OCT 11 2002

K021752

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
FP(hexafocon A) RGP Contact Lens Spherical
ASP(hexafocon A) RGP Contact Lens Aspherical

Applicant information

Date Prepared:	May 20 , 2002
Name:	Lucid Korea Co.,Ltd
Address:	#748 Keochon-ri Ponghwa-eup, Ponghwa-kun, Kyungsangbuk-Province, Korea
Contact Person:	Dong Kun Lee Technical Manager
E-mail Address:	josephDKL@hanmail.net
Phone Number:	82-54-673-8326
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Device Information

Regulatory Classification:	Class II
Product Code:	HQD
Classification Name:	Rigid gas permeable contact lens
Trade Name:	FP(hexafocon A) RGP Contact Lens Spherical ASP(hexafocon A) RGP Contact Lens Aspherical

Equivalent Devices:

The FP(hexafocon A) RGP Contact Lens Spherical, ASP(hexafocon A) RGP Contact Lens Aspherical are substantially equivalent to the currently marketed BOSTON XO(hexafocon A) Rigid Gas Permeable Contact Lens, which was cleared 510(k) Premarket Notification No. K000795 and PVS BASICS (paflufocon E) rigid gas permeable contact lenses, which was cleared 510(k) Premarket Notification No. K984436

Device Description

FP(hexafocon A) RGP Contact Lens Spherical and ASP(hexafocon A) RGP Contact Lens Aspherical are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not aphakic persons with nondiseased eyes. The lens may be disinfected using a chemical(not heat) disinfecting system only.

The FP(hexafocon A) RGP Contact Lens Spherical and ASP(hexafocon A) RGP Contact Lens Aspherical are is hemispherical shell of the following dimentions.

- Diameter: 8.00 to 10.00mm
- Center Thickness: 0.10 to 0.50mm
- Base Curve: 6.00 to 9.00mm
- Power: -20.0 to +20.0 diopter

The physical properties of the lens are

- Specific Gravity 1.27
- Refractive Index 1.415
- Light Transmittance 92%
- Surface Character Hydrophobic
- Wetting Angle 49°
- Water Content <1%
- Hardness(shore D) 81
- Oxygen Permeability 140*(100**) $\{\times 10^{-11}(cm^3O_2 \cdot cm)/(cm^2 \cdot sec \cdot mmHg)@35℃\}$

* gas to gas method

**polarographic method(ISO/Fatt)

Intended Use

FP(hexafocon A) RGP Contact Lens Spherical and ASP(hexafocon A) RGP Contact Lens Aspherical are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not aphakic persons with nondiseased eyes. The lens may be disinfected using a chemical(not heat) disinfecting system only.

Substantial Equivalence:

The following matrix illustrates that the production method, lens function and material of FP(hexafocon A) RGP Contact Lens Spherical, ASP(hexafocon A) RGP Contact Lens Aspherical are substantially equivalent to the predicated device. In addition, the water content, refractive index, specific gravity, wetting angle and light transmission are as well substantial equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2002

Lucid Korea CO., Ltd.
c/o Dong Kun Lee
748 Keochon-ri Ponghwa-eup
Ponghwa-kun
Kyungsangbuk-Province
Republic of Korea

Re: K021752
Trade Name: FP (hexafocon A) RGP Contact Lens Spherical and ASP (hexafocon A) RGP Contact Lens Aspherical
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Permeable Contact Lens
Regulatory Class: Class II
Product Code: HQD
Dated: August 22, 2002
Received: August 27, 2002

Dear Mr. Lee:

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

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

Indications Statement

510(k) Number (if known):

K021752

Device Name:

FP(hexafocon A) RGP Contact Lens Spherical
ASP(hexafocon A) RGP Contact Lens Aspherical

Indications for Use:

FP(hexafocon A) and ASP(hexafocon A) RGP Contact Lens are indicated for daily wear for the correction of refractive amptropia (myopia, hyperopia, astigmatism) in aphakic and not- aphakic persons with nondiseased eyes. The lens may be disinfected using a chemical disinfecting system only.

(PLEASE DO NOT 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)

Linda Lee Cohen M.D

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

510(k) Number 021752