January 29, 2025

Hunan Vathin Medical Instrument Co., Ltd,
Jing Du
RA Manager
1/F, Building 12, Innovation Entrepreneurship Service Center
No.9 Chuanqi West Road, Jiuhua Economic Development Zone
Xiangtan, Hunan 411100
CHINA

Re: K243117
Trade/Device Name: Digital Video Processor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Received: December 27, 2024

Dear Jing Du:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark R. Kreitz -S

for Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243117

Device Name

Digital Video Processor

Indications for Use *(Describe)*

The Digital Video Processor is designed to be used with Vathin medical endoscopes, and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

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

I Submitter

Device submitter:	Hunan Vathin Medical Instrument Co., Ltd.
Address:	1/F, Building 12, Innovation and Entrepreneurship Service Center, No 9 Chuanqi west road, Jiuhua Economic Development Zone, 411100 Xiangtan, Hunan, China
Contact person:	Du Jing Title: Regulatory Affairs Manager Phone: +86-731-5558558 E-mail: charlene@vathin.com
Date of preparation	December 26 2024

II Device

Trade Name of Device:	Digital Video Processor
Common name	Endoscope and Accessories
Classification name	Ureteroscope And Accessories, Flexible/Rigid
Classification	Class II, 21 CFR 876.1500
Product Code:	FGB
Review Panel:	Gastroenterology/Urology

III Predicate device and reference device

	Predicate device
Trade name:	Digital Video Monitor
Regulation number:	21 CFR 876.1500
Classification name:	Ureteroscope And Accessories, Flexible/Rigid
Regulatory class:	Class II
Product code:	FGB
Submitter:	Hunan Vathin Medical Instrument Co., Ltd.
510(k) number:	K231135

IV Device description

The Digital Video Processor is used in conjunction with Vathin endoscopes, and other accessories for endoscopic image processing during endoscopic diagnostic and therapeutic procedures. When used, it receives and processes image signals from a digital endoscope and transfers these signals to a connected monitor.
The Digital Video Processor is for use in professional Healthcare Facility Environment.

V Indications for use

The Digital Video Processor is designed to be used with Vathin medical endoscopes, and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

VI Comparison of technological characteristics with the predicate devices

A comparison of the technological characteristics between the subject and predicate devices is provided below.

Device feature	Proposed Device	Predicate Device
Trade Name	**Digital Video Processor**	**Digital Video Monitor**
Classification Name	Ureteroscope And Accessories, Flexible/Rigid	Ureteroscope And Accessories, Flexible/Rigid
Product Code	FGB	FGB
Regulation Number	21 CFR 876.1500	21 CFR 876.1500
Models	Digital Video Processor: DVP-C10	Digital Video Monitor: DVM-B1
Intended use	This Digital Video Processor is designed to be used with Vathin medical endoscopes, and other ancillary equipment for endoscopic diagnosis, treatment and video observation.	The Digital Video Monitor is specially designed to be used with Vathin medical endoscopes and other auxiliary equipment for the purposes of endoscopic diagnosis, treatment and video observation.
Application field	The device is for use in professional Healthcare Facility Environment.	The device is for use in professional Healthcare Facility Environment.
Intended user	For use by trained clinicians/physicians only.	For use by trained clinicians/physicians only.
Max. resolution	Resolution of output signal: HDMI, SDI, DVI: 1920*1080 CVBS/S-Video: 720*576	1280 x 800

Device feature	Proposed Device	Predicate Device
Display type	/	12.1” touch screen
USB connection	USB3.0 A-type，USB2,0 A-type	A type
Video output	HDMI, SDI, CVBS, S-VIDEO, DVI	HDMI, USB 2.0
Image/Video capture	Yes	Yes

VII Summary of Non-clinical tests:

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the device. The device complies with the IEC 60601-1 and IEC60601-2-18 for safety and the IEC 60601-1-2 for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Content of Premarket Submissions for Device Software Functions” and “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions”.

Performance testing

The following performance testing was conducted on the device to demonstrate equivalency and ensure the device meets its intended use.

- Field of view
- Depth of field
- Geometric distortion
- Image intensity uniformity
- Color performance

VIII Conclusion

The device is substantially equivalent to predicate device. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed predicate device.