AUG 2 9 2003

K032256

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:	July 18, 2003
Name:	**No. 7 Contact Lens Laboratory Ltd.**
Address	Unit 3, Highfields Business Park Sidney Little Road Hastings, East Sussex TN38 9UB England
Contact Person:	Mr. Ashley Pepper Managing Director
Phone Number:	44 142 4850620
Fax:	44 142 4850650
Official Correspondent:	Med-Vice Consulting, Inc.
Regulatory Consultant:	Mr. Martin Dalsing 623 Glacier Drive Grand Junction, CO 81503
Phone Number:	(970) 243-5490
Fax Number:	(970) 243 -5501

Device Information:

Regulatory Classification:	Class II
Product Code:	HQD
Trade Name:	QUASAR® - QUASAR PLUS® - QUASAR TORIC® (hybufocon A, hexafocon A, paflufocon B) Rigid Gas Permeable (RGP) Daily Wear Contact Lens.
Purpose for 510(k)	New Device
Classification Name:	Lenses, Contact (other material), Daily Wear

Equivalent Devices:

The QUASAR® - QUASAR PLUS® - QUASAR TORIC® (hybufocon A, paflufocon B, hexafocon A) Rigid Gas Permeable (RGP) Daily Wear Contact Lens is substantially equivalent to the predicate devices identified below.

Predicate device manufacturer:	Device name:
1.) **Polymer Technology** 1400 North Goodman Street Rochester, NY 14603	**Boston Multifocal**, Daily Wear 510(k) #: K970698
2.) **Polymer Technology** 1400 North Goodman Street Rochester, NY 14603	**Boston XO**, Daily Wear 510(k) #: K000795
3.) **Contamac LTD.** Bearwalden Business Park Saffron Walden Essex CB11 4JX UK	**Hybrid FS**, Daily Wear 510(k) #: K021977
4.) **Paragon Vision Sciences** 947 East Impala Mesa, AZ 85204	**Fluoroperm 60/HDS**, Flexible Wear PMA #: P870024

Device Description:

The QUASAR® - QUASAR PLUS® - QUASAR TORIC® Contact Lenses are fabricated from the hydrophobic contact lens materials (hybufocon A, hexafocon A, paflufocon B). When placed on the human cornea, the QUASAR® - QUASAR PLUS® - QUASAR TORIC® rigid gas permeable contact lenses act as a refracting medium to focus light rays upon the retina.

The QUASAR® and QUASAR TORIC® series of contact lenses are aspheric from center to edge. The QUASAR® and QUASAR TORIC® are designed with the central area consisting of a modified conic profile, which is designed to flatten at a much slower rate than a fixed elliptical curve. (see figure below). This improves centration characteristics and eliminates any significant positive/astigmatic aberration over the central 7mm. This aspheric geometry results in slight apical clearance and close alignment over the mid-peripheral cornea. Edge clearance is achieved by the addition of a second aspheric edge band resulting in the optimal final tear lens profile as shown in the figure below. Constant apical and edge clearance are maintained independent of base curve and the total diameter of the lens.

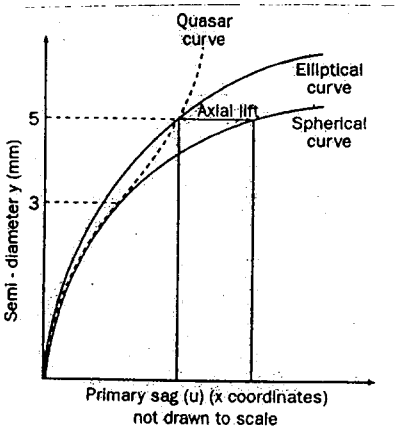

Figure 1 ~ The Quasar curve

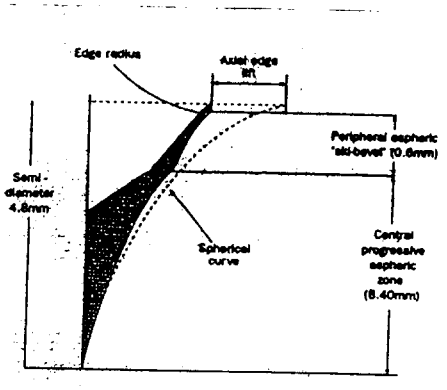

Figure 2 ~ Back surface profile of the Quasar lens

The QUASAR PLUS® multifocal design cleverly utilizes the eyes' own tears to provide precise vision at distance, intermediate and near. The QUASAR PLUS® is a distance center multifocal with a graduated annulus of near vision where the progressive power is incorporated into the optics back surface of the lens. The aspheric design of the optical zone is based upon the patient's degree of ametropia and the reading addition required. By incorporating the asphericity into the back surface, the profile of the tear film will be altered resulting in a fluorescein pattern different than that of a single vision lens.

No 7 Contact Lens Laboratories has been granted referencing rights from the following button material manufacturers. The physical properties of the lenses can be referenced in the corresponding 510(k) and/or PMA

Contamac	Hybrid FS (hybufocon A)	510(k), K021977
Polymer Technology	Boston XO (hexafocon A)	510(k), K000795
Paragon Vision Sciences	FluoroPerm 60/HDS (paflufocon B)	PMA, P870024

Intended Use:

The **QUASAR®** (hybufocon A, hexafocon A, paflufocon B) 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 **QUASAR TORIC®** (hybufocon A, hexafocon A, paflufocon B) 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 **QUASAR PLUS®** (hybufocon A, hexafocon A, paflufocon B) 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.

Substantial Equivalence:

The new device will be manufactured according to specified process controls and a Quality Management System certified to QSR guidelines. The new device will undergo manufacturing, packaging and other process procedures similar to RGP devices currently marketed and distributed by No 7 Contact Lens Laboratory Ltd. The established safety profile (pre-clinical toxicology and manufacturing/chemistry data) of the device was established in the following referenced FDA approvals:

(hybufocon A)	510(k), K021977
(hexafocon A)	510(k), K000795
(paflufocon B)	PMA, P870024

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 chart illustrates that the production method, indications for use, polymer material, specific gravity and oxygen permeability of the QUASAR® - QUASAR PLUS® - QUASAR TORIC® (hybufocon A, hexafocon A, paflufocon B) Rigid Gas Permeable (RGP) Daily Wear Contact Lens are substantially equivalent to the predicate device.

SUMMARY OF SAFETY AND EFFECTIVENESS
Substantial Equivalence Matrix

	Characteristic	NEW DEVICE QUASAR® - QUASAR PLUS® - QUASAR TORIC®	PREDICATE DEVICE Hybrid FS, Boston XO, Fluoroperm 60/HDS	PREDICATE DEVICE Boston Multifocal
1.)	**INDICATION**	Daily wear, Rigid Gas Permeable (RGP) contact lens	Daily wear, Rigid Gas Permeable (RGP) contact lens	Daily wear, Rigid Gas Permeable (RGP) contact lens
2.)	**INTENDED USE**	for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and not aphakic persons with non-diseaased eyes and are presbyopic (Quasar Plus only)	for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and not aphakic persons with non-diseaased eyes	for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and not aphakic persons with non-diseaased eyes and are presbyopic
3.)	**PRODUCTION METHOD**	Lathe-Cut	Lathe-Cut	Lathe-Cut
4.)	**RGP MATERIAL common name**	HyBrid FS Boston XO Fluoroperm 60/HDS	HyBrid FS Boston XO Fluoroperm 60/HDS	Boston ES
a.	Water Content	(hybufocon A) <1% (hexafocon A) < 1% (paflufocon B) < 1%	(hybufocon A) <1% (hexafocon A) < 1% (paflufocon B) < 1%	(enflufocon A) < 1%
b.	Polymer/USAN	Hybrid FS (hybufocon A) Boston XO (hexafocon A) Fluoroperm (paflufocon B)	Hybrid FS (hybufocon A) Boston XO (hexafocon A) Fluoroperm (paflufocon B)	Boston ES (enflufocon A)
c.	Specific Gravity	(hybufocon A) 1.183 (hexafocon A) 1.270 (paflufocon B) 1.160	(hybufocon A) 1.183 (hexafocon A) 1.270 (paflufocon B) 1.160	(enflufocon A) 1.220
d.	Oxygen Permeability (revised Fatt method)	(hybufocon A) = 31 (hexafocon A) = 100 (paflufocon B) = 60	(hybufocon A) = 31 (hexafocon A) = 100 (paflufocon B) = 60	(enflufocon A) = 18

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2003

No. 7 Contact Lens Laboratory Ltd.
c/o Mr. Martin Dalsing
Medvice Consulting, Inc.
623 Glacier Drive
Grand Junction, CO 81503

Re: K032256
Trade/Device Name: QUASAR® - QUASAR PLUS® - QUASAR TORIC®
(hybufocon A, hexafocon A, paflufocon B) Rigid Gas Permeable (RGP)
Daily Wear Contact Lens (clear and tinted)
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Permeable Contact Lens
Regulatory Class: Class II
Product Code: HQD
Dated: July 18, 2003
Received: July 24, 2003

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: The QUASAR® - QUASAR PLUS® - QUASAR TORIC® (hybufocon A, hexafocon A, paflufocon B) Rigid Gas Permeable (RGP) Daily Wear Contact Lens.

INDICATIONS FOR USE:

The **QUASAR®** (hybufocon A, hexafocon A, paflufocon B) 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.

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(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)

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K032256