

## 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:           K991015          

### Applicant information:

Date Prepared: March 24, 1999

Name: **Lamda Polytech Limited**  
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England NN13 7BE

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Martin Dalsing  
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### Device Information:

Device Classification: Class II

Classification Number: LPL

Classification Name: Lenses, Soft Contact, Daily Wear

Trade Name: **LM-70 (lidofilcon A) Spherical and Toric Soft Contact Lens for Daily Wear (clear, lathe-cut)**

**Equivalent Devices:**

The LM-70 (lidofilcon A) Spherical and Toric Soft Contact Lens is substantially equivalent to the following predicate device in terms of intended use and design.

*Predicate device:* "LL-70" manufactured/distributed by Lombart Lenses, LTD.

**Device Description:**

The LM-70 Spherical and Toric Soft Contact Lens is fabricated from lidofilcon A, 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 (lidofilcon A) 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 non-ionic lens material, (lidofilcon A) is a terpolymer of N-vinyl-2-pyrrolidone (NVP) and methyl methacrylate (MMA), cross-linked with ethylene glycol dimethacrylate (EGDMA) and Allyl methacrylate (AMA). It consists of 30% lidofilcon A and 70% water by weight when immersed in normal saline solution buffered with sodium bicarbonate.

The hydrophilic characteristics allow aqueous solutions to enter the lens and in its fully hydrated state the lens is approximately 70% water by weight. The physical properties of the lens are:

<b>Refractive Index</b>	1.52 (dry) 1.41 (hydrated)
<b>Light Transmission</b>	greater than 95%
<b>Water Content</b>	70 % ± 2%
<b>Specific Gravity</b>	1.061 (hydrated)
<b>Oxygen Permeability</b>	38.5 X 10 <sup>-11</sup> (cm <sup>2</sup> /sec) (ml O <sub>2</sub> /ml x mm Hg @ 35°C), (revised Fatt method).

**Intended Use:**

The LM-70 (lidofilcon A) Spherical Soft Contact Lens for daily wear is indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes that are myopic or hyperopic. The lens may be worn by persons who exhibit refractive astigmatism of 0.75 diopters or less that does not interfere with visual acuity. The lens may be disinfected using either a chemical or heat disinfecting system.

The LM-70 (lidofilcon A) Toric Soft Contact Lens for daily wear is indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes that are myopic or hyperopic and/or possesses refractive astigmatism not exceeding 10 diopters. The lens may be disinfected using either a chemical or heat disinfecting system.

**Substantial Equivalence:**

The LM-70 Soft Contact Lens will be manufactured according to specified process controls and an ISO 9001/9002 and CGMP quality assurance program currently in place. The established safety profile (pre-clinical toxicology and manufacturing/chemistry data) of the LM-70 material is equivalent to the predicate device identified previously. Being similar with respect to indications for use, materials, physical construction and safety & effectiveness to the predicate device, 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 device identified above.

The following matrix illustrates the production method, lens function and material characteristics of the LM-70 Spherical and Toric Soft Contact Lens, as well as the predicate device.

**Substantial Equivalence Matrix**

	<b>General S.E. Areas</b>	<b>Lamda Polytech LM-70 (lidofilcon A)</b>	<b>Predicate Device LL-70 (lidofilcon A)</b>
1.)	<b>Intended Use</b>	Visual correction in Not-aphakic persons with non-diseased eyes that myopic or hyperopic	Visual correction in Not-aphakic persons with non-diseased eyes that myopic or hyperopic
2.)	<b>Functionality</b>	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.
3.)	<b>Indications</b>	Daily wear, Soft (hydrophilic) contact lens	Daily wear, Soft (hydrophilic) contact lens
4.)	<b>Production Method</b>	Lathe-cut	Lathe-cut
5.)	<b>FDA Group #</b>	Group # 2 >50% Water, Nonionic Polymers	Group # 2 >50% Water, Nonionic Polymers
6.)	<b>Water Content</b>	70% ± 2 %	70% ± 2 %
7.)	<b>Oxygen Permeability</b>	38.5 X 10 <sup>-11</sup> (cm <sup>2</sup> /sec) (ml O <sub>2</sub> /ml x mm Hg @ 35 degrees C), (revised Fatt method).	34.7 X 10 <sup>-11</sup> (cm <sup>2</sup> /sec) (ml O <sub>2</sub> /ml x mm Hg @ 35 degrees C), (revised Fatt method).
8.)	<b>Specific Gravity</b>	1.061	1.073



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Lamda Polytech Limited  
c/o Mr. Martin Dalsing  
Official Representative and Consultant  
for Lamda Polytech Limited  
MedVice Consulting, Inc.  
623 Glacier Drive  
Grand Junction, Co 81503

Re: K991015

Trade Name: LM-70 (lidofilcon A) Spherical and Toric Soft Contact Lens for Daily Wear  
(clear, lathe-cut)

Regulatory Class: II

Product Code: 86 LPL

Dated: October 5, 1999

Received: October 8, 1999

Dear Mr. Dalsing:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is 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 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 (Pre-market Approval), 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 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 device in the Federal Register. Please note: this response to your premarket notification submission does not affect

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This letter will allow you to begin marketing your device as described in your 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 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 device, 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**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Signature]*  
(Division Sign-Off)  
Division of Ophthalmic Devices  
510(k) Number K991015

Prescription Use   
(Per 21 CFR 801.109)

or

Over-The-Counter Use

(Optional Format 1-2-96)