MAY 3 1 2005

510(K) SUMMARY

LCG System

510(k) Number K 050856

Applicant's Name:

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Contact Person:

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Date Prepared:
March 2005

Trade Name:
The LCG (Liquid Crystal Glasses) System

Classification Name:	Shield, eye, ophthalmic
Medical Specialty:	Ophthalmic
Product Code:	HOY
Device Class:	I (Exempt)
Regulation Number:	886.4750

Panel: Ophthalmic

And:

Classification Name:	Prescription Spectacle Lens;
Medical Specialty:	Ophthalmic
Product Code:	NJH/ HQG
Device Class:	I (Exempt)
Regulation Number:	886.5844

Panel: Ophthalmic

Predicate Devices:

OphthoCare Ltd. believes that the LCG System is substantially equivalent to the combination of the following predicate devices:

- Eye Patches (Product Code: HOY, Regulation Number 886.4750: Ophthalmic eye shield, Class I Exempt, for example: Strabismoscope Undirectional Occluder, Welch Allyn, Inc.; Coverlet Eye Occlusion, Beiersdorf, Inc.

- Spectacle frame (Product Code HQZ, Regulation Number 886.5842)

- Prescription (non-custom) spectacle lens (Product Code: HQG, Regulation Number 886.5844)

- Sunglasses (nonprescription) (Product Code: HQY, Regulation Number 886.5850)

Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act. However, the LCG System complies with the following voluntary standards:

- IEC 60601-1 (1988) + A1 (1991) + A2 (1995)
- IEC/EN 60601-1-2 (2001)
- IEC 60601-1-4 (1996) + A1 (1999)
- EN 1441 (1997)
- ISO 14971 (2000)

Intended Use / Indication for Use:

The LCG (Liquid Crystal Glasses) System is an electronic shutter module intended to provide occlusions of the eye in an intermittent fashion.

Device Description:

The LCG System comprises the following main components:

- **The Spectacles Unit (LCGU)**

The Spectacles Unit (LCGU) comprised of the refractive optical lens, Liquid Crystal Module (LCM) and the electronic control that resides in the holding strap.
The adjustable holding strap contains an electronic controller with an activation button (Tact Switch) and small rechargeable batteries that provide the electric power.

- **The Reporting and Compliance Box (RCB)**

The Reporting and Compliance Box (RCB) is a bedside device that serves as a charger of the spectacle's batteries. In addition, it provides a means to monitor the compliance of the patient, while providing a feedback to the user, as it records the actual wear-time of the glasses, comparing it to the prescribed time.

- **Technician/Factory Setup Software (LCG Set)**

The set up software (LCG Set) is software residing on a PC at the factory and is used for setting the LCGU performance parameters. During setup, the LCGU is connected to the PC via the RCB by means of RS232 link.

Substantial Equivalence:

For the proposed intended use claim of the LCG System, namely, to provide intermittent occlusions of the sound eye, OphthoCare Ltd. is relying on the Eye Patching method, which is customarily used as a means of an eye occluder, to cover the sound eye during amblyopic treatment.

In addition, the LCG spectacle lens and frame are intended for the same purpose as described for the class I spectacle lens and spectacle frame (regulations 886.5844 and 886.5842, respectively).

The LCG System is an evolution of a well-established method to occlude the eye by means of eye occluder; the classical eye patching.

Both methods provide a mean of occlusion for the eye, while only the technique to induce this occlusion is different.

A comprehensive testing program was developed and performed in order to verify that the LCG System does not raise any new safety and effectiveness issues in comparison to its predicate devices. This includes the following testing and activities:

- Electrical safety and electromagnetic compatibility testing according to IEC 60601-1 (and amendments), and IEC 60601-1-2 standards
- Software verification and validation testing
- A set of *in vitro* (bench) performance testing
- Hazard analysis including risk level and solutions performed in compliance with EN 1441 (1997) and AAMI/ISO 14971-1, 2000 for the entire system and for the software

Tests results demonstrate the safe and effective performance of the LCG System according to its specifications.

In conclusion, based on the safety and performance testing results, including software verification and validation process and the analysis of similarities and differences as compared to its predicate devices, OphtoCare Ltd. believes that the LCG System is substantially equivalent to its predicate devices, without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 1 2005

OphthoCare Ltd.
c/o Dorit Winitz, Ph.D.
Biomedical Strategy Ltd.
11 Menachem Begin Street
Ramat Gan 52521, Israel

Re: K050856
Trade/Device Name: LCG (Liquid Crystal Glasses) System
Regulation Number: 21 CFR 886.4750
Regulation: Ophthalmic Eye Shield
Regulatory Class: I
Product Code: HOY, HQG, HQY, HQZ
Dated: March 31, 2005
Received: April 5, 2005

Dear Dr. Winitz:

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) 827-8910. 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/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting 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

510(k) Number (if known): K050856

Device Name: LCG System

Indications for Use:

The LCG (Liquid Crystal Glasses) System is an electronic shutter module intended to provide occlusions of the eye in an intermittent fashion.

Prescription Use √ (Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use____ (Part 21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K050856