MAY 2 0 2004

510(k) SUMMARY

Percutaneous Systems, Inc.'s SLIP Urology Introducer Sheath™

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

SLIP Urology Introducer Sheath™

Percutaneous Systems, Inc.
1300 Crittenden Lane, #301
Mountain View, CA 94043-1359

Phone: (650) 969-8800 x201
Facsimile: (650) 969-8801

Contact Person: Robert Behl, President and CEO

Date Prepared: February 24, 2004

Common or Usual Name

Urology Introducer Sheath

Classification Name

Accessories, Catheter, G-U

Predicate Device

Memcath's Urology Introducer Sheath

Intended Use / Indications for Use

The SLIP Urology Introducer Sheath is intended to facilitate the introduction of catheters or instruments into the urethra. The SLIP Urology 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 SLIP Urology Catheter consists of a sheath, pusher tube, a twist ring, and a guide ring. The pusher tube is pre-loaded with the sheath.

Performance Data

The SLIP Urology Introducer Sheath is identical to the Memcath Urology Introducer Sheath. Thus, no performance data were provided.

Substantial Equivalence

The SLIP Urology Introduction Sheath is identical to the Memcath Urology Introduction Sheath (except for the trade name). The SLIP Urology Introduction Sheath has the same intended use, indications for use, technological characteristics, and principles of operation. Thus, the SLIP Urology Introduction Sheath is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 0 2004

Percutaneous Systems, Inc.
c/o Mr. Howard M. Holstein
Hogan & Hartson L.L.P.
Columbia Square
555 Thirteenth Street, N.W.
Washington DC 20004-1109

Re: K040520
Trade/Device Name: SLIP Urology Introducer Sheath; Models IS2400-08, IS2400-12, IS2400-14, IS2400-16, IS2400-18, IS2400-22 and IS2400-24
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: 78 KNY
Dated: April 30, 2004
Received: April 30, 2004

Dear Mr. Holstein:

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 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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/dsma/dsmamain.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

Indications for Use Statement

510(k) Number (if known): K040520

Device Name: SLIP Urology Introduction Sheath

Indications for Use:

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The SLIP Urology 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)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040520