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.

APR - 7 1998

The assigned 510(k) number is: K980554

Applicant information:

Date Prepared:	February 9, 1998
Name:	Alden Optical Laboratories
Address	13295 Broadway Alden, NewYork 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:

Device Classification:	Class II
Classification Number:	LPL
Trade Name:	**ALDEN CLASSIC TINTED (polymacon) Soft (Spherical & Toric) Daily Wear Contact Lens, Tinted (Transparent/Enhancing)**
Classification Name:	Lenses, Soft Contact, Daily Wear

Equivalent Devices:

The ALDEN CLASSIC TINTED (polymacon) Soft (Spherical & Toric) Daily Wear Contact Lens is substantially equivalent to predicate devices in terms of intended use and design. Predicate devices include MetroTint manufactured by Metro Optics and the BENZ-38 manufactured by Benz Research and Development.

Device Description:

The ALDEN CLASSIC TINTED (polymacon) Soft (Spherical & Toric) Daily Wear Contact lenses are fabricated from polymacon, 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 Blue tint (transparent/enhancing), 7,16-Dichloro-6, 15-dihydro-5, and 9,14,18-anthrazinetetrone is added to the lens.

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 (polymacon) 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 38% water by weight. The physical properties of the lens are:

Refractive Index	1.52 (dry) 1.43 (hydrated)
Light Transmission:	greater than 70% T
Water Content	38 %
Specific Gravity	1.28 (dry) 1.18 (hydrated)
Oxygen Permeability	9×10^{-11} Fatt Units (cm^2/sec)(ml O_2/ml x mm Hg @ 35°C), (revised Fatt method)

Intended Use:

The **ALDEN CLASSIC TINTED (polymacon) 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 **ALDEN CLASSIC TINTED (polymacon) 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.

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-38 (polymacon), 510(k) #K961103. 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 ALDEN CLASSIC TINTED (polymacon) Soft (Spherical & Toric) Daily Wear Contact Lens, Tinted (Transparent/Enhancing) are substantially equivalent to the predicate device. In addition, the water content, polymer, Dk value, refractive index, specific gravity, and light transmission are as well substantially equivalent to the predicate device.

Substantial Equivalence Matrix

	Characteristic	ALDEN CLASSIC TINTED	PREDICATE DEVICE
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	38%	SAME
b.	Polymer Content	62%	SAME
c.	Polymer	polymacon	SAME
d.	DK Value	9	SAME
e.	Refractive Index	1.43 (hydrated)	SAME
f.	Specific Gravity	1.180 (hydrated)	SAME
g.	Light Transmission	greater than 70% T	SAME
h.	Dye Color	Blue (21CDR 73.3119) CI # 69825	SAME **

** The Dye Color in the SE predicate device "Benz-38" is that of phthalocyanato (2) – (copper) being a blue visibility tint and not the Vat blue 6 CI# 69825.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 1998

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

Re: K980554
Trade Name: Alden Classic Tinted (polymacon) Hydrophilic Contact Lens for Daily Wear (Lathe-cut, enhancement tint)
Regulatory Class: II
Product Code: 86 LPL
Dated: February 9, 1998
Received: February 13, 1998

Dear Mr. Dalsing:

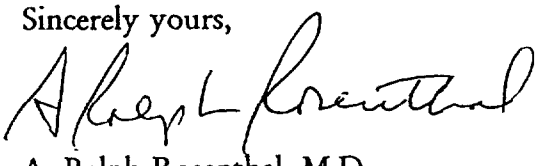
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 at (301) 443-6597.

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: **ALDEN CLASSIC TINTED (polymacon) Soft (Spherical & Toric) Daily Wear Contact Lens, Tinted (Transparent/Enhancing)**

INDICATIONS FOR USE:

The **ALDEN CLASSIC TINTED (polymacon) 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 **ALDEN CLASSIC TINTED (polymacon) 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.

(PLEASE DO OT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K980554

Prescription Use ✓ or Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)