MAY 20 1998

K980485

Attachment 10
510(k) Summary Statement for the
Modified Coherent VersaPulse Select Ho:YAG Single Wavelength and Ho:YAG/Nd:YAG Dual Wavelength Surgical Lasers

I. General Information

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

Contact Person: Anne C. Worden

Summary Preparation Date: February 20, 1998

II. Names

Device Names: Modified Coherent VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and Delivery Accessories.

Primary Classification Name: Laser Powered Surgical Instrument (and Accessories).

III. Predicate Devices

- Coherent VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers (K960413, K933318, K932981, K923575, K914991, K914136, K910037, K902990, and K895518)

IV. Product Description

The modified Coherent VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers are comprised of the following main components:

- a laser console
- a fiber port (for delivery systems)
- control and display panels
- footswitch and handswitch delivery controls
- a remote control unit
- a variety of delivery device systems and accessories

V. Indications for Use

The modified Coherent VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and the delivery systems and accessories that are used with them to deliver Ho:YAG and Ho:YAG/Nd:YAG laser energy are intended for use in surgical procedures involving open, laparoscopic and endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including:

- Ho:YAG - urology; urinary lithotripsy; arthroscopy; discectomy; endonasal surgery; gynecological surgery; and general surgery; and
- Nd:YAG - urology; general surgery; gastroenterology; thoracic and pulmonary surgery; ENT surgery; podiatry; orthopaedics; and with limited indications in gynecology; neurosurgery; ophthalmology; and lumbar discectomy.

The modified Coherent VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers (and the delivery accessories that are used with them to deliver laser energy) are indicated for use in endoscopic holmium laser resection of the prostate (HoLRP) for the treatment of benign prostatic hypertrophy (BPH).

VI. Rationale for Substantial Equivalence

The modified Coherent VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and their delivery device accessories share the same indications for use, similar design features (including control system, wavelengths, beam quality, laser configuration, active medium, cooling system, and controls and displays), functional features (including power, repetition rate, energy, spot sizes and treatment areas), and therefore are substantially equivalent to the Coherent VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers and their delivery device accessories (K960413, K933318, K932981, K923575, K914991, K914136, K910037, K902990, and K895518).

VII. Safety and Effectiveness Information

Clinical data was provided to demonstrate that the Coherent VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers are safe and effective, when indicated for use in endoscopic holmium laser resection of the prostate (HoLRP) for the treatment of benign prostatic hypertrophy (BPH) in the medical specialty of urology.

VIII. Conclusion

The modified Coherent VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers were found to be substantially equivalent to the currently marketed and predicate VersaPulse Select surgical lasers. The modified Coherent VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers share the same indications for use, design features, and similar functional features as, and thus are substantially equivalent to the currently marketed Coherent VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers.

Clinical study results demonstrated that the modified and predicate Coherent VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers are safe and effective for use in endoscopic holmium laser resection of the prostate (HoLRP) for the treatment of benign prostatic hypertrophy (BPH) in the medical specialty of urology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 1998

Ms. Anne C. Worden
Sr. Manager, Regulatory Affairs
Coherent® Medical Group
3270 West Bayshore Road
Post Office Box 10122
Palo Alto, California 94303-0810

Re: K980685
Trade Name: Modified Versapulse Select Ho:YAG/ND:YAG Lasers
Regulatory Class: II
Product Code: GEX
Dated: February 20, 1998
Received: February 23, 1998

Dear Ms. Worden:

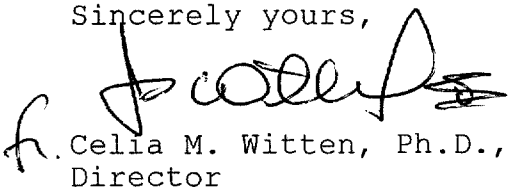
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 2
Indications For Use Statement as Requested by FDA

510(k) Number (if Known): K980685

Device Name : Modified Coherent VersaPulse Select Single Wavelength Ho:YAG & Dual Wavelength Ho:YAG/Nd:YAG Surgical Lasers & Delivery Devices

Indications For Use:

The modified and the currently marketed Coherent VersaPulse Select Single Wavelength (Ho:YAG) and Dual Wavelength (Ho:YAG/Nd:YAG) Surgical Lasers are intended for use in endoscopic holmium laser resection of the prostate (HoLRP) for treatment of benign prostatic hypertrophy (BPH).

(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 K980685

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

(Optional Format 1-2-96)