEVICE

BIOMEDICS® UV ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses are available with in monomer tint (Vat Blue 6) and with ultraviolet absorbing additive (benzophenone based):

- plano to -10.00D Asphere
- with center thickness from 0.025mm to 0.40mm
- with base curves of 8.00mm to 9.20mm
- with diameter of 12.00mm to 18.00mm

The lens material is the same as the one BIOMEDICS® UV described in submission PMA890023/S4 and S7, K982947, K984046, K012425.

The BIOMEDICS® UV ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lens has a spherical posterior surface. The anterior (convex) surface is constructed in lenticular form to provide optimum edge thickness and contour. This front optical surface allows for correction of visual acuity in non-aphakic persons with non-diseased eyes and has been aspherized to control longitudinal spherical aberration of the lens across the power range.

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4. INTENDED USE

[NOTE:] The Intended Use Statement has been upgraded to include a statement regarding ultraviolet light protection from BIOMEDICS® ASPHERE contact lenses that contain a UV additive. The statement is a reference to protection against the transmittance of harmful UV radiation to the cornea and into the eye.

The BIOMEDICS® UV ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses are indicated for the correction of visual acuity in persons with not-aphakic, non-diseased eyes which manifest myopia (nearsightedness), hyperopia (farsightedness) and astigmatic correction lower than -2.00 diopters that does not interfere with visual acuity.

The BIOMEDICS® UV ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses may be prescribed for daily wear. The eye-care practitioner may prescribe the BIOMEDICS® UV ASPHERE (ocufilcon D) Soft (Hydrophilic) contact lenses for single use disposable wear or for scheduled replacement wear, with cleaning, disinfection, and scheduled replacement. When prescribed for scheduled replacement the lens may be disinfected using a chemical (not heat) or hydrogen peroxide disinfecting systems.

BIOMEDICS® UV ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

5. PREDICATE DEVICES

The following predicate lenses were selected to address material (FDA Group IV: high water, ionic polymer), intended use (daily wear) and lens designs (Asphere).

Lens material, spherical lens design and intended use:

BIOMEDICS® UV (ocufilcon D) Sphere Hydrophilic Contact Lenses, FDA Group IV, high water content, ionic soft contact lenses for daily wear marketed internationally by OCULAR SCIENCES Inc. under PMA 890023/S7.

Asphere lens design:

Frequency 55 Asphere Hydrophilic Contact Lenses, FDA Group IV, high water content, ionic soft contact lenses for daily wear marketed internationally by Cooper Vision under K000384.

Indication for Use: The indication for use for the BIOMEDICS® UV ASPHERE is the same as the predicate device under K984046 with the exception of the added statement referencing the UV protection available in the lens that helps to protect against transmission of harmful ultraviolet radiation to the cornea and into the eye. This statement is consistent with other ocufilcon lenses (K992264) manufactured by Ocular Sciences, Inc., and supported by documentation presented in P890023/S7.

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6. CHARACTERISTICS

The characteristics of the BIOMEDICS® UV ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses are compared to the characteristics of the predicate device BIOMEDICS® UV sphere in the following table.

TABLE 1

Material comparison				
	Predicate device BIOMEDICS® UV Sphere		Subject device BIOMEDICS® UV Asphere	
PRODUCTION METHOD	Cast molded process		Cast molded process	
INTENDED USE	Extended and daily wear Correction of ametropia		Daily wear Correction of ametropia	
MATERIAL	ocufilcon D 55%		ocufilcon D 55%	
Type	Group IV		Group IV	
Color additive	Vat Blue 6 Dye CFR 130-20-1		Vat Blue 6 Dye CFR 130-20-1	
UV additive	Yes		Yes	
Dk/Harmonic thickness ANSI Z80.20 (1998) Minus powers -10.00 to -0.25D Plus powers Plano to +8.00D	15.9 x 10 ⁻⁹ 12.2 x 10 ⁻⁹		15.9 x 10 ⁻⁹ 12.2 x 10 ⁻⁹	
Characteristics comparison	Measured	Labeled	Measured	Labeled
Oxygen transmissibility (-3.00D)	18.8 x 10 ⁻⁹	-	19.5 x 10 ⁻⁹	-
Light transmittance	Tv, % @ 20°C Illuminant A with a 2° observer (between 380 and 780 nm) 97.8%	(between 400 and 800 nm) >95%	Tv, % @ 20°C Illuminant A with a 2° observer (between 380 and 780 nm) 98.2%	(between 400 and 800 nm) >95%

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TABLE 2

Lenses design comparison				
	Predicate device BIOMEDICS® UV Sphere		Subject device BIOMEDICS® UV Asphere	
	<i>Measured</i>	<i>Labeled</i>	<i>Measured</i>	<i>Labeled</i>
<i>Characteristics comparison, -3.00 D</i>				
Base Curve, mm	8.61	8.60	8.59	8.60
Diameter, mm	14.19	14.20	14.20	14.20
Power, D	-1.37	-1.50	-1.64	-1.75
	Predicate Asphere design FREQUENCY Asphere		Subject Asphere design BIOMEDICS® UV Asphere	
	<i>Measured</i>	<i>Labeled</i>	<i>Measured</i>	<i>Labeled</i>
<i>Characteristics comparison, -3.00 D</i>				
Power, D	-1.44	-1.75	-1.68	-1.75

7. NON CLINICAL STUDIES

In support to this application we are providing:

- Additional Manufacturing information
- Finished Lens Parameters comparison with the predicate device
- Physicochemical Properties comparison with predicate device
- Labeling Information

By reference PMA890023/S4 and S7, data can be found about:

- Predicate Device
- Chemistry
- Manufacturing process
- Toxicology: lens and packaging materials
- Residual (leachables) Monomer
- Shelf life data
- Microbiology
- Packaging

8. CLINICAL DATA

It was determined that Clinical Studies were not warranted in order to establish the safety and efficacy of the BIOMEDICS® UV ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses. This determination was based on the following:

- The BIOMEDICS® UV ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses were demonstrated to be substantially equivalent to the predicate BIOMEDICS® UV Sphere lenses (PMA890023/S4 and S7, K984046 and K982947) as per measurements of physicochemical characteristics and parameters.
- The BIOMEDICS® UV ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lens design was demonstrated to be substantially equivalent to the predicate Asphere lenses: Frequency Asphere from Cooper Vision (K000384).

9. CONCLUSIONS DRAWN FROM STUDIES

Substantial Equivalence:

The information provided in this 510(k) application establishes that the BIOMEDICS® UV ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses are substantially equivalent in optical, chemical and physical properties of the predicate devices, are equivalent in their final specification to the predicate devices, and do not raise any additional questions of safety and effectiveness. Therefore the device remains substantially equivalent to the predicate device. The labeled indication for use has been upgraded to be consistent with predicate devices in the ocufilcon family of materials and includes a statement regarding UV protection in the labeled indication for use.

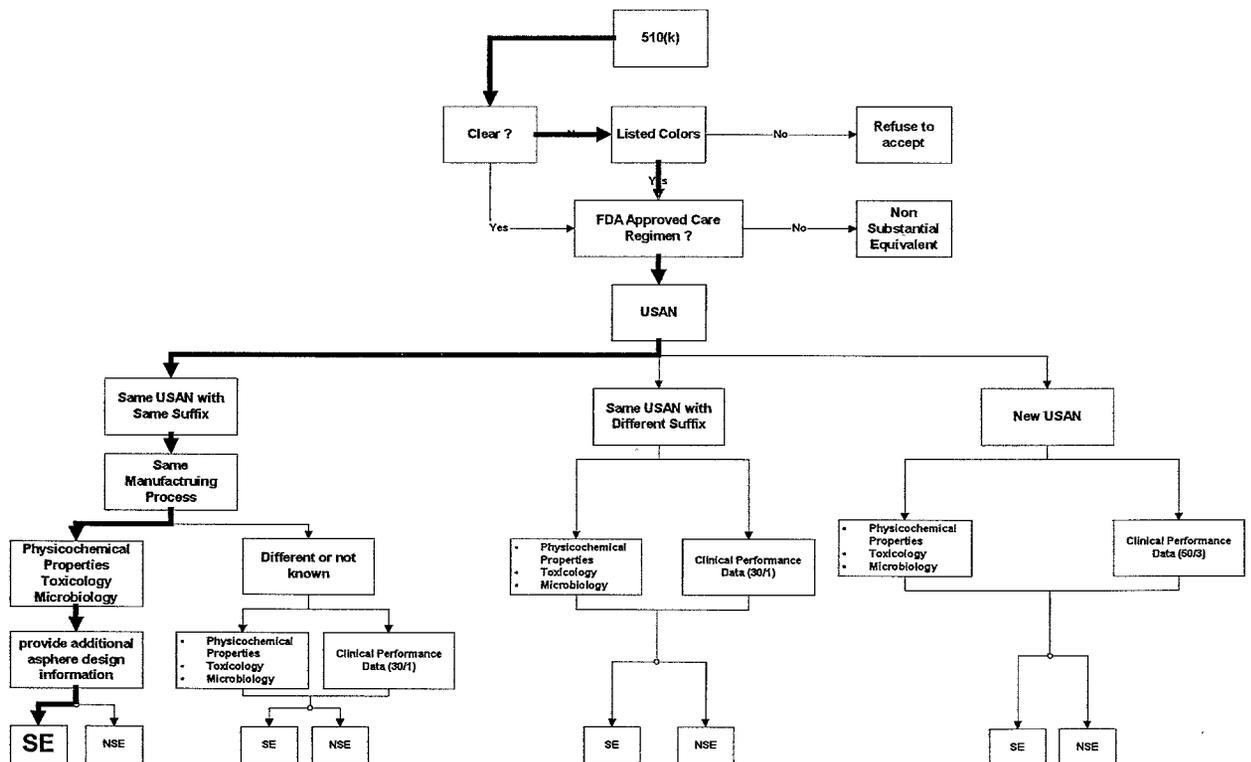
Risk and Benefits:

The risks of the subject device are the same as those normally attributed to the wearing of soft (hydrophilic) contact lenses on a daily wear base. The benefits to the patient are the same as those for other soft (hydrophilic) contact lenses.

10. ROUTE CHOSEN IN THE FLOW CHART FOR 510 (K) DAILY WEAR CONTACT LENS

FIGURE 1

BIOMEDICS® UV Asphere





Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 28 2002

Ocular Sciences, Inc.
c/o Richard E. Lippman, O.D., F.A.A.O.
Senior Consultant
Official Correspondent to Ocular Sciences, Inc.
CL McIntosh, Inc.
12300 Twinbrook Parkway, Suite 230
Rockville, MD 20852

Re: K020193

Trade/Device Name: Biomedics® UV Asphere (ocufilcon D) Soft (hydrophilic) Contact
Lens for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Product Code: LPL, MVN
Dated: January 15, 2002
Received: January 18, 2002

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 (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 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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

INDICATION FOR USE STATEMENT

510(k) Number (if known) _____

Device Name: BIOMEDICS® UV ASPHERE (ocufilcon D) Soft (Hydrophilic) Contact Lenses

Indications for Use:

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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

JR

[Signature]

(Division Sign-off)
Division of Ophthalmic Devices

510(k) Number K020193