MAY - 1 2007

K070628

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:

Applicant information:

Date Prepared:	February 15, 2007
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** (roflufocon A, B, C, D & E) Daily Wear Contact Lens.
Purpose of 510(k):	**Additional Indications for Use.**

Equivalent Devices:

The **OPTIMUM GP** (roflufocon A, B, C, D & E) Daily Wear Contact Lens is 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® (enflufocon A), Boston EO®(enflufocon B), and the Boston XO® (hexafocon A)** Rigid Gas Permeable Contact Lenses 510(k) #K053124
2.) **Lens Dynamics** 14998 W. 6th Avenue, Suite 830 Golden, CO 80401	**Dyna Intra-Limbal Lens** 510(k) #K020006

Device Description:

The **OPTIMUM GP** (roflufocon A, B, C, D & E) Daily Wear Contact Lens may be prescribed in otherwise non-diseased eyes that require a rigid gas permeable lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.

The Safety and Efficacy and description of the **OPTIMUM GP** (roflufocon A, B, C, D & E) Daily Wear Contact Lens was demonstrated in 510(k) K0033594.

The **OPTIMUM GP** (roflufocon A, B, C, D & E) Daily Wear Contact Lens 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** (roflufocon A, B, C, D & E) Daily Wear Contact Lens are available have as lathe cut contact lenses in clear and tinted versions. 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 blocker 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** (roflufocon A, B, C, D & E) Daily Wear 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

Indication for Use:

The **OPTIMUM GP** (roflufocon A, B, C, D & E) Daily Wear Contact Lens may be prescribed in otherwise non-diseased eyes that require a rigid gas permeable lens for the management of irregular corneal conditions such as; keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.

Substantial Equivalence:

The **OPTIMUM GP** (roflufocon A, B, C, D & E) Daily Wear Contact Lens is substantially equivalent and *does not raise* different questions of safety and effectiveness than the predicate device identified previously.

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, EO& XO	Dyna Intra-Limbal Lens
		New Device	*Predicate Device*	*Predicate Device*
1.)	**Indication for Use**	The **OPTIMUM GP** (roflufocon A, B, C, D & E) Daily Wear Contact Lens may be prescribed in otherwise non-diseased eyes that require a rigid gas permeable lens for the management of irregular corneal conditions such as; keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or following refractive (e.g. LASIK) surgery.	The Boston ES® (enflufocon A) , Boston EO® (enflufocon B) and Boston XO® (hexafocon A) RGP contact lenses may be prescribed in otherwise non-diseased eyes that require a rigd contact lens for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.	TheDyna Intra-Limbal (enflufocon or hexafocon A) Lens lens may be prescribed in otherwise non-diseased eyes that requie a rigid contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration or rollowing penetrating keratoplasty.
2.)	**Device and Classification**	Class II Daily wear, Rigid Gas Permeable RGP Contact Lens HQD	Class II Daily wear, Rigid Gas Permeable RGP Contact Lens HQD	Class II Daily wear, Rigid Gas Permeable RGP Contact Lens HQD
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.)	**Water Content**	<1%	<1%	<1%
6.)	**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

MAY - 1 2007

Contamac Ltd.
c/o Mr. Martin Dalsing
Medvice Consulting, Inc.
Official Correspondent/Consultant and US Agent for Contamac Ltd.
2214 Sanford Dr. Ste. B7
Grand Junction, CO 81505

Re: K070628
Trade/Device Name: OPTIMUM GP (roflufocon A, roflufocon B, roflufocon C, roflufocon D and roflufocon E) Daily Wear Contact Lens
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid gas permeable contact lenses
Regulatory Class: Class II
Product Code: HQD
Dated: February 15 2007
Received: March 7, 2007

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, 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

K070628

Device Name: **OPTIMUM GP** (roflufocon A, B, C, D & E) Daily Wear Contact Lens

INDICATIONS FOR USE:

The **OPTIMUM GP** (roflufocon A, B, C, D & E) Daily Wear Contact Lens may be prescribed in otherwise non-diseased eyes that require a rigid gas permeable lens for the management of irregular corneal conditions such as; keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Marc Robbins

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

510(k) Number K070628