K974789

MAR - 9 1998

Attachment 14
510(k) Summary Statement for the
Coherent ULTRAPULSE S Series Carbon Dioxide Surgical Lasers

I. General Information

Submitter:	Coherent Medical Group 3270 West Bayshore Road Palo Alto, CA 94303
Contact Person:	Michelle P. Deeton
Summary Preparation Date:	December 17, 1997

II. Names

Device Names:	Coherent ULTRAPULSE S Series Carbon Dioxide Surgical Lasers and Delivery Accessories
Primary Classification Name:	Laser Powered Surgical Instrument (and Accessories)

III. Predicate Devices

- Coherent ULTRAPULSE Carbon Dioxide Surgical Lasers and Delivery Accessories (K963339, K951812 & K912029) marketed by Coherent Medical Group;
- Coherent Family of Scanner Handpieces for use with Coherent ULTRAPULSE Carbon Dioxide Surgical Lasers (K963339, K951812 and K946304) marketed by Coherent Medical Group.

IV. Product Description

The Coherent ULTRAPULSE S Series Carbon Dioxide Surgical Lasers (and their delivery accessories) are intended to be used to deliver carbon dioxide light energy for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in a variety of medical specialties.

Coherent ULTRAPULSE S Series Carbon Dioxide Surgical Lasers are comprised of the following main components:

- a laser console
- a console articulated arm mount
- a counterbalanced articulated arm
- control and display panels
- system microprocessor control electronics and operating software
- a covered footswitch or handswitch for specific delivery device accessories
- a filtered air pump purge system with an insufflator filter for purge of delivery device accessories
- a variety of delivery device accessories or handpieces.

V. Indications for Use

Coherent ULTRAPULSE S Series Carbon Dioxide Surgical Lasers (and their delivery accessories) are used to deliver light energy and are indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: dermatology; plastic surgery; podiatry; neurosurgery; gynecology; otorhinolaryngology (ENT); arthroscopy (knee surgery); and open and endoscopic general surgery.

In addition, Coherent ULTRAPULSE S Series Carbon Dioxide Surgical Lasers are safe and effective when indicated for use in specific surgical applications in medical specialties including: dermatology; plastic surgery; podiatry; neurosurgery; gynecology; otorhinolaryngology (ENT); arthroscopy (knee surgery); and open and endoscopic general surgery.

VI. Rationale for Substantial Equivalence

Coherent ULTRAPULSE S Series Carbon Dioxide Surgical Lasers (and their delivery accessories) share the same indications for use, similar design features, functional features, and therefore is substantially equivalent to the Coherent ULTRAPULSE Carbon Dioxide Surgical Lasers (K963339, K951812 and K912029) and the Coherent Family of Scanner Handpieces (K963339, K951812 and K946304).

VII. Safety and Effectiveness Information

Safety and effectiveness information was provided to demonstrate that the Coherent ULTRAPULSE S Series Carbon Dioxide Surgical Lasers are safe and effective, when indicated for use for general and specific applications in the medical specialties of dermatology; plastic surgery; podiatry; neurosurgery; gynecology; otorhinolaryngology (ENT); and open and endoscopic general surgery.

VIII. Conclusion

Coherent ULTRAPULSE S Series Carbon Dioxide Surgical Lasers were found to be substantially equivalent to similar currently marketed and predicate surgical laser devices. Coherent ULTRAPULSE S Series Carbon Dioxide Surgical Lasers share the same indications for use, similar design features, and similar functional features as the currently marketed Coherent ULTRAPULSE Carbon Dioxide Surgical Lasers and delivery devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 9 1998

Ms. Michelle P. Deeton
Regulatory Affairs Associate
Coherent® Medical Group
3270 West Bayshore Road
Palo Alto, California 94303

Re: K974789
Trade Name: Coherent ULTRAPULSE S Series Carbon Dioxide Surgical Lasers and Delivery Accessories
Regulatory Class: II
Product Code: GEX
Dated: December 17, 1997
Received: December 22, 1997

Dear Ms. Deeton:

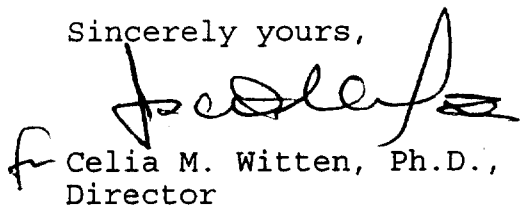
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined these devices are substantially equivalent (for the indications for use stated in the enclosures) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date 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 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 devices 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices 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

Enclosures

Attachment 2
Indications For Use Statement as Requested by FDA

510(k) Number (if Known): K974789

Device Name : **Coherent ULTRAPULSE S Series CO_2 Surgical Lasers and Delivery Devices**

Indications For Use:

Coherent ULTRAPULSE S Series Carbon Dioxide 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 coagulation of soft tissue in medical specialties including: dermatology, plastic surgery, podiatry, neurosurgery, gynecology, otorhinolaryngology (ENT), arthroscopy (knee), and open and endoscopic general surgery.

Coherent ULTRAPULSE S Series Carbon Dioxide Surgical Lasers are indicated for use in the performance of specific surgical applications in dermatology, plastic surgery, podiatry, neurosurgery, gynecology, otorhinolaryngology (ENT), and open and endoscopic general surgery as follows:

Dermatology & Plastic Surgery

- The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of:
  - Laser skin resurfacing
  - Laser derm-abrasion
  - Laser burn debridement.

*** Indications For Use Continued on Next Page (3 pages total) ***

(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 K974789

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____
(Optional Format 1-2-96)

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

510(k) Number (if Known):_____

Device Name : Coherent ULTRAPULSE S Series CO_2 Surgical Lasers and Delivery Devices

Indications For Use:

Continued from previous page:

Dermatology & Plastic Surgery - Continued

- Laser skin resurfacing (ablation and/or vaporization) in dermatology and plastic surgery for the treatment of wrinkles, rhytids and furrows.

  Clinical study demonstrated that skin resurfacing of wrinkles, rhytids, and furrows with the ULTRAPULSE CO_2 surgical laser increases the amount of sub-epidermal collagen.

- Laser skin resurfacing (ablation and/or vaporization) of soft tissue in dermatology and plastic surgery for the reduction, removal, and/or treatment of:
  - actinic keratosis
  - solar/actinic elastosis
  - actinic cheilitis
  - lentigines
  - uneven pigmentation/dyschromia
  - acne scars
  - surgical scars
  - keloids
  - hemangiomas (including buccal hemangiomas)
  - tattoos
  - telangiectasia
  - squamous cell carcinoma
  - epidermal nevi
  - xanthelasma palpebrarum
  - syringoma
  - verrucae vulgares (warts).

Dermatology, Plastic Surgery & General Surgery

- Laser incision and/or excision of soft tissue in dermatology, plastic and general surgery for the performance of blepharoplasty.

- Laser incision and/or excision of soft tissue in dermatology, plastic and general surgery for the creation of recipient sites for hair transplantation.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974789

*** Indications For Use Continued on Next Page (page 2 of 3) ***

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

510(k) Number (if Known):_____

Device Name :__Coherent ULTRAPULSE S Series CO_2 Surgical Lasers and Delivery Devices

Indications For Use:

Continued from previous page:

Podiatry

- Laser ablation, vaporization, and/or excision of soft tissue in podiatry for the reduction, removal, and/or treatment of:
  - verrucae vulgares (warts)
- Laser ablation, vaporization, and/or excision in podiatry for matrixectomy.

Otorhinolaryngology (ENT)

- Laser incision, excision, ablation and/or vaporization of soft tissue in otorhinolaryngology for the treatment of:
  - choanal atresia
  - leukoplakia of larynx
  - nasal obstruction
  - adult and juvenile papillomatosis polyps
  - rhinophyma
  - verrucae vulgares (warts)

Gynecology

- Laser incision, excision, ablation and/or vaporization of soft tissue in gynecology for the treatment of:
  - cervical intraepithelial neoplasia
  - condyloma acuminata
  - leukoplakia (vulvar dystrophies)
  - vulvar and vaginal intraepithelial neoplasia

Neurosurgery

- Laser incision, excision, ablation and/or vaporization of soft tissue in neurosurgery for the treatment of:
  - basal tumor-meningioma
  - posterior fossa tumors
  - peripheral neurectomy
  - lipomas/large tumors

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974789

Prescription Use X
(Per 21 CFR 801.109)