

**510(k) SUMMARY**

DEC 12 2006

**Percutaneous Systems, Inc.'s CYSTOGLIDE INTRODUCER  
SHEATH Advertising Claims**

**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: August 15, 2005

**Common or Usual Name**

Urology Introducer Sheath

**Classification Name**

Accessories, Catheter, G-U

**Predicate Device**

PSI's UPDATED SLIP Urology Introducer Sheath  
Astra Tech's LoFric catheter  
Rusch's MMG/O'Neil catheter

**Intended Use / Indications for Use**

The CYSTOGLIDE INTRODUCER SHEATH is intended to facilitate the introduction of catheters or instruments into the urethra. The CYSTOGLIDE INTRODUCER SHEATH is indicated for use 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 INTRODUCER SHEATH consists of a film, a sheath, a stabilizing ring, and an obturator. The sheath is isolated from the skin microflora by the ViaShield film membrane.

### **Performance Data**

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

### **Substantial Equivalence**

The CYSTOGLIDE INTRODUCER SHEATH has similar intended use, indications for use, principles of operation and technological characteristics as the predicate devices. The CYSTOGLIDE INTRODUCER SHEATH is substantially equivalent to the cleared UPDATED SLIP Urology Introducer Sheath, the LoFric Intermittent Catheter and the MMG/O'Neil catheter.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

DEC 12 2006

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

Re: K052298  
Trade/Device Name: CYSTOGLIDE INTRODUCER SHEATH  
Regulation Number: 21 CFR §876.5130  
Regulation Name: Urological catheter and accessories  
Regulatory Class: II  
Product Code: KNY  
Dated: October 11, 2006  
Received: October 12, 2006

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.



*Protecting and Promoting Public Health*

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). 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,



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

Enclosure

**Indications for Use Statement**

510(k) Number (if known): \_\_\_\_\_

Device Name: CYSTOGLIDE INTRODUCER SHEATH

Indications for Use:

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

The CYSTOGLIDE INTRODUCER SHEATH is indicated for use 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       

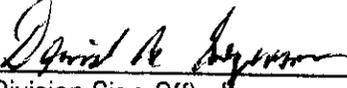
(Per 21 C.F.R. 801.109)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)  
Division of Reproductive, Abdominal, and  
Radiological Devices  
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