DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 2005

Alden Optical Laboratories, Inc.
c/o Charles H. Creighton
President
13295 Broadway
Alden, NY 14004-1398

Re: K052703
Trade/Device Name:
Alden Classic (polymacon) Multifocal Contact Lens (Spherical and Toric designs);
Alden Classic 55 (methafilcon A) Multifocal Contact Lens (Spherical and Toric designs);
Alden HP 49 (hioxifilcon B) Multifocal Contact Lens (Spherical and Toric designs);
Alden HP 59G (hioxifilcon A) Multifocal Contact Lens (Spherical and Toric designs).

Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: September 27, 2005
Received: September 28, 2005

Dear Mr. Creighton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment E

Indications For Use Statement

Device Name:

Alden Classic (polymacon) Multifocal (Spherical and Toric), Alden Classic 55 (methafilcon A) Multifocal (Spherical and Toric), Alden HP 49 (hioxifilcon B) Multifocal (Spherical and Toric), and Alden HP 59G (hioxifilcon A) Multifocal (Spherical and Toric) Soft Contact Lenses

Indications for Use:

The Alden Classic (polymacon), Alden Classic 55 (methafilcon A), Alden HP 49 (hioxifilcon B) and Alden HP 59G (hioxifilcon A) Multifocal (Spherical and 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 refractive ametropia (myopia, hyperopia, and astigmatism) and presbyopia.

The lenses are available for either conventional or planned replacement modalities.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Daniel W. C. Brown, PH.D.
(Division Sign-Off)

Division of Ophthalmic Devices

510(k) Number K052703