FEB 4 2000

510(k) Summary

Surgical Lightstic™ 180

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR §807 for the Surgical Lightstic™ 180.

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Contact Person: same

Date Prepared: November 5, 1999

Name of Device and Name/Address of Sponsor

Surgical Lightstic™ 180
CardioFocus, Inc.
126B Mid-Tech Drive
West Yarmouth, MA 02673

Common or Usual Name

Laser Fiber

Classification Name

Surgical Laser Instrument Accessories

Predicate Devices

Rare Earth Medical Lightstic™ Model 180, Dornier's Lasertrode Fiber, Xintec's Polaris™ Diode Laser System and Accessories, and CeramOptec's Ceralas Diode Laser Systems.

Intended Use

The Surgical Lightstic™ 180 is intended to be used as a surgical instrument for coagulation of soft tissue in conjunction with or without endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, cystoscopes, gastroscopes, colonoscopes), and coagulation of soft tissue in the contact mode in both open or closed surgical procedures (with or without handpiece).

The Surgical Lightstic™ 180 is indicated for use in medicine and surgery with 980 - 1064 wavelength laser energy in the following surgical specialties: General Surgery, Plastic Surgery, and Dermatology.

Technological Characteristics and Substantial Equivalence

From a clinical perspective and comparing design specifications, the CardioFocus Surgical Lightstic™ 180 and the predicate device are substantially equivalent and have the same intended use.

CardioFocus, Inc. believes the minor differences of the CardioFocus Surgical Lightstic™ 180 and its predicate fiber laser accessories should not raise any concerns regarding the overall safety and effectiveness.

Performance Data

None required.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 4 2000

CardioFocus, Inc.
c/o Mr. William A. Knape
Clinical Pathways
987 University Avenue, Suite 14
Los Gatos, California 95032

Re: K993834
Trade Name: Surgical Lightstic™ Models 180L and 180C
Regulatory Class: II
Product Code: GEX
Dated: November 11, 1999
Received: November 12, 1999

Dear Mr. Knape:

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 Stephen Rhodes

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K993834

Device Name: Surgical Lightstic™ 180

Indications For Use: The Surgical Lightstic™ 180 is intended to be used as a surgical instrument for coagulation of soft tissue in conjunction with or without endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, cystoscopes, gastroscopes, colonoscopes), and coagulation of soft tissue in the contact mode in both open or closed surgical procedures (with or without handpiece).

The Surgical Lightstic™ 180 is indicated for use in medicine and surgery with 980 – 1064 nm wavelength laser energy in the following surgical specialties: General Surgery, Plastic Surgery, and Dermatology.

Note: These are additional indications to the already cleared indications for market release in K962068.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993834

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