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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.

The assigned 510(k) number is: **K033594**

Applicant information:

Date Prepared:	November 16, 2003
Name:	**CONTAMAC Ltd.**
Address	Bearwalden Business Park Saffron Walden Essex England CB11 4JX
Contact Person:	Robert McGregor
Phone number:	44-1799 542 000
US Agent:	Medvice Consulting, Inc. Martin Dalsing
Phone number	(970) 243-5490
Fax number	(970) 243-5501

Device Information:

Device Classification:	Class II
Classification Number:	HQD
Classification Name:	Lenses, Rigid Gas Permeable, Daily Wear
Trade Name:	**OPTIMUM GP (Oxygen Permeable) Daily Wear Contact Lenses.**

Equivalent Devices:

The **OPTIMUM GP** (roflufocon A), (roflufocon B), (roflufocon C), (roflufocon D), & (roflufocon E) Rigid Gas Permeable (RGP) Daily Wear Contact Lens are substantially equivalent to the following predicate devices.

Predicate devices:

Predicate device manufacturer:	Device name:
1.) **Polymer Technology** 1400 North Goodman Street Rochester, NY 14603	**Boston ES Multifocal**, Daily Wear 510(k) #: K970698
2.) **Polymer Technology** 1400 North Goodman Street Rochester, NY 14603	**Boston XO**, Daily Wear 510(k) #: K000795
	BOSTON XO, EO, ES, 7 RXD, Daily Wear 510(k) #: K002025 (wet shipped lenses)
3.) **Paragon Vision Sciences** 947 E. Impala Avenue Mewa, AZ 85204	**FluoroPerm 30**, 510(k) #: K940277 **FluoroPerm 60**, 510(k) #: K940277 **FluoroPerm 90**, 510(k) #: K940277 **FluoroPerm 151**, 510(k) #:K940277 **FluoroPerm HDS**, P87024-S36
4.) **Metro Optics, Inc.** 15802 Vision Drive Pflugerville, TX 78660	**ComfortKone**, Daily Wear 510(k) # K990264 (Keratoconus Contact Lens Design)

Device Description:

The **OPTIMUM GP** series of contact lenses are fabricated from the hydrophobic contact lens materials (roflufocon A), (roflufocon B), (roflufocon C), (roflufocon D), & (roflufocon E). When placed on the human cornea, the OPTIMUM GP rigid gas permeable contact lenses act as a refracting medium to focus light rays upon the retina.

The **OPTIMUM GP** Contact Lens for Daily Wear are available as lathe cut contact lenses with spherical, aspheric, bifocal, multifocal or toric anterior and/or posterior designs in clear and tinted versions.

The **OPTIMUM GP** Contact Lens for Daily Wear is a rigid gas permeable methacrylate copolymer of Methyl methacrylate, 1,1,1,3,3,3 - Hexafluoroisopropyl Methacrylate, Methacryloxypropyl Tris(trimethylsiloxy) silane, 1,3-bis(methacryloxypropyl)-1,1,3,3-tetrakis(trimethyl siloxy)disiloxane, 2-Hydroxyethyl Methacrylate, and Methacrylic acrylic acid cross-linked with Ethylene Glycol Dimethacrylate.
The OPTIMUM GP Contact Lens for Daily Wear incorporates a visibility tint to make the lens more visible for handling. The tinted lenses contain one or more of the following color additives: D&C Green No.6, C.I. Solvent yellow No. 18, and FD&C Red No. 17.

UV Blocker
In the **OPTIMUM GP** Contact Lens with UV Blocker, a Benzophenone UV blocking monomer is used to block UV radiation. The UV Blocker is 2,2'-Dihydroxy-4,4'dimethoxybenzophenone. The UV blocking for OPTIMUM GP averages > 98% in the UVB range of 280nm – 315nm and 95% in the UVA range of 316 – 380nm.

The physical properties of the **OPTIMUM GP** Contact Lens are:

	(roflufocon A)	(roflufocon B)	(roflufocon C)	(roflufocon d)	(roflufocon e)
Refractive Index	1.4527	1.4454	1.4406	1.4333	1.4332
Light Transmission (clear)	>97%	>97%	>97%	>97%	>97%
Light Transmission (tinted)	>90%	>90%	>90%	>90%	>90%
Wetting Angle (Dynamic contact receding angle)	12°	13°	6°	3°	6°
Specific Gravity	1.189	1.181	1.178	1.166	1.155
Oxygen Permeability (Dk) ISO/FATT Method	26×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)	46×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)	65×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)	100×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)	125×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)
Visitint lenses contain one or more of the following color additives and conform to: 21 CFR Part 73 & 74, Subpart D Medical Devices	D & C Green No. 6, FD & C Red No. 17 CI Solvent Yellow 18	D & C Green No. 6, FD & C Red No. 17 CI Solvent Yellow 18	D & C Green No. 6, FD & C Red No. 17 CI Solvent Yellow 18	D & C Green No. 6, FD & C Red No. 17 CI Solvent Yellow 18	D & C Green No. 6, FD & C Red No. 17 CI Solvent Yellow 18

Intended Uses:

The **OPTIMUM GP** (roflufocon A, roflufocon B, roflufocon C, roflufocon D, and roflufocon E) **Spherical** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be disinfected with a chemical disinfection system only.

The **OPTIMUM GP** (roflufocon A, roflufocon B, roflufocon C, roflufocon D, and roflufocon E) **Toric** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear 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 10.00 diopters.
The lens may be disinfected with a chemical disinfection system only.

The **OPTIMUM GP** (roflufocon A, roflufocon B, roflufocon C, roflufocon D, and roflufocon E) **Multifocal/Bifocal** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear 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 4 diopters and are presbyopic requiring add power of up to +4.00 diopters. The lens may be disinfected with a chemical disinfection system only.

The **OPTIMUM GP** (roflufocon A, roflufocon B, roflufocon C, roflufocon D, and roflufocon E) **Keratoconus** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for persons requiring Keratoconus management with otherwise non-diseased eyes. The lens may also 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 disinfection system only.

Description of Safety:

A series of preclinical testing were performed to demonstrate the safety and effectiveness of the OPTIMUM GP Rigid Gas Permeable Contact Lens material. The results of all testing demonstrated that the safety and effectiveness of the OPTIMUM GP Rigid Gas Permeable Contact Lens is equivalent to the currently marketed predicate devices previously identified. A summary of these results from the preclinical studies is presented below.

Toxicology:

In-Vitro Cytotoxicity: ISO 10993-5 was conducted in accordance with standards on test article. The test article meets the requirements of the Agarose Overlay Method.

Systemic Toxicity: The lens material meets the requirements of the systemic injection test and is considered non-toxic.

Acute Ocular Irritation: Acute ocular irritation test was performed and produced no ocular irritation.

Packaging

The primary container for shipping the OPTIMUM GP Rigid Gas Permeable Contact Lenses is the Alcon Contact Lens Case, with clearance under 510(k) K974281. The lens is shipped (wet) non-sterile in the OPTIMUM by Lobob Cleaning and Disinfecting Storage solution, with clearance under 510(k) 014162. The solution contains lauryl sulfate salt of imidazoline, octylphenoxy polyethoxyethanol and preserved with benzyl alcohol.

Shelf Life

The OPTIMUM GP Rigid Gas Permeable lens is a hydrophobic contact lens material with <1% water content. When the OPTIMUM GP lenses are shipped dry, shelf life studies are not required for clearance of this material.

When the OPTIMUM GP lenses are shipped wet, shelf life studies are required for clearance of this material. See following Bioburden Testing to Evaluate 30 –Day Storage (Shelf Life) in a Cleaning, Disinfecting and Storage GP Solution:

Contamac performed stability, compatibility and microbiology testing on OPTIMUM GP Contact Lenses wet shipped in OPTIMUM by Lobob GP Cleaning, Disinfecting and Storage Solution and stored for up to 30 days. This testing combined with utilization of the contact lens container identified supports the claim of substantial equivalence to Boston RGP lenses wet shipped and stored for up to 30 days.

Stability/Compatibility ~ The Fluorosilicone acrylate OPTIMUM GP Rigid Gas Permeable Contact Lenses were subjected to a thirty-day soak in OPTIMUM by Lobob GP Cleaning, Disinfecting and Storage solution according to the lens compatibility protocol. The average changes for each parameter (diameter, base curve and power), relative to the initial measurements were determined.
After soaking in the contact lens carrying cases at room temperature for thirty days the OPTIMUM GP rigid gas permeable contact lenses were determined to be physically compatible with OPTIMUM by Lobob GP solutions.

Microbiology ~ A bioburden study was completed. A set of test lenses was cleaned with OPTIMUM by Lobob Extra Strength Cleaner for rigid gas permeable lenses and subjected to bioburden testing. In this test, lenses were tested to validate the storage in OPTIMUM by Lobob GP Cleaning, Disinfecting and Storage Solution. Testing showed that the colony forming units (CFU) per lens was less than 2. The acceptance criteria is 100 CFU per lens.

Solution Compatibility

Studies were conducted on blue tinted lens material. Lenses were run through 30 cycles of cleaning and conditioning to establish the compatibility of the lens material with the recommended care regimen. The parameters of the base curve, back vertex power, total diameter and overall lens physical appearance were recorded prior to and upon completion of 30 cycles. Initial and final data were compared. There were no significant changes to lens parameters after 30 complete cycles.

Clinical Testing

Below is a summary of the clinical study carried out to evaluate the safety and efficacy of the OPTIMUM GP Rigid Gas Permeable Contact Lens material when used as a daily wear contact lens for the correction of visual acuity.

A total of 272 eyes (136 patients) were entered into the study by 10 investigators. Prior to entry into this study each patient was required to read and sign a statement of informed consent. All patients who signed a Statement of Informed Consent are accounted for in this report. Of the 272 eyes (136 patients enrolled), 246 eyes (123 patients) completed the study.

The safety and efficacy measures for the study were:

Safety: Adverse Events, Positive Slit Lamp Findings,
Symptoms/Complaints and Keratometry Changes.

Efficacy: Refractive Changes, Lens Visual Acuity, Lens
VA Line Changes, Comfort and Vision, Average Wearing time.

The sponsor concludes that OPTIMUM Rigid Gas Permeable Contact Lens material is equivalent in safety and efficacy to the predicate devices.

Substantial Equivalence:

The **OPTIMUM GP** Rigid Gas Permeable Contact Lens is substantially equivalent and *does not raise* different questions of safety and effectiveness than the predicate device identified previously. The difference between the devices is the USAN name.

The following comparison table depicts characteristics of the **OPTIMUM GP** material, as well as the predicate devices.

Substantial Equivalence table

	Characteristics Comparison	OPTIMUM GP	BOSTON ES, XO	FLUOROPERM 30, 60, 90, 151, HDS
		New Device	*Predicate Device*	*Predicate Device*
1.)	**Functionality**	After machining from the optical blank, the contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	After machining from the optical blank, the contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	After machining from the optical blank, the contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.
2.)	**Indication for Use**	Daily wear, Rigid Gas Permeable RGP Contact Lens	Daily wear, Rigid Gas Permeable RGP Contact Lens	Daily wear, Rigid Gas Permeable RGP Contact Lens
3.)	**Production Method**	Lathe-cut	Lathe-cut	Lathe-cut
4.)	**FDA Group #**	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate
5.)	**USAN name**	roflufocon A, B, C, D, E	enflufocon A, B	paflufocon A, B, C, D
6.)	**Water Content**	<1%	<1%	<1%
7.)	**UV Absorber/Blocker available**	YES	YES	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2004

CONTAMAC Ltd.
c/o Martin Dalsing
Medvice Consulting, Inc.
623 Glacier Dr.
Grand Junction, CO 81503

Re: K033594
Trade/Device Name: OPTIMUM GP (roflufocon A, roflufocon B, roflufocon C, roflufocon D and roflufocon E) Daily Wear Contact Lenses
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid gas permeable contact lens.
Regulatory Class: Class II
Product Code: HQD
Dated: February 23, 2004
Received: February 24, 2004

Dear Mr. Dalsing:

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) 594-4613. 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/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

INDICATIONS FOR USE STATEMENT

Device Name: **OPTIMUM GP (Oxygen Permeable) Daily Wear Contact Lenses.**

INDICATIONS FOR USE:

The **OPTIMUM GP** (roflufocon A, roflufocon B, roflufocon C, roflufocon D, and roflufocon E) **Spherical** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be disinfected with a chemical disinfection system only.

Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Daniel W. Brown, Ph.D.
(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K033594

INDICATIONS FOR USE STATEMENT

Device Name: **OPTIMUM GP (Oxygen Permeable) Daily Wear Contact Lenses.**

INDICATIONS FOR USE:

The **OPTIMUM GP** (roflufocon A, roflufocon B, roflufocon C, roflufocon D, and roflufocon E) **Toric** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear 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 10.00 diopters.
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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Karen Waburton
(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K033594

INDICATIONS FOR USE STATEMENT

Device Name: **OPTIMUM GP (Oxygen Permeable) Daily Wear Contact Lenses.**

INDICATIONS FOR USE:

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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)

Karen Waibaston
(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K033594

INDICATIONS FOR USE STATEMENT

Device Name: **OPTIMUM GP (Oxygen Permeable) Daily Wear Contact Lenses.**

INDICATIONS FOR USE:

The **OPTIMUM GP** (roflufocon A, roflufocon B, roflufocon C, roflufocon D, and roflufocon E) **Keratoconus** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for persons requiring Keratoconus management with otherwise non-diseased eyes. The lens may also 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 disinfection system only.

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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)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number 033594