

JUN 23 1998

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:

K981252

Applicant information:

Date Prepared: April 2, 1998

Name: Alden Optical Laboratories
Address: 13295 Broadway
Alden, New York 14004

Contact Person: Mr. Charles H. Creighton
Phone Number: 800.253.3669

US Consultant: Med-Vice Consulting, Inc.
Mr. Martin Dalsing
623 Glacier
Grand Junction, CO 81503

Phone Number: 970.243.5490
Fax Number: 970.243.5501

Device Information:

Regulatory Classification: Class II

Product Code: 86 LPL

Trade Name: **OxyLens (hioxifilcon B) Soft (Spherical & Toric) Daily Wear Contact Lens (Clear & Blue Visibility Tint, Lathe-cut from Lens Blank)**

Classification Name: Lenses, Soft Contact, Daily Wear

Equivalent Devices:

The OXYLENS (hioxifilcon B) Soft (Spherical & Toric) Daily Wear Contact Lens is substantially equivalent to predicate devices in terms of intended use and design. Predicate devices include our own "Alden Classic" series (spherical and toric lens) manufactured by Alden Optical Labs, "Satureyes" and "Satureyes Toric" manufactured by Metro Optics and the "BENZ-G 3X" manufactured by Benz Research and Development.

Device Description:

The OXYLENS (hioxifilcon B) Soft (Spherical & Toric) Daily Wear Contact lenses are fabricated from hioxifilcon B, which in the dry (unhydrated) state may be machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

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 (hioxifilcon B) soft hydrophilic contact lens has a spherical back 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.

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 48% water by weight. The physical properties of the lens are:

Refractive Index	1.515 (dry) 1.404 (hydrated)
Light Transmission (clear)	greater than 95% T
Light Transmission (tinted)	greater than 95% T
Color Pigment Name	Phthalocyanine Blue
Water Content	48 % ± 2%
Specific Gravity	1.308 (dry) 1.136 (hydrated)
Oxygen Permeability	15×10^{-11} (cm ² /sec) (ml O ₂ /ml x mm Hg @ 35°C), (revised Fatt method).

Intended Use:

The OXYLENS (hioxifilcon B) Spherical Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 1.50 diopters or less where the astigmatism does not interfere with visual acuity.

The OXYLENS (hioxifilcon B) Toric Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism.

The lenses are available within a planned replacement program with frequency of replacement determined by the practitioner.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a quality assurance program. The device will undergo manufacturing, packaging and sterilization procedures similar to devices currently marketed and distributed by Alden Optical Laboratories. The established safety profile (pre-clinical toxicology and manufacturing/chemistry data) of the device is equivalent to the BENZ-G 3X (hioxifilcon B), 510(k) #K964528. Being similar with respect to indications for use, materials, physical construction and safety & effectiveness to the predicate devices, this meets the requirements per section 510(k) of the act regarding substantial equivalence and does not raise different questions of safety and effectiveness than the predicate devices identified above.

The following matrix illustrates that the production method, lens function and material of the OxyLens (hioxifilcon B) Soft (Spherical & Toric) Daily Wear Contact Lens (Clear & Blue Visibility Tint, Lathe-cut from Lens Blank), are substantially equivalent to the predicate device(s). In addition, the water content, polymer, Dk value, refractive index, specific gravity, and light transmission are as well substantially equivalent to the predicate device.

SUMMARY OF SAFETY AND EFFECTIVENESS Substantial Equivalence Matrix

	Characteristic	OXYLENS (hioxifilcon B)	PREDICATE DEVICES
1.)	PRODUCTION METHOD	Lathe-Cut	SAME
2.)	LENS FUNCTION	Refractive medium that focuses light rays from near and distant objects on the retina, while compensating for refractive error, including (astigmatism)	SAME
3.)	MATERIAL	Hydrophilic Polymer	SAME
a.	Water Content	48%	SAME/SIMILAR
b.	Polymer Content	52%	SAME/SIMILAR
c.	Polymer	hioxifilcon B	SAME/SIMILAR
d.	DK Value	15	SAME/SIMILAR
e.	Refractive Index	1.404 (hydrated)	SAME/SIMILAR
f.	Specific Gravity	1.136 (hydrated)	SAME/SIMILAR
g.	Light Transmission	greater than 95 % T	SAME/SIMILAR



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 1998

Alden Optical Laboratories, Inc.
C/O Martin J. Dalsing
623 Glacier Drive
Grand Junction, CO 81503

Re: K981252

Trade Name: OxyLens (hioxifilcon B) Soft (Spherical & Toric) Daily Wear Contact Lens (Clear & Blue Visibility Tint, Lathe-cut from Lens Blank)

Regulatory Class: II

Product Code: 86 LPL

Dated: April 2, 1998

Received: April 6, 1998

Dear Mr. Dalsing:

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.

Page 2 - Mr. Martin J. Dalsing

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 FOR USE STATEMENT

Device Name: **OXYLENS (hioxifilcon B) Soft (Spherical & Toric) Daily Wear Contact Lens
(Clear & Blue Visibility Tint, Lath-cut from Lens Blank)**

INDICATIONS FOR USE:

The **OXYLENS (hioxifilcon B) Spherical Soft Contact Lenses** for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 1.50 diopters or less where the astigmatism does not interfere with visual acuity.

The **OXYLENS (hioxifilcon B) Toric Soft Contact Lenses** for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 10 Diopters.

The lenses are available within a planned replacement program with frequency of replacement determined by the practitioner.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

or

Over-The-Counter Use

(Optional Format 1-2-96)

Mig-Chuen Shui

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K981252

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