K091600

Pg 1 of 3

510k Summary

Submitted by:

Percuvision LLC
765 North Hamilton Road, Suite 260A
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Telephone: 614-337-8700
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Establishment Registration Number: To be assigned

AUG 2 5 2009

Contact

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MEDIcept, Inc.
200 Homer Avenue
Ashland, MA 01721
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Device Name

Common Name:	Microendoscope Video System
Proprietary Name:	DirectVision™ Guide System

Classification

Device:	DirectVision ™ Guide System
Medical Specialty:	Urologic
Device Class:	21 CFR 876.1500, Endoscope and Accessories, Class II
Product Codes	FGC (Endoscope)

Predicate Devices

510(K):	K020310
Trade Names:	Davlite Microendoscope
Manufacturer:	Davlite Technologies. 37 Kris Allen Dr Holden, MA 01520
Device Class:	21 CFR 876.1500, Endoscope and Accessories, Class II
Product Code:	GCJ
Regulation #:	876.1500

K 091600

Pg 2 of 3

General Description

The DirectVision™ Guide System is comprised of two (2) distinct components: a flexible semi-rigid microendoscope, and a handheld camera with integral LED illumination and camera control unit (CCU). The microendoscope is designed to work with the Schoelly Imaging Inc. FSC2 light source and CCU (K090601). The DirectVision™ Guide System is indicated for use in the endoscopic examination of the urethra and bladder, when placing the PercuCath™ Urologic Catheter (K090262). The catheter 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. The microendoscope coupler is connected to the cleared camera and integral light source such that the light source is collinear with the light fiber optic bundle and the camera is collinear with the image fiber optic bundle. The image transmitted through the image fiber optic bundle to the camera is then displayed on a monitor accessory for the clinician to view.

Intended Use:

The DirectVision™ Guide System is indicated for use in the visual examination of the urethra and bladder when placing the PercuCath Urologic Catheter.

Comparison to Predicate Device(s):

		DirectVision™ Guide System	**Davlite Microendoscope**
Intended Use		It is intended to be used in the visual examination of the urethra and bladder when placing the PercuCath™ Urinary Catheter.	This device is to be used by physicians for viewing an interior cavity of the human body through either a natural opening or an incision
Design	Stiffness	Flexible	Flexible
	Light Carrier	Glass Fiber Optic bundle	Glass Fiber Optic bundle
	Image Carrier	Glass Fiber Optic bundle	Glass Fiber Optic bundle
	Lens	Objective lens at tip	Objective lens at tip
	Camera Adapter	Yes	Yes
	Body Contact Material	Biocompatible Polyimide and glass	Biocompatible Polymer and glass
Performance Standard		ISO 8600	ISO 8600
Biocompatiblity		Yes	Yes
Sterility		Supplied non sterile	Supplied non sterile
Re-Use		Multi use	Multi use

Performance Standards

No applicable mandatory performance standards or special controls exist for this device. Form 3654 may be found in Attachment H

The DirectVision™ Guide System meets the requirements of the following recognized consensus standards, where applicable:

- ISO 8600-1:2005
  Optics and Photonics – Medical Endoscopes Information to be Provided by the Manufacturer for the Processing of Resterilizable Medical Devices

- AAMI TIR12: 2004
  Designing, Testing, and Labeling Reusable Medical Devices for Preprocessing in Health Care Facilities

- AAMI / ANSI ST81:2004,
  Sterilization Of Medical Devices - Information To Be Provided By The Manufacturer For The Processing Of Resterilizable Devices

- AAMI / ANSI ST35:2003
  Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings

- IEC 60601-2-18
  Particular Requirements for the Safety of Endoscopic Equipment

- ISO10993-1:2003
  Biological Evluation of Medical Devices

Substantial Equivalence

The DirectVision™ Guide System microendoscope is substantially equivalent to the Davlite Microendoscope manufactured by Davlite Technologies in materials, intended use, and basic design concept.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Errol O. Singh, M.D.
President & CEO
Percuvision , LLC
765 North Hamilton Road, Suite 260A
GAHANNA OH 43230

AUG 2 5 2009

Re: K091600
Trade/Device Name: DirectVision™ Guide System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGC
Dated: June 3, 2009
Received: June 3, 2009

Dear Dr. Singh:

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); 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/cdrh/mdr/ 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 (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

Indications for Use Statement

510(k) Number (if known): K091600

Device Name: DirectVision™ Guide System

Indications for Use:

The DirectVision™ Guide System is indicated for use in the visual examination of the urethra and bladder when placing the PercuCath Urologic Catheter.

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 K091600