OCT 4 1999

K992466

Ocu-Ease Optical Products, Inc.
510(k) Premarket Notification
Ocu-Flex-38 Keratoconus (polymacon) Soft Contact Lens for Daily Wear

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Ocu-Ease
Optical Products, Inc.

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Pinole, California 94564
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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.

Assigned 510(k) Number: _____

Applicant Information:

Date Prepared:	July 20, 1999
Name:	Ocu-Ease Optical Products, Inc.
Address:	629 Tennent Avenue Pinole, CA. 94564
Contact Person:	Charles R. Vermette President
Phone/Fax Number:	Phone: (510)724-0384 Fax: (510)724-4842
Establishment Registration No.:	2916547

Device Information:

Regulatory Classification:	Class II
Product Code:	LPL
Device Trade Name:	Ocu-Flex-38 Keratoconus (polymacon) Soft Contact Lens for Daily Wear (Clear and Tinted, lathe-cut)

SUMMARY OF SAFETY AND EFFECTIVENESS
(continued)

Classification Name:	Lenses, Contact (other material), Daily Wear
Classification Number:	886.5925
Panel:	Ophthalmic

Equivalent Devices:

The Ocu-Flex-38 Keratoconus (polymacon) Soft Contact Lens for Daily Wear is substantially equivalent to the predicate device identified below in terms of intended use and design.

Predicate Device:

Harrison Keratoconus Lens
PMA #N17976 (hefilcon A)
Manufactured By: Paragon Vision Sciences
Flexlens Products

Device Description:

The Ocu-Flex-38 Keratoconus (polymacon) Soft Contact Lens is a hydrophilic polymer of 2-hydroxyethyl-methacrylate crosslinked with ethylene glycol dimethacrylate. When fully hydrated in a 0.9% sodium chloride solution, the lens is 38% water and 62% polymacon by weight. In that fully hydrated state the lens is soft and readily wet by saline and aqueous solution.

The Ocu-Flex-38 Keratoconus (polymacon) Soft Contact Lens is a spherical conic lens. It is designed to provide optimum comfort and visual acuity to the keratoconus patient. The Ocu-Flex-38 Keratoconus (polymacon) Soft Contact Lens design begins with a spherical 5.0mm optic zone that fits the peak of the cone and provides for good visual acuity. The lens then flattens into the base curve, which is considered the fitting curve of the lens. The cone curve will vary in rate of change depending on how far the keratoconus has advanced and creates optimal corneal alignment. The design finishes with a peripheral curve to maintain alignment and comfort.

SUMMARY OF SAFETY AND EFFECTIVENESS
(continued)

The physical properties of the lens are:

Refractive Index	1.43
Light Transmission	96% of visible light
Specific Gravity	1.18
Water Content	38%
Color Pigment Names	[phthalocyaninato(2-)] copper
Oxygen Permeability	8.41×10^{-11} (cm^3 O2 cm)/sec cm^2 mm Hg@35°C (Fatt Method)

Intended Use:

The Ocu-Flex-38 Keratoconus (polymacon) Soft Contact Lens is indicated for daily wear for persons requiring Keratoconus management with otherwise non-diseased eyes. The lens may be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not-aphakic persons. The lens may be disinfected with a chemical or heat disinfection system.

Substantial Equivalence:

The new device will be manufactured according to specified process controls and a Quality Management System certified to CGMP guidelines. The new device will undergo manufacturing, packaging and other process procedures similar to soft contact lens devices currently marketed and distributed by Ocu-Ease Optical Products, Inc. in the USA. The established safety profile (pre-clinical toxicology and manufacturing/chemistry data) of the device is equivalent to the Harrison Keratoconus Lens (soft lens), PMA #N17976 (Hefilcon A). Being similar with respect to indications for use, materials, physical construction and safety and effectiveness to the predicate device, 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 device identified above.

The following matrix illustrates that the production method, lens function and material of the Ocu-Flex-38 Keratoconus (polymacon) Soft Contact Lens for Daily Wear is 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.

Signed: _____ Date: 07/20/1999
Charles R. Vermette, President

Ocu-Ease Optical Products, Inc.

510(k) Premarket Notification

Ocu-Flex-38 Keratoconus (polymacon) Soft Contact Lens for Daily Wear

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Summary of Safety and Effectiveness

Substantial Equivalence Matrix

	Characteristic	Ocu-Flex-38 (polymacon) Soft Keratoconus Contact lens		*Predicate Device:* Flexlens Harrison Keratoconus Lens
1.)	**PRODUCTION METHOD**	Lathe-cut		Lathe-cut
2.)	**LENS FUNCTION**	Keratoconus management. Refractive medium that focuses light rays from near and distant objects on the retina, while compensating for refractive error, including (astigmatism)		Keratoconus management. Refractive medium that focuses light rays from near and distant objects on the retina, while compensating for refractive error, including (astigmatism)
3.)	**MATERIAL**	Soft Contact Lens - Group 1, Low Water, Non-ionic polymer		Soft Contact Lens - Group 1, Low Water, Non-ionic polymer
a.	Water Content	38%		45%
b.	Polymer	(polymacon)		(hefilcon A)
c.	Oxygen Permeability	8.41×10^{-11} at 35C		$16X10^{-11}$ at 35C
d.	Refractive Index	1.41		1.43
e.	Specific Gravity	1.18		1.09
f.	Light Transmission	96%T		96%T

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 4 1999

Mr. Charles R. Vermette
President
Ocu-Ease Optical Products, Inc.
629 Tennent Avenue
Pinole, CA 94564

Re: K992466
Trade Name: Ocu-Flex-38 Keratoconus (polymacon) Soft Contact Lens for Daily Wear
Regulatory Class: II
Product Code: LPL
Dated: July 20, 1999
Received: July 23, 1999

Dear Mr. Vermette:

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 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). 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

510(k) Number (if known):_____

Device Name: Ocu-Flex-38 Keratoconus (polymacon) Soft Contact Lens

Indications of Use:

The Ocu-Flex-38 Keratoconus (polymacon) Soft Contact Lens is indicated for daily wear for persons requiring Keratoconus management with otherwise non-diseased eyes. The lens may be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not-aphakic persons. The lens may be disinfected using a chemical or heat disinfecting systems.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Ophthalmic Devices

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K 992466

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)