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: **K983278**

Applicant information:

Date Prepared:	September 14, 1998
Name:	Alden Optical Laboratories
Address	13295 Broadway Alden, NewYork 14004
Contact Person:	Charles H. Creighton
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USA Consultant:	MedVice Consulting, Inc.
Phone Number:	Martin Dalsing (970) 243-5490

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Trade Name:	**OXYLENS TINTED, PROSTHETIC (hioxifilcon B), Soft Daily Wear Contact Lens, Tinted (lathe-cut)**
Classification Name:	Lenses, Soft Contact, Daily Wear

Substantially Equivalent Devices:

The OXYLENS TINTED, PROSTHETIC (hioxifilcon B), Soft Daily Wear Contact Lens, Tinted (lathe-cut) is substantially equivalent to the "ALDEN CLASSIC PROSTHETIC" (polymacon) Tinted, Soft Contact lens (lathe-cut) and the BENZ-G 3X (hioxifilcon B) Soft (Spherical and Toric) Daily Wear Contact Lens, the predicate devices.

Device Descriptive Characteristics:

The OXYLENS TINTED, PROSTHETIC (hioxifilcon B), Soft Contact Lens is 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. A tint mixture containing; *Blue* 7,16-Dichloro-6, 15-dihydro-5,9,14,18-anthrazinetetrone, *Green* 16,17 – Dimethoxydinaphtho [1,2,3 –cd:3',2',1' –lm] perylene-5,10-dione, and *Brown* 16,23 – Dihydrodinaphtho [2,3-a:2',3' –i] napth [2',3',:6,7] indolo [2,3-c] carbazole-5,10,15,17,22,24-hexone is added to the lens.

The tint mixture (**BLACK**) is processed into the contact lens to enhance or alter the apparent eye color, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lenses for cosmetic management of conditions such as corneal, iris or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not aphakic persons or for occlusive therapy for conditions such as diplopia, amblyopia or extreme photophobia.

Tint Patterns Available:

1. **Clear lens with Black Pupil.** Pupil sizes available in 2.0 mm to 12.5 mm.

2. **Black Occluder Lens.** A Central Black area that occludes light. Available to full lens diameter in 0.5 mm increments.

3. **Black Annular with clear pupil.** Black Annular diameter range 7.5 mm to full lens diameter in 0.5 mm increments. Clear Pupil diameter range 2.0 mm to 7.5 mm in 0.5 mm increments.

4. **Tinted lens with Black Pupil.** Uses the Alden Classic Tinted (polymacon 38%) contact lens with black pupil. Pupil sizes available in 2.0 mm to 12.5 mm diameter.

The OXYLENS TINTED may contain a single listed color additive, or may contain a combination of color additives in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect. The color additives are added to the contact lens for enhancing and/or altering the apparent color of the eye.

In the hydrated state, the OXYLENS TINTED, PROSTHETIC lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a color altering 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:	greater than 70% T *
Water Content	48 %
Specific Gravity	1.308 (dry) 1.136 (hydrated)
Color additives	Vat Brown 1, Vat Blue 6, Vat Green 1, Vat Yellow3, Vat Orange 1
Oxygen Permeability	15×10^{-11} Fatt Units (cm^2/sec)(ml O_2/ml x mm Hg @ 35 °C), (revised Fatt method)

* Patients may experience a reduction in visibility while wearing a dark shade of lens in conditions of low illumination.

Intended Uses:

The **OXYLENS PROSTHETIC (hioxifilcon B), Tinted Soft Contact Lens** is indicated for daily wear to enhance or alter the apparent eye color, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lenses for cosmetic management of conditions such as corneal, iris or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not aphakic persons or for occlusive therapy for conditions such as diplopia, amblyopia or extreme photophobia. The lens may be disinfected with either a chemical or a heat disinfection system.

The **OXYLENS TINTED (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 lens may be disinfected with either a chemical or a heat disinfection system.

The **OXYLENS TINTED (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 lens may be disinfected with either a chemical or a heat disinfection system.

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

Substantial Equivalence:

The devices 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 devices is equivalent to the Alden Classic Tinted (polymacon) 510(k) #K980554, the Oxylens (hioxifilcon B) 510(k) # K981252 and the Benz-G 3X (hioxifilcon B) 510(k) # K964528. Being similar with respect to 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 the production methods, lens functions and material characteristics of the OXYLENS TINTED, PROSTHETIC (hioxifilcon B), Soft Daily Wear Contact Lens (lathe-cut), as well as the predicate devices.

Substantial Equivalence Matrix

	Characteristic	OXYLENS PROSTHETIC	OXYLENS TINTED	PREDICATE DEVICE(s)
1.)	**PRODUCTION METHOD**	Lathe-Cut	Lathe-Cut	Lathe-Cut
2.)	**LENS FUNCTION**	Enhance or alter the apparent eye color, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lenses for cosmetic management of conditions such as corneal, iris or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not aphakic persons or for occlusive therapy for conditions such as diplopia, amblyopia or extreme photophobia.	Refractive medium that focuses light rays from near and distant objects on the retina, while compensating for refractive error, including (astigmatism), including enhancing and/or altering the apparent eye color.	Enhance or alter the apparent eye color, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lenses for cosmetic management of conditions such as corneal, iris or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not aphakic persons or for occlusive therapy for conditions such as diplopia, amblyopia or extreme photophobia.
3.)	**MATERIAL**	Hydrophilic Polymer	Hydrophilic Polymer	Hydrophilic Polymer
a.	Water Content	48%	48%	38%, 48%
b.	Polymer Content	52%	52%	62%, 52%
c.	Polymer	hioxifilcon B	hioxifilcon B	Polymacon, hioxifilcon B
d.	DK Value	15	15	9, 15
e.	Refractive Index	1.404 (hydrated)	1.404 (hydrated)	1.430, 1.404 (hydrated)
f.	Specific Gravity	1.136 (hydrated)	1.136 (hydrated)	1.18, 1.136 (hydrated)
g.	Light Transmission	greater than 70 % T (N/A for non-sighted eyes)	greater than 70 % T	greater than 70 % T
h.	Color Additives	**Vat Green 1**, Green (21 CFR 73.3120) CI# 59825	**Vat Green 1**, Green (21 CFR 73.3120) CI# 59825	**Vat Blue 6**, Blue (21 CFR 73.3119) CI# 69825
		Vat Brown 1, Brown (21 CFR 73.3117) CI# 70800	**Vat Brown 1**, Brown (21 CFR 73.3117) CI# 70800	Not Applicable for Clear Contact Lens
		Vat Blue 6, Blue (21 CFR 73.3119) CI# 69825	**Vat Yellow 3**, Yellow (21 CFR 73.3118) CI# 61725	
			Vat Orange 1, Orange (21 CFR 73.3112) CI# 59105	
			Vat Blue 6, Blue (21 CFR 73.3119) CI# 69825	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 1998

Alden Optical Laboratories, Inc.
c/o Mr. Martin Dalsing
623 Glacier Drive
Grand Junction, CO 81503

Re: K983278
Trade Name: OXYLENS TINTED PROSTHETIC (hioxifilcon B) Tinted Soft Daily Wear Contact Lens (lathe-cut)
Regulatory Class: II
Product Code: 86 LPL
Dated: September 14, 1998
Received: September 17, 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 (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 FOR USE STATEMENT

Device Name: **OXYLENS TINTED, PROSTHETIC (hioxifilcon B), Soft Daily Wear Contact Lens, Tinted (lathe-cut).**

INDICATIONS FOR USE:

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W. C. Brown, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K983278

Prescription Use X
(Per 21 CFR 801.109)

Over-The-Counter Use ___

(Optional Format 1-2-96)