APR - 2 2003

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: K030167

Applicant information:

Date Prepared:	January 14, 2003
Name:	**ClearLab PTE, Ltd.**
Address	139, Joo Seng Raod #06-01 ATD Centre, Singapore 368362
Contact Person:	Steve Newman
Phone number:	Country code 65+ 67491090
Fax number:	Country code 65+ 62848534
Parent Company:	1800 CONTACTS, Inc. 66 E. Wadsworth Park Drive 3rd. Floor Draper, UT 84020
FDA US Agent/ Official Correspondent:	Medvice Consulting, Inc. Martin Dalsing
Phone number	(970) 243-5490
Fax number	(970) 243-5501

Device Information:

Device Classification:	Class II
Classification Number:	LPL
Classification Name:	Lenses, Soft Contact, Daily Wear
Trade Name:	**MIERU (etafilcon A) Daily Wear Contact Lens clear and visibility tint, with UV blocker.**

Equivalent Predicate Devices:

The MIERU (etafilcon A) Soft Contact Lenses are substantially equivalent to the following predicate devices:

1. **IGEL 55UV** (methafilcon A), K020855, Manufactured by IGEL Visioncare Pte. Ltd.
2. **Frequency 58** (etafilcon A), K980634, manufactured by Aspect Vision Care.
3. **AcuVue 2** (etafilcon A), K962804, manufactured by Vistakon.

Device Description:

The MIERU (etafilcon A) Soft (hydrophilic) Contact Lens is available as a single vision spherical lens, aspherical multifocal lens and as a back surface astigmatic (toric) lens. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

The ionic lens material, (etafilcon A) is a co-polymer of 2- hydroxyethyl methacrylate and methacrylic acid cross-linked with 1,1,1 – trimethylol propane trimethacrylate and ethylene glycol demethacrylate. It consists of 42% etafilcon A and 58% water by weight when immersed in buffered saline solution. The lens polymer contains a UV absorbing compound and is available clear or with a blue visibility-handling tint, color additive 'Reactive Blue 19', 21 CFR part 73.3121. The (etafilcon A) name has been adopted by the United States Adopted Names Council (USAN).

In the MIERU Contact Lens with UV Blocker, a Benzophenone UV absorbing monomer is used to block UV radiation. The UV blocking for MIERU averages > 99% in the UVB range of 280nm – 315nm and 83% in the UVA range of 316 – 380nm.

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 hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 58% water by weight. The physical properties of the lens are:

Refractive Index	1.4050 (wet)
Light Transmission (clear)	greater than 95%
Light Transmission (tinted)	greater than 91%
Water Content	58 %
Specific Gravity	1.017 (hydrated)
Oxygen Permeability	19.9×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ $35^{\circ}C$), (revised Fatt method).

Intended Use:

The **MIERU (etafilcon A) Spherical** Soft 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. The lens may be worn by persons who exhibit refractive astigmatism of .75 diopters or less where the astigmatism does not interfere with visual acuity.

The **MIERU (etafilcon A) Toric** Soft 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 may have astigmatism of 7.00D or less.

The **MIERU (etafilcon A) Multifocal** Soft 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 no more than 2.00 D of astigmatism and can obtain satisfactory visual acuity in a power range of +4.00D to –5.00D and have near add requirements up to 3.00D.

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.

Technological Characteristics:

The technological characteristics of the MIERU contact lens as compared to the technological characteristics of the predicate devices are illustrated in the following table.

Pre-Clinical equivalency / Device	ClearLab800 (etafilcon A) new device	Frequency 58 (etafilcon A) predicate device	AcuVue 2 (etafilcon A) predicate device	Igel 55 UV (methafilcon A) predicate device
Intended Use	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.
Functionality	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina.
Indications	Daily wear, Soft (hydrophilic) contact lens	Daily wear, Soft (hydrophilic) contact lens	Daily wear, Soft (hydrophilic) contact lens	Daily wear, Soft (hydrophilic) contact lens
Production Method	Cast-molded	Cast-molded	Cast-molded	Cast-molded
FDA Group #	Group # 4 >50% Water, Ionic Polymers	Group # 4 >50% Water, Ionic Polymers	Group # 4 >50% Water, Ionic Polymers	Group # 4 >50% Water, Ionic Polymers
USAN name	etafilcon A	etafilcon A	etafilcon A	methafilcon A
Water Uptake(%)	58.0%	58.0%	58.0%	55.0%
Oxygen Permeability	19.9 x 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).	20.2 x 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).	19.9 x 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).	19.6 x 10-11 (cm2/sec) (ml O2/ml x mm Hg @ 35 degrees C), (revised Fatt method).
Specific Gravity	1.017	1.054	1.021	1.062

Summary of Non-Clinical Performance Data:

The following non-clinical tests were conducted as recommended by the Premarket Notification 510(k) guidance document for Daily Wear Contact Lenses, revised May 1994.

1. Toxicology testing
    a. Cytotoxicity
    b. USP Ocular Irritation
    c. USP Systemic Injection
2. Leachability / Residual monomer Studies
3. Physiochemical property testing

Clinical Studies:

No clinical data is required for this submission.

Conclusions Drawn from the Studies:

The MIERU Soft Contact Lens is substantially equivalent to the predicate devices and *does not raise* different questions of safety and effectiveness than that of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2003

ClearLab PTE, Ltd.
c/o Martin Dalsing
Medvice Consulting, Inc.
623 Glacier Drive
Grand Junction, CO 81503

Re: K030167
Trade/Device Name: MIERU (etafilcon A) Daily Wear Contact Lens clear and visibility tint, with UV blocker
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: March 17, 2003
Received: March 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: **MIERU (etafilcon A) Daily Wear Contact Lens clear and visibility tint, with UV blocker.**

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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 ✓ (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 K030167