K982110

NOV 6 1998

510 (K) Summary

SUBMITTER:

Submitted on behalf of:

Company Name:	Optech, Inc.
Address:	6341 South Troy Circle Englewood, CO 80111-6415
Phone:	303 708-1390
Fax:	303 708-1392

CONTACT PERSON: James A. Brooks

DATE SUMMARY PREPARED: **June 10, 1998**

TRADE NAME: The PolyVue 43™ (ocufilcon A) Spherical, Toric and Aspherical Multifocal Hydrophilic Contact Lenses for Daily Wear (clear and visibility tinted)

COMMON NAME: contact lens

SUBSTANTIALLY EQUIVALENT TO:

The PolyVue 43™ (ocufilcon A) Spherical, Toric and Aspherical Multifocal Hydrophilic Contact Lenses for Daily Wear (clear and visibility tinted) is equivalent to Specialty UltraVision's Specialty T (ocufilcon A) Toric Hydrophilic Contact lens for daily wear as currently marketed in the U.S.

The PolyVue 43™ (ocufilcon A) Spherical, Toric and Aspherical Multifocal Hydrophilic Contact Lenses for Daily Wear (clear and visibility tinted) are substantially equivalent to Specialty UltraVision's Specialty T (ocufilcon A) Toric lens. PolyVue 43™ (ocufilcon A) Spherical, Toric and Aspherical Multifocal Hydrophilic Contact Lens (clear and visibility tinted) is the same lens material that received marketing clearance pursuant to K963764 for Specialty UltraVision, Inc. This lens conforms to and is substantially equivalent to spherical, aspherical, presbyopic and astigmatic lens designs that are currently marketed in the United States. The intended use and target population are substantially equivalent.

This lens is in Group 3 ionic, low water content polymers 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 PolyVue 43™ (ocufilcon A) Spherical, Toric and Aspherical Multifocal Hydrophilic Contact Lenses for Daily Wear (clear and visibility tinted) and the Specialty T (ocufilcon A) Soft (Hydrophilic) Toric Contact Lens for Daily Wear are substantially equivalent.

SIMILARITIES and DIFFERENCES:

PARAMETER	PolyVue 43™	Specialty T Toric
material	ocufilcon A	ocufilcon A
indication for use	myopia, hyperopia, presbyopia and astigmatism	myopia, hyperopia and astigmatism
water content	43%	44.1%
light transmittance	98.513	98.493
Dk (35°C)	11.340 X 10^{-11}	11.267 X 10^{-11}
modulus	36.50 g/mm^2	35.96 g/mm^2
tensile strength	34.68 g/mm^2	33.98 g/mm^2
elongation @ break	169.26 %	165.27%
toughness	31.9668 g/mm^2	31.8468 g/mm^2
color	clear and visibility tinted	clear
refractive index	1.427	1.427
Powers	-20.00 TO +20.00 d	-20.00 to+20.00 D

DESCRIPTION of the DEVICE:

Soft contact lenses are hemispherical shells manufactured of polymerized material of HEMA and methacrylic acid crosslinked with EGDMA, 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 of functional conditions of the eye including myopia (nearsightedness), hyperopia (farsightedness), presbyopia 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. Spherical and aspheric curves as well as beveled edge configurations are built into the lens for aiding in lens centration and comfort as well as providing additional add power for near and blocking spherical aberration.

PERFORMANCE

Optech, Inc. has carried out a complete performance evaluation of the PolyVue 43™ (ocufilcon A) Spherical, Toric and Aspherical Multifocal Hydrophilic Contact

Lenses for Daily Wear (clear and visibility tinted). This assessment addressed the following issues:

1. Cytotoxicity Test
2. Systemic Injection Test
3. Eye Irritation Test
4. Compatibility testing
5. Preservative Uptake and Release
6. Leachability of color additives and residual monomers

These studies demonstrate that the material is non toxic, compatible with standard lens care regimens and that the residual monomers and color additive leachability is within acceptable limits.

Concerning compatibility testing, the recommended lens care products (cleaning, rinsing and disinfection) have been approved for use with lenses of the same lens group. Therefore, no additional compatibility testing is included.

With regard to preservative uptake and release studies, since the subject contact lens has the same surface electric charge as the predicate device (same material being used) no additional studies need be conducted.

We have also included in this submission the results of 10 multifocal lenses, manufactured to variety of prescribed specifications to verify ability of the manufacturer to make these lenses.

INDICATIONS FOR USE:

Device Name: PolyVue 43™ (ocufilcon A) Spherical, Toric and Aspherical Multifocal Hydrophilic Contact Lens (clear and visibility tinted)

The Polyvue 43™ (ocufilcon A) Spherical, Toric and Aspherical Multifocal Hydrophilic Contact Lens (clear and visibility tinted) is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia), presbyopia and astigmatism in aphakic and non-aphakic persons with non-diseased eyes.

Eyecare practitioners may prescribe the lens for daily wear in a Frequent Replacement Program. The lenses may be disinfected using heat, chemical or hydrogen peroxide disinfection systems.

PARAMETERS AVAILABLE:

PolyVue 43™ (ocufilcon A) Spherical, Toric and Aspherical Multifocal Hydrophilic Contact Lens (clear and visibility tinted)

	Spherical and Aspherical Multifocal	Toric
Powers:	+20.00 to -20.00D	+20.00 to -20.00D
Center Thickness:	0.03 to 0.40mm	0.101 to 0.520mm
Diameter:	14.0, 14.5mm	14.0, 14.5, 15.0mm
Base Curve:	8.3 to 8.6mm	8.0 to 9.3mm
Cylinder Powers:	N/A	-0.50 to -16.00 in 0.25 D steps
Axis:	N/A	1° to 180° in 1° steps

For the Multifocal Design

Add Powers:	Continuous adds to 3.25 D

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 6 1998

James A. Brooks
6341 S. Troy Circle
Unit E
Englewood, CO 80111-6415

Re: K982110/S1
Trade Name: PolyVue 43™ (ocufilcon A) Spherical, Toric and Aspherical Multifocal Hydrophilic Contact Lenses for Daily Wear (clear and visibility tinted, lathe cut from molded buttons)
Regulatory Class: II
Product Code: 86LPL
Dated: August 25, 1998
Received: August 27, 1998

Dear Mr. Brooks:

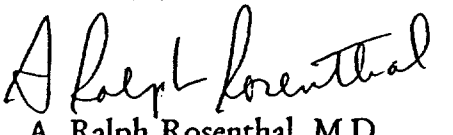
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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

Device Name: PolyVue 43™ (ocufilcon A) Spherical, Toric and Aspherical Multifocal Hydrophilic Contact Lenses for Daily Wear (clear and visibility tinted)

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

Philip - Chuen Shu

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K982110

Prescription Use ✓ or Over-The-Counter Use _____

(Optional Format 1-2-96)