SEP 8 1999

K992472

FDA Premarket Notification [510(k)] Summary

Preparation Date: 21 July 1999

Contact: Gerald S. Palecki, Director, Quality and Regulatory

Device Name: Proprietary: *SureGuide* CO_2 Laser Beam Delivery System

Common: CO_2 Laser Waveguide

Predicate Devices: CO_2 Laser Waveguide, reference K943543 & K960475.

Device Description:

The *SureGuide* CO_2 Laser Beam Delivery System is an accessory for CO_2 laser systems. Its two primary components are a laser system interface adapter and a fiber cable assembly consisting of a hollow silica fiber having an internal coating that reflects and propagates CO_2 laser energy and a flexible protective outer cover.

The SureGuide CO_2 Fiber Cable has FSMA 905 series fiber optic connectors on each end and may be used with CO_2 laser systems that provide such connectors between the laser system and various beam delivery accessories.

Intended Use:

The *SureGuide* is intended for use with CO_2 laser systems for general and plastic surgery procedures, neurosurgery, ophthalmology, oral surgery, oto-rhino-laryngology, podiatry, gynecology, and urology procedures for incision, excision, vaporization, ablation, coagulation, and cauterization of soft tissue.
Refer to the laser system Directions for Use manual for specific indications for Use.

Technological Characteristics Compared to Predicate Devices:

The *SureGuide* CO_2 Laser Beam Delivery System has the same technological characteristics and materials as the Medical Optics, Inc. flexible fiber cable assembly and it is functionally equivalent to the Luxar fiber assembly. Clinicon Corportation purchased the products of Medical Optics, Inc. and holds a license from Rutgers University to manufacture the SureGuide flexible cable assembly.

The laser adapter design is derived from the Medical Optics laser system flexible cable assembly interface adapter and has a section designed to fit the Luxar LX-20 mast interface. Beam alignment and focus optics are built into the interface adapter to allow correction of inherent beam alignment variations between laser systems and provides optimization of laser beam coupling into the *SureGuide*.

Non-Clinical Tests:

The *SureGuide* performance characteristics have been evaluated through testing and analysis of laser power loss and beam quality from the guide when the laser is energized, compared to similar devices cleared for marketing in the past. The performance of the *SureGuide* is comparable.

Conclusions Drawn from Tests and Analysis:

The predicted energy transmission levels and beam quality meet criteria established through evaluation of the *SureGuide* on various commercially available medical CO_2 laser systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 8 1999

Mr. Gerald S. Palecki
Director, Quality and Regulatory
Clinicon Inc.
5825 Avenida Encinas
Carlsbad, California 92008

Re: K992472
Trade Name: SUREGUIDE CO_2 Laser Beam Delivery System
Regulatory Class: II
Product Code: GEX
Dated: July 21, 1999
Received: July 26, 1999

Dear Mr. Palecki:

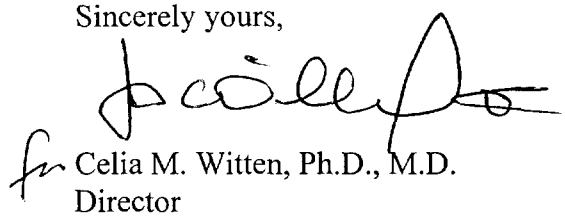
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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

510(k) Number: K992472

Device Name: *SureGuide* CO_2 Laser Beam Delivery System

Indications for Use:

The *SureGuide* CO_2 Laser Beam Delivery System is indicated for use in general and plastic surgery, neurosurgery, ophthalmology, oral surgery, oto-rhino-laryngology, podiatry, gynecology, and urology procedures for incision, excision, vaporization, ablation, coagulation, and cauterization of soft tissue.

The specific *SureGuide* CO_2 Laser Beam Delivery System indications are dependent upon the cleared indications for use of the laser system and laser system accessories to which it is attached.

(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 K992472

(Optional Format 3-10-98)

Prescription Use X
(Per 21 CFR 801.109)