

510(k) Summary

MAY 16 2011

Advertising Language for the Accordion Stone Management Device

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

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Date Prepared: February 1, 2011

Common or Usual Name

Urology Retrieval Device

Classification Name

Ureteral stone dislodger
21 CFR 876.4680
Class II
Product Code FFL

Predicate Devices

Accordion Stone Management Device, Percutaneous Systems, Inc. (K052048)
Stone Cone, Boston Scientific Corporation (K864874)

Intended Use

The PercSys Accordion® Stone Management Device is intended to be used in endoscopic procedures to bypass, entrap and remove calculi and other foreign objects from the urinary tract, to prevent retrograde migration of calculi during lithotripsy, and to guide instrumentation within the ureter.

Device Description

The Accordion device consists of a film membrane preloaded onto a two-part wire guide with a removable handle. The device is advanced within the urinary system similar to a wire guide, then, once the film membrane is in the desired position, the film folds into a helical coil (a film-based occlusion) which occupies the lumen of the anatomy in which it resides. In this manner, the occlusion limits migration of stones and stone fragments during lithotripsy. The shaft of the device is 0.97mm (0.038 inch) in outer diameter, has a 150 cm working length, and the film occlusion can be formed into either a 7 mm or 10 mm diameter helical coil. The device is visible under fluoroscopic imaging due to marker bands on either side of the film component and radiopaque disc embedded in the film. The Accordion device is provided sterile and is a single-use only device.

Performance Data

Bench top and clinical data from the literature were submitted in support of the proposed performance claims for this 510(k) submission, as well as in support of documenting that the changes in device materials and sterilization method has not affected design specifications.

Substantial Equivalence

The subject of this 510(k) is the device that was cleared under K052048 (with a few modifications) and is equivalent in technology and intended use to the Stone Cone (K864874). Both the Accordion and Stone Cone devices have a component to reduce migration of stones and stone fragments during lithotripsy. Both are advanced via the working channels of endoscopes and can be used in either ureteroscopic cases (advanced retrograde) or percutaneous nephrolithotomy cases (advanced antegrade). The antiretropulsion component of the Accordion device is a film, while that of the Stone Cone is a wire spiral. The main purpose of this 510(k) submission is to obtain clearance of performance claims to be used in labeling.

Conclusions

The bench top and clinical data show the Accordion device is as safe and as effective as the predicate devices and support the proposed advertising claims.



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

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

MAY 16 2011

Re: K102887

Trade/Device Name: PercSys Accordion® Stone Management Device
Regulation Number: 21 CFR §876.4680
Regulation Name: Ureteral stone dislodger
Regulatory Class: II
Product Code: FFL
Dated: May 9, 2011
Received: May 10, 2011

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. 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

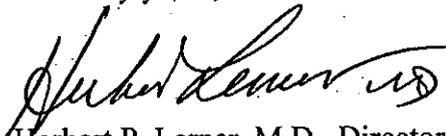
adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102887

Device Name: PercSys Accordion[®] Stone Management Device

Indications for Use:

The PercSys Accordion[®] Stone Management Device is intended to be used in endoscopic procedures to bypass, entrap and remove calculi and other foreign objects from the urinary tract, to prevent retrograde migration of calculi during lithotripsy, and to guide instrumentation within the ureter.

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, Gastro-Renal, and
Urological Devices
510(k) Number K102887

Page __ of __