K090262

## 5. 510(k) Summary as required by 21 CFR 807.92(c)

MAY 28 2009

**510(k) Owner:** Percuvision LLC
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Gahanna, Ohio 43230
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**Contact person:** Barbara S. Fant, Pharm.D.
Clinical Research Consultants, Inc.
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Suite 201
Cincinnati, OH 45220
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**Date:** November 04, 2008

**Trade Name:** PercuCath™ Urinary Catheter

**Common name:** Urological Foley catheter

**Classification Name:** Class II; 21 CFR 876.5130, Urological Catheter and Accessories

**Product Code:** EZL; Catheter, Retention Type, Balloon

**Identification of a Legally Marketed Predicate Device**

The PercuCath™ Urinary Catheter is substantially equivalent to the Bardex® Lubri-Sil® 3-Way Foley Catheter marketed by C.R. Bard, Inc., 510(k) Premarket Notification Number: K002868 FDA Product Code EZL. Secondly, it is substantially equivalent to the Dover® 100% Silicone Foley Council Tip Catheter with manufactured by Tyco Healthcare, 510(k) Premarket Notification Number: K860484, FDA Product Code KOD.

**General Description**

The PercuCath™ Urinary Catheter is a flexible tubular device that is inserted through the urethra and used to pass fluids to and from the urinary tract. The PercuCath™ Urinary Catheter is a 100% silicone, latex-free, triple lumen (3-Way) Foley catheter with a lubricious hydrophilic coating and a straight or angled council tip to facilitate insertion. It is composed of a silicone tube that trifurcates into three lumens, a silicone balloon, and a two-way valve. When activated, the valve permits flow in either of two directions, i.e., for inflation or deflation of the balloon. Of the three lumens, one lumen is used for urinary drainage and can

be connected to a urine collection container (drainage bag or urine meter); one lumen has a two-way valve for inflation/deflation of the Foley balloon; and, the third lumen can be used for irrigation of the bladder. The council tip has an opening (eyelet) in the tip that can be used to pass a guidewire or similar device to facilitate catheter insertion. The PercuCath™ Urinary Catheter will be available with a single eyelet or double eyelet, 14 through 24 Fr. Shafts (i.e.,14, 16, 18, 20, 22, and 24), and either a 10 cc or 30 cc balloon.

**Indications for Use and Intended Use**

The PercuCath™ Catheter is indicated for use in the drainage and/or collection and/or measurement of urine. It is intended to be used as a urological catheter inserted through the urethra for the purpose of draining urine and other fluids from the urinary tract. However, drainage is sometimes accomplished by suprapubic or other placement of the catheter, such as the nephrostomy tract.

**Performance Data**

Mechanical testing was performed on the PercuCath™ Urinary Catheter and the results demonstrate that the PercuCath™ Urinary Catheter met the design specifications for the device and were substantially equivalent to the predicate devices.

**Basis of Substantial Equivalence**

The PercuCath™ Urinary Catheter is substantially equivalent to the Bardex® Lubri-Sil® 3-Way Foley Catheter manufactured by C.R. Bard, Inc. in material, intended use, basic design concept, and biomechanical properties. Secondly, it is substantially equivalent to the Dover® 100% Silicone Foley Council Tip Catheter in its intended use and its council tip with an eyelet.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2009

Percuvision LLC
% Mr. Jeff D. Rongero
Senior Project Engineer
UL Health Sciences
Underwriters Laboratories, Inc.
12 Laboratory Drive
RESEARCH TRIANGLE PARK NC 27709-3995

Re: K090262
Trade/Device Name: PercuCath Urinary Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZL
Dated: May 12, 2009
Received: May 13, 2009

Dear Mr. Rongero:

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 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.

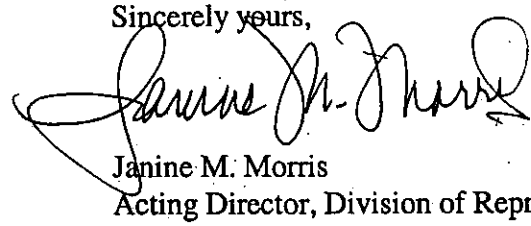
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

| | | |
|---|---|---|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology) | (240) 276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | (240) 276-0115 |
| 21 CFR 892.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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## 4. Indications for Use Statement

510(k) Number (if known): K090262

Device Name: PercuCath™ Urinary Catheter

**Indications for Use:**

The PercuCath™ Catheter is indicated for use in the drainage and/or collection and/or measurement of urine. It is intended to be used as a urological catheter inserted through the urethra for the purpose of draining urine and other fluids from the urinary tract. However, drainage is sometimes accomplished by suprapubic or other placement of the catheter, such as the nephrostomy tract.

Prescription Use __X_____ OR Over-The-Counter Use _____

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090262