510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

K974599

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.

MAR - 2 1998

The assigned 510(k) number is: K974599

Applicant information:

Date Prepared:	November 28, 1997
Name: Address	**Opti-Center Laboratories** 4375 Ouimet Street Sherbrooke (Quebec) Canada JIL 1X5
Contact Person: Phone number:	Robert Mercure (819) 564-8114
USA Consultant: Phone number	Martin Dalsing (970) 243-5490

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Lenses, Soft Contact, Daily Wear
Trade Name:	**UltraVue/P, UltraVue/C (hioxifilcon B) Soft (Multifocal) Daily Wear Contact Lens (Clear & Blue Visibility Tint, Lathe-cut from Lens Blank)**

Equivalent Devices:

The UltraVue/P, UltraVue/C (hioxifilcon B) Soft (Multifocal) Daily Wear Contact Lens is substantially equivalent to the following predicate devices in terms of intended use and design. Predicate devices include: the Bi-Soft manufactured by Lombart Lenses, the LifeStyle 4-Vue and LifeStyle Xtra manufactured by The LifeStyle Co., the Horizon 55 Bicon manufactured by Westcon, the Ocu-Flex-53 manufactured by Ocu-Ease Optical, the SimulVue manufactured by Unilens Corp and the BENZ-G 3X manufactured by BENZ Research and Development Corp.

Device Description:

The UltraVue/P, UltraVue/C (hioxifilcon B) Soft (Multifocal) Daily Wear Contact Lenses are 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.

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 (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)
Color Pigment Name	Phthalocyanine Blue
Light Transmission (clear)	greater than 95% T
Light Transmission (tinted)	greater than 95% T
Water Content	48 % ± 2%
Specific Gravity	1.308 (dry) 1.136 (hydrated)
Oxygen Permeability	15×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (revised Fatt method).

Intended Use:

The UltraVue/P, UltraVue/C (hioxifilcon B) Soft (Multifocal) 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 are presbyopic. The lens may be worn by persons who may exhibit astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity.

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 Les Laboratories Opti-Center Inc. The established safety profile (pre-clinical toxicology and manufacturing/chemistry data) of the device is equivalent to the BENZ-G 3X, 510(k) #K964528. 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 UltraVue/P, UltraVue/C (hioxifilcon B) Soft (Multifocal) Daily Wear Contact Lens (Clear & Blue Visibility Tint, Lathe-cut from Lens Blank), are substantially equivalent to the predicate devices. In addition, the water content, polymer, DK value, refractive index, specific gravity, and light transmission are as well substantially equivalent to the predicate devices.

Substantial Equivalence Matrix

	Characteristic	UltraVue/P Multifocal	UltraVue/C Multifocal	PREDICATE DEVICES
1.)	PRODUCTION METHOD	Lathe-Cut	Lathe-Cut	SAME
2.)	LENS FUNCTION	Refractive medium that focuses light rays from distant, intermediate and near objects on the retina, while compensating for refractive error.	Refractive medium that focuses light rays from near, intermediate and distant objects on the retina, while compensating for refractive error.	SAME
3.)	MATERIAL	Hydrophilic Polymer	Hydrophilic Polymer	SAME
a.	Water Content	48%	48%	Similar
b.	Polymer Content	52%	52%	Similar
c.	Polymer	hioxifilcon B	hioxifilcon B	polymacon, tefilcon, ocufilcon, hefilcon
d.	DK Value	15	15	8.4, 8.0, 18.1, 11.3
e.	Refractive Index	1.404 (hydrated)	1.404 (hydrated)	Similar
f.	Specific Gravity	1.136 (hydrated)	1.136 (hydrated)	Similar
g.	Light Transmission	greater than 95% T	greater than 95% T	Similar

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 2 1998

Mr. Martin J. Dalsing
Official Correspondent and
US Consultant for
Opti-Center Laboratories, Inc.
623 Glacier Drive
Grand Junction, CO 81503

Re: K974599
Trade Name: UltraVue/P, UltraVue/C (hioxifilcon B) Soft (Multifocal) Daily Wear Contact Lens (Clear & Blue Visability Tint, Lathe-cut from Lens Blank)
Regulatory Class: II
Product Code: 86 LPL
Dated: November 28, 1997
Received: December 9, 1997

Dear Mr. Dalsing:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined these devices are 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 these devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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 devices 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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: **UltraVue/P, UltraVue/C (hioxifilcon B) Soft (Multifocal) Daily Wear Contact Lens (Clear & Blue Visibility Tint, Lathe-cut from Lens Blank)**

INDICATIONS FOR USE:

The UltraVue/P, UltraVue/C (hioxifilcon B) Soft (Multifocal) 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 are presbyopic. The lens may be worn by persons who exhibit astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity.

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

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)

Daniel W. C. Brown, PH.D.
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K974599