K972347

SEP 19 1997

Attachment 12
510(k) Summary Statement for the
Coherent VersaPulse Aesthetic 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: June 20, 1997

II. Names

Device Names: Modified Coherent VersaPulse Aesthetic Surgical Lasers and Delivery Accessories.

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

III. Predicate Devices

- Coherent VersaPulse Aesthetic Surgical Lasers and Delivery Accessories (K960032)
- Candela ALEXLAZR (TL-1) Alexandrite Laser (K944090)
- Continuum Biomedical Medlite/Erbium 2.94 Surgical Laser (K961748)

IV. Product Description

The Coherent VersaPulse Aesthetic Surgical Lasers (and its delivery accessories) are intended to be used to deliver: frequency doubled, Q-switched frequency doubled, and Q-switched Nd:YAG; Q-switched Alexandrite:YAG laser energy for use in surgical applications requiring the photothermolysis (photocoagulation) of soft tissue; and Er:YAG laser energy for use in surgical applications requiring the excision, incision, ablation, vaporization, and coagulation of soft tissue in medical specialties including: general and plastic surgery; and dermatology.
Coherent VersaPulse Aesthetic Surgical Lasers are comprised of the following main components:

- a laser console and tower;
- a counterbalanced articulated arm and delivery systems;
- a fiber port and delivery systems;
- control and display panels;
- footswitch and handswitch delivery controls;
- a remote control unit; and
- a variety of delivery device accessories (articulated arm and fiber handpieces, scanners, and epidermal cooling devices).

V. Indications for Use

The Coherent VersaPulse Aesthetic Surgical Lasers and the Delivery Accessories that are used with them to deliver 532 nm, 1064 nm and 755 nm laser energy that are indicated for use in surgical applications requiring photothermolysis of soft tissue, and 2940 nm laser energy that is indicted for use in surgical applications requiring excision, incision, ablation, vaporization, and coagulation of soft tissue in medical specialties including: general and plastic surgery; and dermatology.

VI. Rationale for Substantial Equivalence

The Coherent VersaPulse Aesthetic Surgical Lasers and their delivery device accessories share the same indications for use, similar design features (including control system, wavelengths, beam quality, laser tube 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 Aesthetic Surgical Lasers and their delivery device accessories (K960032), the Candela ALEXLAZR (TL-1) Alexandrite Surgical Lasers (K944090), and the Continuum Biomedical Medlite/Erbium 2.94 Surgical Laser (K961748).

VII. Safety and Effectiveness Information

No performance data 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 modified Coherent VersaPulse Aesthetic Surgical Lasers and the predicate laser systems and accessories.

VIII. Conclusion

The modified Coherent VersaPulse Aesthetic Surgical Lasers were found to be substantially equivalent to similar currently marketed surgical laser devices. The modified Coherent VersaPulse Aesthetic Surgical Lasers share the same indications for use, similar design features, and similar functional features as the currently marketed surgical lasers and delivery devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 1997

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

Re: K972347
Trade Name: Modified Coherent VersaPulse Aesthetic Surgical Laser Systems and Compatible Delivery System Accessories
Regulatory Class: II
Product Code: GEX
Dated: June 20, 1997
Received: June 24, 1997

Dear Ms. Worden:

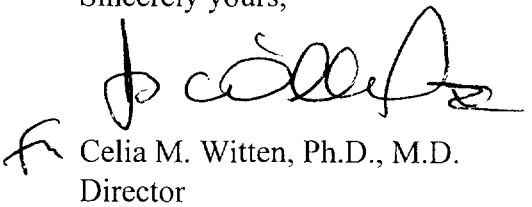
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date 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. Failure to comply with the GMP regulation may result in regulatory action. 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,



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): K972347

Device Name : Modified Coherent VersaPulse Aesthetic Surgical Laser Systems and Compatible Delivery System Accessories

Indications For Use:

The modified Coherent VersaPulse Aesthetic Surgical Lasers (and the delivery accessories that are used with them to deliver laser energy) are indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and photothermolysis (photocoagulation, or coagulation) of soft tissue in medical specialties including: dermatology; plastic surgery; and general surgery as follows:

a. Laser Wavelengths

532 nm: Non-Q-switched pulsed and Q-Switched modes - Indicated for the removal of light colored tattoos (yellow, green, red), treatment of cutaneous lesions including colored vascular lesions (i.e., port wine hemangiomas/ stains - PWS), pigmented lesions and other cutaneous lesions - these indications include:

The treatment (hemostasis, color lightening, blanching, flattening and reduction of lesion size) of the following general categories of lesions:

- Vascular lesions
  - angiomas
  - hemangiomas (port wine h., cavernous h., cherry h., spider h.)
  - telangiectasia

*** 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 General Restorative Devices
510(k) Number K972347

Prescription Use ✓ 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): K972347

Device Name : Modified Coherent VersaPulse Aesthetic Surgical Laser Systems and Compatible Delivery System Accessories

Indications For Use:

a. Laser Wavelengths - Continued from previous page

532 nm - Continued:

- Benign pigmented lesions
  - nevi
  - lentigines (senile and solar)
  - chloasma
  - cafe-au-lait (macules)
  - tattoos
- Other pigmented cutaneous lesions
  - verrucae
  - skin tags
  - keratoses
  - plaques;

1064 nm: Indicated for the removal of dark colored tatoos (blue-black tatoos), the treatment of cutaneous lesions, including colored vascular lesions (port wine hemangiomas/stains - PWS), and the treatment of pigmented lesions;

755 nm: Indicated for the treatment of pigmented lesions (e.g., epidermal and dermal lesions, including Nevus of Ota/Ito) and of multicolored tattoos, such as black, blue, green and other colors;

2940 nm: Indicated for use in surgical applications requiring excision, incision, ablation, vaporization and coagulation of soft tissue using laser energy emitted by Er:YAG in general and plastic surgery and dermatology.

b. Epidermal Chiller Tip Accessory (Only for Use with 532 nm Wavelength)

The Epidermal Chiller Tip accessory, is intended for use only with the 532 nm wavelength, for use in cooling or chilling the epidermis of the treatment site both prior to and during laser treatment to minimize thermal injury to nonvascular structures during laser treatment of telangiectases and other vascular lesions (i.e., port wine stains), to protect the epidermis from thermal necrosis (thus reducing possible complications such as scabbing, scarring, and/or hyperpigmentation), and to minimize the discomfort or degree of pain experienced by the patient during laser treatment due to partial anesthesia from cooling, in dermatology and plastic surgery.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972347