Special 510(k) Summary

MAY 27 2011

A) Submitted by: PercuVision
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Contact: MEDIcept
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F. David Rothkopf
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B) Device Name:

Common Name: Urologic Catheter

Proprietary Name: DirectVision® Catheter, Uncoated

Device Class: 21 CFR 876.5130 Urological Catheter and Accessories, Class II

Product Code EZL (Catheter, Retention Type, Balloon)

C) Predicate: K090262 **PercuCath™ Urinary Catheter (with lubricious coating)**
K860484 **Dover Foley Catheter**

D) Device Description:

The DirectVision® Catheter, Uncoated is a flexible tubular device that is inserted through the urethra and used to pass fluids to and from the urinary tract. It is a 100% silicone, latex-free, triple lumen (3-Way) Foley catheter with a straight or angled council tip to facilitate insertion. The DirectVision® Catheter, Uncoated is composed of a silicone tube that trifurcates into three (3) lumens, a silicone balloon, and a two-way valve. 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. This catheter device will be available with a single or double drainage eyelet, 14 through 24 French shafts, and either a 10 cc or 30 cc balloon. The DirectVision® Catheter, Uncoated is designed to be usable with the PercuVision DirectVision™ Guide System (K091600). In the DirectVision™ Guide System, the DirectVision® Catheter, Uncoated provides a sheath around the microendoscope to facilitate its use. The catheter also incorporates a channel to be used for supplying irrigation to the microendoscope tip for clearing away debris from the field of view during use.

E) Intended Use:

The DirectVision® Catheter, Uncoated 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.

F) Comparison to Predicate Device(s):

		DirectVision® Catheter, Uncoated	**PercuCath™ Urinary Catheter (with lubricious coating)**	**Dover Foley Catheter**
510K Number			K090262	K860484
Product code		EZL	EZL	KOD
Indication for Use		For use in the drainage and/or collection and/or measurement of urine.	For use in the drainage and/or collection and/or measurement of urine.	For use in the drainage and/or collection and/or measurement of urine.
Intended Use		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.	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.	Not available
Design	Coating	Uncoated	Coated	Uncoated
Sterility		Supplied sterile	Supplied sterile	Supplied sterile
Biocompatible		Yes	Yes	Yes

Substantial Equivalence Discussion

There is no change in Indication for Use or Intended use of the DirectVision® Catheter, Uncoated. The DirectVision® Catheter, Uncoated is identical in all aspects to the PercuVision PercuCath™ Catheter Urinary Catheter with lubricious coating, except for being uncoated. The DirectVision® Catheter, Uncoated is similar to the Dover Foley catheter, which also does not have a lubricious coating. PercuVision does not believe that removal of the coating raises new issues of safety or effectiveness, and that the DirectVision® Catheter, Uncoated is substantially equivalent to the predicates in terms of materials, intended use, basic design concept and biomechanical properties.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

PercuVision, LLC
c/o F. David Rothkopf
President
MEDIcept, Inc.
200 Homer Avenue
ASHLAND MA 01721

MAY 27 2011

Re: K110214
Trade/Device Name: DirectVision® Catheter, Uncoated
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZL
Dated: May 3, 2011
Received: May 4, 2011

Dear Mr. Rothkopf:

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): K110214

Device Name: DirectVision® Catheter, Uncoated

Indications for Use:

The DirectVision® Catheter, Uncoated is indicated for use in the drainage and/or collection and/or measurement of urine.

Prescription Use X 21CFR 801, Subpart D **OR** Over-the-Counter Use _ 21 CFR 876.1500

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110214