MAY 13 1999

K991259

Attachment 13
Special 510(k) Summary Statement

I. General Information

Submitter: Coherent Medical Group
2400 Condensa Street
Santa Clara, California, U. S. A.
95051-0901

Contact Person: Kathy A. Maynor

Summary Preparation Date: April 9, 1999

II. Names

Device Names: Coherent Medical Group Delivery Devices for use with the Coherent Novus Verdi Frequency-Doubled Nd:YAG Photocoagulator

Primary Classification Name: Laser Powered Surgical Instrument and Delivery Device Accessories

III. Predicate Devices

- B. V. International Viridis/Evergreen 532 nm Surgical Laser (K960867);
- Coherent Medical Group Slit Lamp Adapter System (K913127);
- Coherent Medical Group Indirect Ophthalmoscope (K885196);
- Coherent Medical Group Endocoagulation Probe (K812219).

IV. Product Description

The devices that are subject to this Special 510(k) Premarket Notification are the Coherent Laser Indirect Ophthalmoscope, the Acculite Endokit/Endoprobe, the LaserLink HS and LaserLink Z Slip Lamp Laser Delivery Adapter and the Coherent Novus Verdi Frequency-Doubled Nd:YAG Ophthalmic Photocoagulator.

V. Indications For Use

The Intended Use for the Coherent Novus Verdi Frequency-Doubled Nd:YAG Photocoagulator is unchanged as indicated in the 510(k) Premarket Notification (K960867) for the Viridis Surgical Laser.

VI. Rational for Substantial Equivalence

The Coherent Medical Group Delivery Devices for use with the Coherent Novus Verdi Frequency-Doubled Nd:YAG Photocoagulator share the same indications for use, similar design features, functional features and are therefore substantially equivalent to the predicate Viridis Surgical Laser (K960867) and Coherent Medical Group predicate devices (K913127, K885196, K812219).

VII. Safety and Effectiveness Information

Safety and effectiveness information was provided to demonstrate that the Coherent Medical Group Delivery Devices for use with the Coherent Novus Verdi Frequency-Doubled Nd:YAG Photocoagulator are safe and effective for use in surgical procedures as indicated in K960867.

VIII. Conclusion

The Coherent Medical Group Delivery Devices for use with the Coherent Novus Verdi Frequency-Doubled Nd:YAG Photocoagulator were found to be substantially equivalent to similar currently marketed and predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 1999

Ms. Kathy A. Maynor
Vice President of Regulatory, Compliance and
Clinical Affairs
Coherent, Inc.
2400 Condensa Street
Santa Clara, California 95051

Re: K991258
Trade Name: Novus Verdi Delivery Systems
Regulatory Class: II
Product Code: GEX
Dated: April 9, 1999
Received: April 13, 1999

Dear Ms. Maynor:

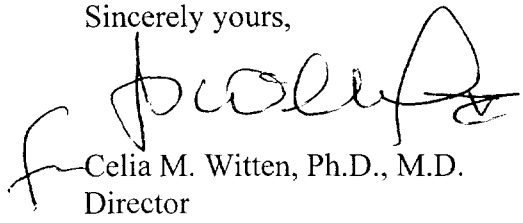
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Premarket 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 requirement, 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 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 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) 594-4595. 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,



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 11

Indications for Use Statement

510(K) Number: K991258

Device Name : Novus Verdi Delivery Systems

Indications for Use:

Clinical Indications with a Slit Lamp Delivery System
This system is indicated for use in retinal photocoagulation for the treatment of ophthalmic conditions including: Proliferative Diabetic retinopathy, macular degeneration, and retinal detachment.

Clinical Indications with a Laser Indirect Ophthalmoscope Delivery System
This system has the same clinical indications as the slit lamp delivery system, but it can only be used for peripheral photocoagulation.

Clinical Indications with an Endophotocoagulation (EPCP) Delivery System
The EPCP probe has been designed as a means for intraocular photocoagulation as an adjunct to vitrectomy surgery. Specific indications for use for the EPCP include treatment of complicated rhegmatogenous and tractional retinal detachments, proliferative vitreoretinopathy, proliferative diabetic retinopathy, and various retinal vascular tumors.

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 General Restorative Devices
510(k) Number K991258

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