October 26, 2017

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

Re: K172325
Trade/Device Name: Rhapsody H-30 Holmium Laser System
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: July 31, 2017
Received: August 1, 2017

Dear Colin 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 (DICE) 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 (DICE) 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 -S3

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)*
K172325

Device Name
Rhapsody H-30 Holmium Laser System

Indications for Use *(Describe)*
The Rhapsody H-30 Holmium Laser System is intended for incision, excision, resection, ablation, vaporization, coagulation, hemostasis of soft tissue, or stone fragmentation during open surgical, laparoscopic, percutaneous or endoscopic procedures in urologic, gynecologic, gastroenterological, or pulmonary applications.

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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510(k) Summary

Rhapsody H-30 Holmium Laser System
(21 CFR § 878.4810)
Date Prepared: October 26, 2017

Submitted By:

Applicant:	Cook Incorporated
Contact:	Colin S. Jacob
Applicant Address:	Cook Incorporated P.O. Box 489 750 Daniels Way Bloomington, IN 47402
Contact Phone Number:	(812) 335-3575 x 104965
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	Rhapsody H-30 Holmium Laser System
Common Name:	Powered Laser Surgical Instrument
Classification Name/Panel:	General & Plastic Surgery
Regulation:	21 CFR § 878.4810
Product Code:	GEX

Predicate Devices:

- H-30 Holmium Laser System (K130444)

Device Description:

The Rhapsody H-30 Holmium Laser System is an enclosed, transportable solid-state (i.e., Ho:YAG) laser source unit. The laser system unit produces a beam of coherent near-infrared light (2100 nm wavelength) upon activation by depressing a footswitch pedal. The beam is directed to the treatment zone by means of a compatible optical delivery system, such as a holmium laser fiber. Components of the unit include a footswitch pedal and rotatable control panel. The system is a reusable, non-sterile device and is supplied in a wooden shipping crate.

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Indications for Use:

The Rhapsody H-30 Holmium Laser System is intended for incision, excision, resection, ablation, vaporization, coagulation, hemostasis of soft tissue, or stone fragmentation during open surgical, laparoscopic, percutaneous or endoscopic procedures in urologic, gynecologic, gastroenterological, or pulmonary applications.

Comparison to Predicate Devices:

The Rhapsody H-30 Holmium Laser System and the predicate device, H-30 Holmium Laser System (K130444), are substantially equivalent in that these devices have the same intended use and principles of operation. The differences in technological characteristics (i.e., software and minor internal components) do not raise different questions of safety and/or effectiveness when comparing to the predicate device.

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Comparison to Predicate Device

	PRIMARY PREDICATE	SUBJECT DEVICE
	H-30 Holmium Laser System	**Rhapsody H-30 Holmium Laser System**
510(k)	K130444	Subject of submission
Manufacturer	Cook Incorporated	Cook Incorporated
Regulation	21 CFR § 878.4810 General & Plastic Surgery	IDENTICAL TO PREDICATE
Product Code	GEX	IDENTICAL TO PREDICATE
Classification	Powered Laser Surgical Instrument	IDENTICAL TO PREDICATE
Indications for Use	The H-30 Holmium Laser System is indicated for use in fragmentation of urinary calculi and soft tissue applications. The H-30 Holmium Laser System is indicated for use in urinary procedures where fragmentation of stones and soft tissue incision, hemostasis, vaporization, and ablation are indicated.	The Rhapsody H-30 Holmium Laser System is intended for incision, excision, resection, ablation, vaporization, coagulation, hemostasis of soft tissue, or stone fragmentation during open surgical, laparoscopic, percutaneous or endoscopic procedures in urologic, gynecologic, gastroenterological, or pulmonary applications.
Principles of Operation	Generates pulsed laser energy for delivery to the surgical site via silica core laser fibers	IDENTICAL TO PREDICATE
Fundamental Scientific Technology	Solid-state, holmium yttrium aluminum garnet (Ho:YAG), pulsed laser operating at 2100 nanometers	IDENTICAL TO PREDICATE

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Comparison to Predicate Devices (continued)

	PRIMARY PREDICATE	SUBJECT DEVICE
	H-30 Holmium Laser System	**Rhapsody H-30 Holmium Laser System**
Technological Characteristics		
Laser Wavelength	2100 nm	IDENTICAL TO PREDICATE
Maximum Output	30 W	IDENTICAL TO PREDICATE
Repetition Rate	5 to 20 Hz	IDENTICAL TO PREDICATE
Visible Aiming Beam	Variable Intensity <3 mW, 532 nm	IDENTICAL TO PREDICATE
Laser Activation	Foot switch	IDENTICAL TO PREDICATE
Minimum Energy	0.5 J at 5 Hz	IDENTICAL TO PREDICATE
Maximum Energy	3.5 J at 5 Hz	IDENTICAL TO PREDICATE
Electrical Pulse Width	Short: 350 to 800 µs Long: 800 to 1200 µs	IDENTICAL TO PREDICATE
Input Voltage	115 & 230 V (full power)	IDENTICAL TO PREDICATE
Fiber Communication	1) Detects a resistor embedded within the fiber to identify the size of the attached fiber and limit the laser energy to the fiber's maximum allowable power output. 2) Communicates with a printed circuit board (two-way communication) embedded within the laser fiber to display extra information onscreen, or recording use information for the laser system and the fiber such as power setting, number of pulses, and error codes.	IDENTICAL TO PREDICATE
Max Flash-lamp Voltage	700 V	IDENTICAL TO PREDICATE
Blast Shield	User accessible	IDENTICAL TO PREDICATE
Water Reservoir	Plastic	IDENTICAL TO PREDICATE
Filter	De-ionized cartridge & strainer	IDENTICAL TO PREDICATE
Enclosure	Metal with cabinet & flat top	IDENTICAL TO PREDICATE
Control Panel	Rotatable	IDENTICAL TO PREDICATE
Water Pump	Fixed	Fixed with slightly different orientation
Firmware	1.5 version	1.6 version
Fan Shrouds	None	Present
Ferrite	None	Present

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Performance Data:

The subject device, Rhapsody H-30 Holmium Laser System, was subjected to applicable testing to assure reliable design and performance under the testing parameters. The tests are listed below:

Table 2.0-2: Rhapsody H-30 Holmium Laser System Testing Summary

Test Report	Result
Test # RT20110616	Testing must demonstrate that LCK 1.6 firmware performs as intended. Test results met predetermined criteria.
H-30 Litho family: Software Verification and Validation	
Test # 28110456-001	Test article must demonstrate to comply with IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance. Test results met predetermined criteria.
IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	
Test # 031714_502_PR #95252	Test articles must demonstrate acceptable output energy within ± 10% of the factory setting and each system must fire for a minimum of 30 minutes at maximum output energy of 2.5J@ 12Hz on short pulse width. Test results met predetermined criteria.
Evaluation of Rhapsody H-30 – Addition of Fan Shroud, Optimization of Cooling Lines and Alignment Procedure	

Conclusion:

For these tests, all pre-determined acceptance criteria were met. The results of these tests show that the Rhapsody H-30 Holmium Laser System meets the design input requirements based on the intended use. Furthermore, these results support the conclusion that the differences between the subject device, Rhapsody H-30 Holmium Laser System, and the predicate device, H-30 Holmium Laser System, do not raise new questions of safety or effectiveness and support a determination of substantial equivalence.