K080525

APR 17 2008

## 510(k) SUMMARY

**Submitted by:**

Cindy Foote
Regulatory Affairs Specialist
Cook Urological, Incorporated
750 Daniels Way
P.O. Box 489
Bloomington, Indiana 47402-0489
February 15, 2007

**Device:**

Trade Name: Cook® Odyssey Holmium Laser System

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

**Predicate Devices:**

The Cook® Odyssey Holmium Laser System is similar with respect to indications for use and technology to existing predicate devices in commercial distribution. Specifically, the Cook® Odyssey Holmium Laser System is similar to the VersaPulse® Power Suite (K011703) manufactured by Lumenis, distributed by Boston Scientific Corporation and the Medilas H 20 (K061455) manufactured by Dornier Med Tech, distributed by Gyrus ACMI. The Cook® Odyssey Holmium Laser System is identical to the Odyssey™ 30 (K951910) manufactured and distributed by Convergent Laser Technologies and distributed by Cook Urological, Incorporated.

**Device Description:**

The Cook® Odyssey Holmium Laser System is used in fragmentation of urinary calculi and soft tissue applications. The Cook® Odyssey Holmium Laser System is a pulsed holmium YAG laser emitting laser radiation at 2100 nanometer and a 30 Watt maximum average power. The holmium wavelength is highly absorbed by water for tissue ablation with minimal lateral thermal damage. In the case of laser lithotripsy, laser energy vaporizes water in the calculus causing it to crumble into small enough particles to pass easily through the urinary tract. The Cook® Odyssey Holmium Laser System is a completely enclosed transportable unit.

**Substantial Equivalence:**

The Cook® Odyssey Holmium Laser System is comparable with respect to intended use to the published predicate device description and meets the requirements for 510(k) substantial equivalence.

**Test Data:**

Applicable testing was performed in accordance with United States Food and Drug Administration recommendations and recognized national and international standards. Testing data and information is included in this submission. All testing results were acceptable.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2008

Cook Urological, Inc.
% Ms. Cindy Foote
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47404

Re: K080525
Trade/Device Name: Cook® Odyssey 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: II
Product Code: GEX
Dated: April 1, 2008
Received: April 2, 2008

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): K080525

Device Name: Cook® Odyssey Holmium Laser System

Indications for Use: Indicated for use in fragmentation of urinary calculi and soft tissue applications. The Cook® Odyssey Holmium Laser System is indicated for use in Urinary, Gastroenterology, Pulmonary, Gynecology, and General Surgery procedures where fragmentation of stones and soft tissue incision, hemostasis, vaporization and ablation are indicated.

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)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K080525