DEC 1 0 2002

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: **K023077**

Applicant information:

Date Prepared:	September 12, 2002
Name:	**Ocu-Ease Optical Products, Inc.**
Address	629 Tennent Avenue Pinole, CA 94564
Contact Person:	Charles R. Vermette
Phone number:	(800) 521-8984
USA Consultant:	Deanna Werber or Martin Dalsing Medvice Consulting, Inc. 623 Glacier Drive Grand Junction, CO 81503
Phone number	(970) 243-5490 Fax (970) 243-5501 Email: dwerber@fdapproval.com

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Lenses, Soft Contact, Daily Wear
Trade Name:	**OCU-FLEX Pediatric Aphakic (ocufilcon B) Spherical Soft Contact Lens for Daily Wear (lathe-cut).**

Purpose of 510(k) submission:

NEW DEVICE ~

Ocu-Ease Optical Products, Inc. proposes to manufacture the OCU-FLEX PEDIATRIC APHAKIC, (ocufilcon B) Spherical Soft Contact Lens for Daily Wear (lathe-cut). Data supporting substantial equivalency to the predicate devices, performance, and safety and efficacy of the OCU-FLEX PEDIATRIC APHAKIC, (ocufilcon B) Soft Contact Lens for Daily Wear (lathe-cut) is contained in this submission.

Equivalent Device:

The **OCU-FLEX PEDIATRIC APHAKIC (ocufilcon B) Soft Contact Lens for Daily Wear (lathe-cut)** is substantially equivalent to the following predicate devices.

- Pediatric/Aphakic lens (methafilcon A) manufactured by Flexlens Products (K950294)

Device Description:

The **OCU-FLEX PEDIATRIC APHAKIC (ocufilcon B) Soft Contact Lens for Daily Wear (lathe-cut)** is fabricated from ocufilcon 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.

The aphakic lens designs are made for daily wear for the correction of refractive hyperopia in pediatric aphakic persons. The design elements of the **OCU-FLEX PEDIATRIC APHAKIC (ocufilcon B) Soft Contact Lens for Daily Wear (lathe-cut)** is intended to accommodate pediatric patients. The lens design has a higher power range and smaller lens to compensate for the thickness for the increased power.

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 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 non-ionic lens material, **ocufilcon B**, is a copolymer of 2-hydroxyethyl methacrylate (2-HEMA) methacrylic acid and cross-linked with ethylene glycol dimethacrylate (EGDMA). It consists of 47% ocufilcon B and 53% water by weight when immersed in normal saline solution buffered with sodium bicarbonate. The lenses are available in clear and with a blue visibility-handling tint, Reactive Blue 21.

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 53% water by weight. The physical properties of the lens are:

Refractive Index	1.41
Light Transmission (clear)	greater than 95% T
Light Transmission (tinted)	greater than 95% T
Water Content	53 %
Specific Gravity	1.18
Oxygen Permeability	18.1×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ $35^{\circ}C$), (revised Fatt method).

Intended Use:

The **OCU-FLEX PEDIATRIC APHAKIC (ocufilcon B) Spherical** Soft Contact Lens are indicated for daily wear for the correction of hyperopia in pediatric aphakic persons.

The lens may be disinfected with chemical (not heat) disinfection system.

Pre-Clinical Performance Data:

ocufilcon B

Pre-clinical performance data addressing the cytotoxicity test, systemic injection test, and ocular eye irritation test for can be referenced for the **ocufilcon B** in PMA # P820051.
Pre-clinical data addressing Reactive Blue 21 can be referenced in Ocu-Ease Optical Products, Inc. 510(k) K960291.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a quality assurance program already in place at Ocu-Ease Optical Products, Inc. The device will undergo manufacturing, packaging and sterilization procedures similar to devices currently marketed and distributed by Ocu-Ease Optical Products, Inc.

The device is similar with respect to indications for use, materials, physical construction and safety & 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 devices identified above.

The following table illustrates that the production method, lens function and indications for use of the **OCU-FLEX PEDIATRIC APHAKIC (ocufilcon B) Spherical Soft Contact Lens for Daily Wear (lathe-cut)** substantially equivalent to the predicate devices.

Substantial Equivalence Table

	CHARACTERISTICS	OCU-FLEX PEDIATRIC APHAKIC (ocufilcon B) Spherical Soft Contact Lens for Daily Wear	X-Cel Contacts Flexlens Pediatric Aphakic
1.)	**INDICATION**	Daily wear, Soft Contact Lens	Daily wear, Soft Contact Lens
2.)	**INTENDED USE**	The OCU-FLEX PEDIATRIC APHAKIC (ocufilcon B) Spherical Soft Contact Lens are indicated for daily wear for the correction of hyperopia in pediatric aphakic persons.	The Flexlens 55 (methafilcon A) Soft Contact Lens is indicated for Daily Wear use for the correction of visual refractive ametropia and secialized uses such as atypical ametropia, examples include but are not limited to: adult and pediatric aphakia and irregular astigmatism created by keratoconus or trauma or post keratoplasty.
3.)	**MATERIAL**	HYDROPHILIC	HYDROPHILIC
a.	dk/l	18.1	18.8
4.)	**DESIGN**	Aphakic Spherical	Aphakic Spherical
5.)	**PARAMETERS**		
a.	Base Curve (mm)	6.0 mm to 8.5 mm	6.0 mm to 10.8 mm
b.	Dia (mm)	8.0 mm to 11.0 mm	10.0 mm to 16.0 mm
c.	Powers Available	+10.00 to +40.00 diopters	Plano to +30.00 diopters
d.	Thickness	Varies with power	Varies with power
e.	Optical Zone	4.5mm - 8.0mm	4.5mm - 8.0mm

INDICATIONS FOR USE STATEMENT

Device Name: **OCU-FLEX PEDIATRIC APHAKIC (ocufilcon B) Spherical Soft Contact Lens for Daily Wear (lathe-cut)**

INDICATIONS FOR USE:

The **OCU-FLEX PEDIATRIC APHAKIC (ocufilcon B) Spherical** Soft Contact Lens are indicated for daily wear for the correction of hyperopia in pediatric aphakic persons.

The lens may be disinfected with chemical (not heat) disinfection system.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2002

Ocu-Ease Optical Products, Inc.
c/o Ms. Deanna Werber
Medvice Consulting, Inc.
623 Glacier Drive
Grand Junction, CO 81503

Re: K023077
Trade/Device Name: Ocu-Flex Pediatric Aphakic (ocufilcon B) Spherical Soft Contact Lens for Daily Wear (lathe-cut clear & visi-tint)
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: September 12, 2002
Received: September 16, 2002

Dear Ms. Werber:

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) 594-4692. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE STATEMENT

Device Name: **OCU-FLEX PEDIATRIC APHAKIC (ocufilcon B) Spherical Soft Contact Lens for Daily Wear (lathe-cut)**

INDICATIONS FOR USE:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Judith Lee Cohen MD
(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number 023077

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

(Optional Format 1-2-96)