DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 18, 2015

Cook Incorporated
Mr. David E. Chadwick
750 Daniels Way
P.O. Box 489
Bloomington, Indiana 47402

Re: K133788
Trade/Device Name: Cook Holmium Laser Fiber
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Instrument, Surgical, Powered
Regulatory Class: Class II
Product Code: GEX
Dated: March 2, 2015
Received: March 3, 2015

Dear Mr. Chadwick:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 yours,

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)*
K133788

Device Name
Cook Holmium Laser Fiber

Indications for Use *(Describe)*

Used for incision/excision, ablation, and coagulation (hemostasis) when attached to a cleared Ho:YAG laser system comprised of any standard SMA-type connector and an output power of up to 100 watts, for the indications for which the system has 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.

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WWW.COOKMEDICAL.COM

5. 510(k) Summary

Cook Incorporated
Cook Holmium Laser Fiber
510(k) Summary
21 CFR 807.92

Date Prepared: 17 March 2015

Submitted By:

Applicant: Cook Incorporated
Address: 750 Daniels Way
P.O. Box 489
Bloomington, IN 47402

Phone Number: 1 (800) 468-1379
Fax Number: (812) 332-0281

Contact: David E. Chadwick
Contact Address: Cook Incorporated
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402

Contact Phone Number: 800-346-2686 or 812-339-2235
Contact Fax Number: 812-332-0281

Device Information:

Trade name: Cook Holmium Laser Fiber
Common name: Laser Instrument, Surgical, Powered
Classification: Class II
Regulation: 21 CFR §878.4810
Product Code: GEX

Predicate Device:

Cook Holmium Laser Fiber

K124030, July 1, 2013

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Indications for Use:

The Cook Holmium Laser Fiber is intended for incision/excision, ablation, and coagulation (hemostasis) when attached to a cleared Ho:YAG laser system comprised of any standard SMA-type connector and an output power of up to 100 Watts, for the indications for which the system has been cleared.

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 six sizes, and will be sold in boxes of three.

Comparison to Predicate Device:

The proposed devices are substantially equivalent to the predicate in terms of intended use, duration of use, principles of operation, and technological characteristics.

Discussion of Tests and Test Results:

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

1. Tensile Testing – Testing shows the tensile force during proper clinical use should not fracture the materials and/or bonds.
2. Bend Radius Testing – Testing shows that the fibers met the minimum bend radius requirements.
3. Energy Transmission Testing – Testing shows that fibers transmit laser energy with not more than 20% loss from laser output to fiber output.
4. Accelerated Aged Testing – Testing shows that devices accelerated-aged to the equivalent of three years meet performance requirements for tensile, bend radius, and energy transmission testing.
5. Biocompatibility Testing – Testing, in conformance with ISO 10993-1, shows the device is biocompatible.
6. Laser System Compatibility Testing – Testing shows that the Cook Holmium Laser Fiber is compatible with other cleared Ho:YAG laser systems.

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7. Steam Sterilization Validation – Testing shows that the Cook Holmium Laser Fiber is compatible with recommended autoclave cycles for sterility and functionality.

8. Sterrad Sterilization Validation – Testing shows that the fiber is compatible with recommended Sterrad cycles for sterility and functionality.

9. Cleaning Validation – Testing shows that the fiber is compatible with recommended cleaning procedures.

Conclusions Drawn from the Tests:

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its intended use.