JAN 23 2008

K073496

510(k) SUMMARY

Submitted by:

Cindy Foote
Regulatory Affairs Specialist
Cook Urological, Incorporated
1100 West Morgan Street
Spencer, IN 47460
November 20, 2007

Device:

Trade Name: OptiLite™ Holmium Laser Fibers

Proposed Classification Name: Laser Instrument, Surgical, Powered
21 CFR Part 878.4810
Class II, GEX

Predicate Devices:

The OptiLite™ Holmium Laser Fibers are similar with respect to indications for use and technology to existing predicate devices in commercial distribution. Specifically, the OptiLite™Holmium Laser Fibers are similar to the AccuFlex™ Holmium Laser Fibers (K994010) manufactured by InnovaQuartz, Incorporated, distributed by Boston Scientific Corporation. The OptiLite™Holmium Laser Fibers are identical to the OptiLITE™ IX Laser Surgery Accessories (K992866) manufactured by Convergent Laser Technologies and distributed by Cook Urological, Incorporated.

Device Description:

The OptiLite™ Holmium Laser Fibers are intended to be used with legally cleared laser systems to deliver laser energy. The fiber delivery system is typically used in conjunction with a rigid or flexible endoscope to access the surgical site. The laser fibers work on the principle of total internal reflection. Laser energy is focused into a glass silica fiber at the proximal end and traverses the length of the fiber by means of total reflection. The fiber is able to contain the laser beam and funnels the laser energy from the proximal end to the distal end.

Substantial Equivalence:

The Cook® Cervical Ripening Balloon is comparable with respect to intended use to the published predicate device description and meets the requirements for 510(k) substantial equivalence.

Test Data:

Biocompatibility, sterility and performance testing were performed in accordance to Food and Drug Administration guidance's and recognized international standards. Testing data and information is included in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 2008

Cook Urological, Inc.
% Ms. Cindy Foote
Regulatory Affairs Specialist
1100 W. Morgan Street
Spencer, Indiana 47460

Re: K073496
Trade/Device Name: OptiLite™ Holmium Laser Fibers
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: November 26, 2007
Received: December 12, 2007

Dear Ms. Foote:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): 073496

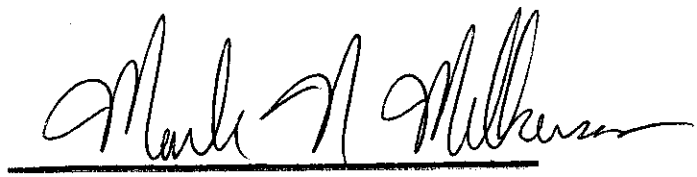
Device Name: OptiLite™ Holmium Laser Fibers

Indications for Use: Indicated for incision/excision, ablation, and coagulation (homeostasis) when attached to cleared laser systems such as KTP, Nd:YAG, Argon, Diode, Ho:YAG and ER:YAG wavelengths for the indications for which the lasers have been cleared.

Prescription Use?___X_____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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,
and Neurological Devices

510(k) Number K073496