DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 31, 2017

Zhuhai Pusen Medical Technology Co., Ltd.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
Millburn, NJ 07041

Re: K172098
Trade/Device Name: Medical Video Endoscope System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Dated: August 22, 2017
Received: August 23, 2017

Dear Dave Yungvirt:

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 contact the Division of Industry and Consumer Education (DICE) 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education (DICE) 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,

Charles Viviano -S

For Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172098

Device Name
Medical Video Endoscope System

Indications for Use *(Describe)*
This instrument has been designed to be used with endo-therapy accessories such as a biopsy forceps and other ancillary equipment for endoscopy and endoscopic surgery within urinary tract and interior of the kidney.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

K172098

A. Submitter's Name, Address and Phone and Fax Number

Name & Address of the manufacturer: Zhuhai Pusen Medical Technology Co., Ltd.

5/F, Building 1, No 33, Keji San Road,
High-tech Zone, Tangjiawan Town, Zhuhai,
Guangdong, PRC.

Phone: 86-07566880096

Fax: 86-07566880401

B. Contact person:

Ms. Wang ChangShen

Manager, Regulatory Affairs

Phone: 86-07566880865

C. Date prepared:

August 17, 2017

D. Name of the device:

Trade name: Medical Video Endoscope system

Common name: Ureteroscope and Accessories, Flexible/rigid

Model Number of the Handle: PU3022、PU3022A

Model Number of the Video system: UTV100

Classification: 21 CFR 876.1500 Endoscope and accessories. Class II

Product Code: FGB

E. Predicate Device:

Trade name: Karl Storz Flexible Video-Uretero-Renoscope System

Common name: Ureteroscope and Accessories, Flexible/rigid

Classification: Endoscope and accessories. 21 CFR 876.1500. Class II

Premarket Notification: Storz K131369

F. Device description:

The Medical Video Endoscope system is designed to provide image solution for endoscopy and endoscopic surgery, and perform procedures in the urinary tract and interior of the kidney using appropriate accessory devices (e.g. laser fibers, forceps baskets).

The optical fiber transmits the light emitting from the LED light built in the handle to the coelom. The complementary metal-oxide-semiconductor CMOS imaging sensor in the distal tip of the insertion shaft receives the reflected light from the surface of mucosa and transforms the light into electric signal. The cable transfers the electric signal to the data processing center of the Eview, where the electric signal is processed. As a result the color imaging of the capillary network and mucosal morphology is displayed on the screen of the Eview.

The Medical Video Endoscope system is a digital flexible ureteroscope system that consists of the Eview (the video system, touch PC with data processing center) and the Uscope. The Uscope is provided sterile (sterilized by EO) and intended to be single-use.

The Uscope, as provided sterile, contains an insertion portion, handpiece and the cable. The handpiece is made with polymer plastic, Contacted with users. The insertion portion, as the part connected with patients, includes the sheath which is braided tube made of SUS 304 stainless steel and PEBAX, the controllable portion and the distal tip. The controllable portion is made of SUS 304 stainless steel, covered with silicone rubber. The distal tip is made with ABS. There is a working channel that terminates at the distal tip, which is indirect patient-contacting component, made of Fluorinated ethylene propylene.

The Eview, the video system contains touch PC with data processing center and provide energy to Uscope. The Eview can be powered by the main line or lithium battery.

G. Intended Use

This instrument has been designed to be used with endo-therapy accessories such as

a biopsy forceps and other ancillary equipment for endoscopy and endoscopic surgery within urinary tract and interior of the kidney.

The intended use of subject and predicate devices are the same. Both of the subject and predicate devices are indicated for endoscopic examination in the urinary tract and can be used to examine the interior of the kidney, and using additional accessories to perform various diagnostic and therapeutic procedures.

The Medical Video Endoscope system is for use in a hospital or qualified medical institution. The system is only to be used by skilled physicians trained in clinical endoscopic techniques and procedures.

H. Technological Characteristics

The technological principle for both the subject and predicate devices is based on the use of an LED light integrated in the handle and fiber light guides to illuminate the cavity under examination, and the CMOS imaging sensor located at the tip of the insertion portion to transfers the video signal to the image system.

The following basic technological elements are the same or similar for the subject and predicate devices:

Compared items	**Subject device**	**Predicate device**
Same technological characteristics		
Scope type	Flexible	Flexible
anatomical site	Urinary tract and interior of the kidney	Urinary tract and interior of the kidney
target population	Adults	Adults
where used (hospital, home, ambulance, etc)	Hospitals	Hospitals
Digital video technology	CMOS	CMOS
Illumination source	LED	LED

Up/down deflection (°)	Up 270 ° Down 270 °	Up 270 ° Down 270 °
Direction of view	0 °	0 °
Similar technological characteristics		
Field of view	120 °	90 °
Maximum insertion portion width (mm)	3.2	2.9
Working length(mm)	650	700
Minimum instrument channel width (mm)	1.0	1.2
Image system	UTV100 as the image system	Image 1HD system

The main difference between the Medical Video Endoscope system and the predicate devices is reusability. The Uscope of the subject device is single-use and provided sterile, while the predicate devices are reusable. This does not create a difference in intended use.

The technological characteristics of the Medical Video Endoscope system and the predicate device are substantially equivalent.

I. Non-Clinical Performance Data

The Medical Video Endoscope system has been verified for its safety and effectivity based on the following performance data.

Electrical safety of the system was evaluated in accordance with IEC 60601-1:2012, and AAMI/ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 and IEC 60601-2-18:2009. Electromagnetic compatibility was evaluated in accordance with IEC 60601-1-2:2007. All evaluation acceptance criteria were met.

Biocompatibility evaluation for the Medical Video Endoscopy system was conducted

in accordance with the Guidance document “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process” June 16, 2016, and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices −Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA.

The body contact category is “Surface – Mucosal Membrane” with a contact duration of “Limited” (<24 hours). The Following tests were performed as recommended: Cytotoxicity, Irritation and Sensitization. All evaluation acceptance criteria were met.

Sterile barrier systems were evaluated in accordance with ISO 11607:2006. Sterilization Process has been validated accordance with ISO 11135:2014.

Technological characteristics have been tested for its functions as intended, including verification of performance characteristics per ISO 8600-1:2015(Fourth Edition) (The maximum insertion portion width, the minimum instrument channel width, field of view, direction of view, deflection) and performances characteristics relevant to functions as intended (Image quality, Illumination, Articulation, Leak, Flow rate of water).

The results of Non-Clinical Performance testing demonstrate that the Medical Video Endoscope is considered safe and effective for its intended use.

Conclusion:

The Medical Video Endoscope is substantially equivalent to the predicate device and does not raise any questions of safety and effectiveness.