March 29, 2019

Zhuhai Pusen Medical Technology Co., Ltd.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd.
Warren, NJ 07059

Re: K190648
Trade/Device Name: Pusen™ Eview™ Medical Video Endoscope Image Processor, Model PV210
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FET
Dated: March 11, 2019
Received: March 13, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Angel A. Soler-garcia -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190648

Device Name
Pusen™ Eview™ Medical Video Endoscope Image Processor, Model PV210

Indications for Use *(Describe)*
This equipment has been designed to be used to process signals from an endoscope and convert it to a signal that can be displayed on the monitor.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

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

Zhuhai Pusen Medical Technology Co., Ltd.

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Phone: 86-07566880096

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Contact Person: Ms. Wang ChangShen

Manager, Regulatory Affairs

Phone: 86-07566880865

Date prepared: February 22, 2019

2. Device:

Trade name: Pusen ™ Eview™ Medical Video Endoscope Image Processor

Model Number: PV210

Common name: Endoscopic Video Imaging System/Component, Gastroenterology-Urology

Classification: 21 CFR 876.1500 Endoscope and accessories. Class II

Product Code: FET

3. Predicate Device:

Trade name: Image 1 SPIES

Premarket Notification: K131953

4. Device description:

The Medical Video Endoscope Image Processor PV210 is a video processor which is intended and designed for use during endoscopic procedures. It receives and processes image signals from digital endoscope and outputs signals to a medical monitor to display.

PV210 has integrated software to control the operation of the device.

PV210 is a reusable device and do not require sterilization before use, as there is no direct/in-direct patient contact material. It needs to be cleaned and disinfected before use, the cleaning and disinfection method is validated and recommend in the User Manual.

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

5. Indications for Use

This equipment has been designed to be used to process signals from an endoscope and convert it to a signal that can be displayed on the monitor.

6. Comparison of Technological Characteristics

The predicate and subject devices are both video processors that can be used for the visualization of endoscopic procedures, while the predicate device can work with camera head, therefore it can also be used for microscopic procedures. There are similarities and differences in the technological characteristics.

These similarities are:

- Have the same intended use in endoscopic procedures.
- Have similar functions such as: light source control, enhancement control, white balance, zoom and HD video output.
- Are used in conjunction with digital endoscope and medical monitor.
- Reusable
- Powered by main line

These differences are:

- the predicate supports both camera head and digital endoscope while the subject only supports digital endoscope
- the predicate supports image and video storage while the subject is not capable of storage
- the predicate supports display brightness control while the subject only supports

predetermined display brightness setting which cannot be adjusted

- The predicate supports 3G-SDI and DVI-D video output formats while the subject supports SDI, DVI-D, VGA and VIDEO output formats.
- The predicate incorporates an external keyboard to control the system operation while the subject does not have an external keyboard, it is equipped with buttons on front panel to control the system operation.

The technological differences between the subject and predicate devices do not raise different questions of safety or effectiveness. Bench testing as identified below was conducted to verify and validate that the product performs as intended.

7. Non-Clinical Performance Data

The following bench testing conducted for the subject device PV210 demonstrates substantial equivalence in safety:

Electrical safety
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.
According to the test result, the subject device conforms to the requirements of the above standards.

Electromagnetic compatibility (EMC)
Electromagnetic compatibility was evaluated in accordance with IEC 60601-1-2:2007.
According to the test result, the subject device conforms to the requirements of the above standard.

Software Verification and Validation testing
Software verification and validation testing were conducted.
According to the test result, the subject device conforms to software and system requirements.

Bench testing of performance specifications were completed and demonstrate that the device met all requirements.

8. Conclusion:

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