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510(k) Summary

NOV 13 2008

Percutaneous Systems, Inc.'s Coaxial Accordion Stone Management Device

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Percutaneous Systems, Inc.
3260 Hillview Avenue Suite 100
Palo Alto, CA 94304

Phone: (650) 493 - 4200
Facsimile: (650) 493 - 4201

Contact Person: Thomas Lawson

Date Prepared: September 16, 2008

Common or Usual Name

Urology Retrieval Device

Classification Name

G-U Devices

Predicate Devices

Accordion Urological Occluding Guidewire, Percutaneous Systems, Inc.
Open-end Ureteral Catheter, Cook Urologic.

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Intended Use

The Coaxial Accordion Stone Management Device Urological is intended to be used endoscopically to entrap and remove calculi and other foreign objects from the urinary tract and facilitate drainage and retrograde pyelogram.

Technological Characteristics

The Coaxial Accordion Stone Management Device consists of a film membrane attached onto a cannula with a removable handle.

Performance Data

Not required.

Substantial Equivalence

The Coaxial Accordion Stone Management Device has the same intended use, indications for use, and principles of and very similar technological characteristics as the predicate devices. Thus, the Coaxial Accordion device is substantially equivalent to the cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2008

Thomas Lawson, Ph.D.
Vice President, Clinical & Regulatory Affairs
Percutaneous Systems, Inc.
3260 Hillview Avenue, Suite 100
PALO ALTO CA 94304

Re: K082803
Trade/Device Name: Coaxial Accordion Stone Management Device
Regulation Number: 21 CFR 876.4680
Regulation Name: Ureteral Stone Dislodger
Regulatory Class: II
Product Code: FFL
Dated: September 18, 2008
Received: September 24, 2008

Dear Dr. Lawson:

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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 Biometrics' (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,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082803

Device Name: Coaxial Accordion Stone Management Device

Indications for Use:

The Coaxial Accordion Stone Management Device is intended to be used endoscopically to entrap and remove calculi and other foreign objects from the urinary tract and facilitate drainage and retrograde pyelogram.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K082803