Attachment 18
510(k) Summary Statement for the
Coherent Popeye Ophthalmic Lasers

DEC - 9 1997

K973470

I. General Information

Submitter: Coherent Medical Group
3270 West Bayshore Road
Palo Alto, CA 94303

Contact Person: Karen L. Baker

Summary Preparation Date: September 10, 1997

II. Names

Device Names:

Coherent Popeye Ophthalmic Laser

Coherent Popeye Ophthalmic Laser in combination with the Coherent Ultima 2000 Argon Laser Photocoagulator

Coherent Popeye Ophthalmic Laser in combination with the Coherent Ultima 2000SE Argon Laser Photocoagulator

Primary Classification Name: Nd:YAG laser for posterior capsulotomy; and Ophthalmic laser

III. Predicate Devices

Coherent 7970 Nd:YAG Laser (P830054/S13, S14, S17-S19, S22);
Coherent 7901 Nd:YAG Laser (P830054/S13, S14, S17-S19, S22);
Nidek YC-1200 Ophthalmic YAG Laser (K893987; K901481);
Lasag Microruptor 2 Nd:YAG Ophthalmic (P840012, K885164);
Zeiss Visulas YAG II Laser (K926452);
Alcon 3000LE Nd:YAG Ophthalmic Laser System (K897099);
Coherent Novus 2000/ Nd:YAG Laser System (K893709, P830054/S22);
Ultima 2000 and 2000SE Argon Laser Photocoagulators (K913127);
Nidek Ophthalmic Models YC-1200/Photocoagulator Combination Ophthalmic Laser (K901481).

IV. Product Description

The Coherent Popeye Ophthalmic Laser is intended to be used to deliver Q-switched Nd:YAG laser energy for use in photodisruption of ocular tissue, including: discission of the posterior capsule of the eye (posterior capsulotomy) discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients. The Coherent Popeye Ophthalmic Laser when used in combination with a Coherent Ultima 2000 or Ultima 2000SE Argon Laser Photocoagulator is intended to be used to deliver argon laser energy for use in the treatment of ocular pathology.

The Coherent Popeye Ophthalmic Lasers are comprised of the following main components:

- a laser/optics module;
- a laser power supply/control console;
- a remote control unit;
- a covered footswitch;
- a laserized mirror.

V. Indications for Use

The Coherent Popeye Ophthalmic Lasers are indicated for use in the photodisruption of ocular tissue using laser energy emitted by a Nd:YAG laser. These indications include: discission of the posterior capsule of the eye (posterior capsulotomy) and; discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients. The Coherent Popeye Ophthalmic Laser when used in combination with the Coherent Ultima 2000 or Ultima 2000SE has the capability of delivering argon laser energy. The Coherent Ultima 2000 and Ultima 2000SE are indicated for use in the treatment of ocular pathology using blue-green and green argon laser energy.

VI. Rationale for Substantial Equivalence

The Coherent Popeye Ophthalmic Lasers share the same indications for use, similar design features (including control system, wavelengths, laser mode structure, laser active medium, cooling system, aiming beams, and controls and displays), functional features (including pulse energy, power, repetition rates, burst mode, pulse interval, spot sizes, laser energy delivery control (footswitch), and type of delivery systems) and therefore are substantially equivalent to, the predicate devices referenced in Section III.

VII. Safety and Effectiveness Information

System and software hazard analysis information and software verification and validation information was submitted in conjunction with this Premarket Notification submission. The determination of substantial equivalence was based

upon the comparison of the technical characteristics between the Coherent Popeye Ophthalmic Lasers and the predicate laser systems.

VIII. Conclusion

The Coherent Popeye Ophthalmic Lasers were found to be substantially equivalent to similar predicate laser devices. The Coherent Popeye Ophthalmic Lasers share the same indications for use, similar design features, and similar functional features as the predicate ophthalmic laser systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Karen Baker
Sr. Manager, Regulatory Affairs
Coherent Medical Group
3270 West Bayshore Road
P. O. Box 10122
Palo Alto, California 94303-0810

DEC - 9 1997

Re: K973470
Trade Name: Coherent Popeye Nd:YAG Ophthalmic Laser and Accessories
Coherent Popeye Nd:YAG Laser in Combination with an Ultima 2000 or 2000SE Argon Photocoagulator and Accessories
Regulatory Class: II
Product Code: GEX
Dated: September 10, 1997
Received: September 12, 1997

Dear Ms. Baker:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification

submissions does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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) 594-4595. Additionally, for questions on the promotion and advertising of your devices, 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,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2
Indications for Use Statement as Requested by FDA

510(K) Number (if Known): K973470

Device Name: **Coherent Popeye Nd:YAG Ophthalmic Laser**
Coherent Popeye Nd:YAG Laser in Combination with an Ultima 2000 or 2000SE Argon Photocoagulator

Indications for Use:

a. The **Coherent Popeye Ophthalmic Laser** is indicated for use in photodisruption of ocular tissue using laser energy emitted by a Nd:YAG laser. These indications include:

discission of the posterior capsule of the eye (posterior capsulotomy)
discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients

***** Indications for Use Continued on Next Page *****

(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 Dental, Infection Control,
and General Hospital Devices
510(k) Number K973470

Prescription Use: X OR Over-The-Counter Use:_____
(Per 21 CFR 801.109)

Optional Format 1-2-96

Attachment 2 - Continued
Indications for Use Statement as Requested by FDA

510(K) Number (if Known): _____

Device Name: **Coherent Popeye Nd:YAG Ophthalmic Laser**
Coherent Popeye Nd:YAG Laser in Combination with an Ultima 2000 or 2000SE Argon Photocoagulator

The **Coherent Popeye Ophthalmic Laser in Combination with the Ultima 2000 or Ultima 2000SE Argon Photocoagulator** is indicated for:

a. Popeye Nd:YAG 1064 nm wavelength - Indicated for use in photodisruption of ocular tissue using laser energy emitted by a Nd:YAG laser. These indications include:

- discission of the posterior capsule of the eye (posterior capsulotomy) and;
- discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients.

b. Ultima 2000/Ultima 2000SE - Indicated for use in the treatment of ocular pathology using blue-green and green argon laser energy. These indications include:

- photocoagulation of both anterior and posterior segments including:
  - iridotomy, iridectomy and trabeculoplasty in angle closure glaucoma and open angle glaucoma;
  - retinal photocoagulation, panretinal photocoagulation and intravitreal endophotocoagulation of vascular and structural abnormalities of the retina and choroid including;

    - diabetic retinopathy;
    - choroidal neovascularization;
    - branch retinal vein occlusion;
    - subretinal neovascularization in disciform macular degeneration.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973470

Attachment 2 - Continued

Indications for Use Statement as Requested by FDA

510(K) Number (if Known): _____

Device Name: **Coherent Popeye Nd:YAG Ophthalmic Laser**
Coherent Popeye Nd:YAG Laser in Combination with an Ultima 2000 or 2000SE Argon Photocoagulator

The **Coherent Popeye Ophthalmic Laser in Combination with the Ultima 2000 or Ultima 2000SE Argon Photocoagulator** (Indications continued)

Laser Indirect Ophthalmoscope

The Laser Indirect Ophthalmoscope is indicated for use in the following ophthalmic treatments:

- diabetic retinopathy (pan-retinal photocoagulation);
- retinopexy;
- segmental peripheral photocoagulation;
- segmental photocoagulation;
- cloudy vitreous cavities; and,
- pediatric retinal repairs (under general anesthesia)

Acculite Endoprobe

The Acculite Endoprobe is indicated for use in the following ophthalmic applications:

- photocoagulation of the anterior and posterior segment, including:

  - anterior segment treatment in the surgical management of glaucoma;
  - endophotocoagulation in vitreoretinal surgery - including panretinal photocoagulation, retinopexy, and treatment of neovascularization.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973470