DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 24, 2017

Cook Incorporated
Mr. Colin Jacob
Capital Equipment Specialist, Regulatory Affairs
750 Daniels Way, P.O. Box 489
Bloomington, Indiana 47402

Re: K163197
Trade/Device Name: Cook Holmium Laser Fiber
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: May 12, 2017
Received: May 12, 2017

Dear Mr. Jacob:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163197

Device Name
Cook Holmium Laser Fiber

Indications for Use *(Describe)*
Intended for stone fragmentation, incision, excision, ablation, coagulation (hemostasis) when attached to the H-30 Holmium Laser System or Odyssey Holmium Laser System for the indications for which the lasers have been cleared.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

Cook Holmium Laser Fiber (21 CFR §878.4810)
Date Prepared: May 19, 2017

Submitted By:

Applicant:	Cook Incorporated
Contact:	Colin Jacob
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 x 104965
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	Cook Holmium Laser Fiber
Common Name:	Laser Instrument, Surgical, Powered
Classification Name/Panel:	Powered Laser Surgical Instrument - General & Plastic Surgery
Regulation:	21 CFR §878.4810
Product Code:	GEX

Predicate Devices:

- Primary - Cook Holmium Laser Fiber (K124030, July 1, 2013)
- Secondary – Quanta System Surgical Laser Fibers (K131473, October 24, 2013)

Device Description:

The Cook Holmium Laser Fibers are supplied sterile in peel-open packages. The multi-use fibers have a color coded connector to identify the four different fiber sizes, and will be sold individually. The single-use fibers have a red connector and come in four different sizes, and will be sold in boxes of three.

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Indications for Use:

Intended for stone fragmentation, incision, excision, ablation, coagulation (hemostasis) when attached to the H-30 Holmium Laser System or Odyssey Holmium Laser System for the indications for which the lasers have been cleared.

Comparison to Predicates:

The proposed devices are identical to the predicate in terms of principles of operation, technological characteristics and duration of use.
Differences between the proposed device and the primary predicate are:

- Additional compatible laser system in indications for use
- Extended STERRAD® cycles for resterilization
- Additional indication for use for stone fragmentation - This indication for use for stone fragmentation has been cleared in the secondary predicate. This secondary predicate has similar technology to the proposed device.

Performance Data:
The device was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of:

- Laser System Compatibility Testing - Testing shows that the Cook Holmium Laser Fiber is compatible with the Cook Medical Odyssey Holmium Laser System.
- Steam Sterilization Validation - Testing shows that the fiber is compatible with recommended autoclave cycles for sterility and functionality.
- STERRAD® Sterilization Validation - Testing shows that the fiber is compatible with specified STERRAD® cycles for sterility and functionality.

Conclusion:

The results of these tests support a conclusion that the Cook Holmium Laser Fiber met the design input requirements based on the intended use and support a determination of substantial equivalence.