K052134
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SEP 2 2 2005

510(k) SUMMARY

Percutaneous Systems, Inc.'s CYSTOGLIDE DILATING INTRODUCER SHEATH

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

Percutaneous Systems, Inc.
1300 Crittenden Lane, #101
Mountain View, CA 94043-1359

Phone: (650) 969-8800 x 204
Facsimile: (650) 969-8801

Contact Person: Thomas Lawson

Date Prepared: July 25, 2005

Common or Usual Name

Urology Dilating Introducer Sheath

Classification Name

Accessories, Catheter, G-U

Predicate Device

PSI's UPDATED SLIP Urology Introducer Sheath
Cook Urological's Urethral Dilator Set

Intended Use / Indications for Use

The CYSTOGLIDE DILATING INTRODUCER SHEATH is intended to facilitate the dilation of urethral strictures and the introduction of catheters or instruments into the urethra. The CYSTOGLIDE DILATING INTRODUCER SHEATH is indicated for use as a urethral dilator and as a guide for urological catheters or instruments inserted into the urethra and as a lubricious barrier between the urethral tissue and the catheter or instrument.

Technological Characteristics

The CYSTOGLIDE DILATING INTRODUCER SHEATH consists of a film, a sheath, a stabilizing ring, and an obturator. The device can be front-loaded or back-loaded over a urological guidewire.

Performance Data

Performance data demonstrated no significant difference in the performance of the CYSTOGLIDE DILATING INTRODUCER SHEATH and the predicate device.

Substantial Equivalence

The CYSTOGLIDE DILATING INTRODUCER SHEATH has similar intended use, indications for use, principles of operation and technological characteristics as the predicate devices. The CYSTOGLIDE DILATING INTRODUCER SHEATH Urology Introducer Sheath is substantially equivalent to the cleared UPDATED SLIP Urology Introducer Sheath and the Urethral Dilator Set.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 2 2005

Thomas Lawson, Ph.D.
VP, Clinical & Regulatory Affairs
Percutaneous Systems, Inc.
1300 Crittenden Lane, Suite 101
MOUNTAIN VIEW CA 94043-1359

Re: K052134
Trade/Device Name: CYSTOGLIDE DILATING INTRODUCER SHEATH
Models CD2421, CD2319, CD2117, CD1915 and CD1713
Regulation Number: 21 CFR §876.5520
Regulation Name: Urethral dilator
Product Code: FAH and KOE
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Product Code: KNY
Regulatory Class: II
Dated: July 25, 2005
Received: August 5, 2005

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 (Premarket Approval), 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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K052134

Indications for Use Statement

510(k) Number (if known): K052134

Device Name: CYSTOGLIDE DILATING INTRODUCER SHEATH

Indications for Use:

The CYSTOGLIDE DILATING INTRODUCER SHEATH Urology is intended to dilate urethral strictures and to facilitate the introduction of catheters and instruments into the urethra.

The CYSTOGLIDE DILATING INTRODUCER SHEATH is indicated for use as a urethral dilator and as a guide for urological catheters or instruments inserted into the urethra and as a lubricious barrier between the urethral tissue and the catheter or instrument.

Prescription Use ___X____ AND/OR Over-The-Counter Use____

(Per 21 C.F.R. 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052134