Tech-Image CO., LTD.
℅ Yin-Jiun Tseng
CEO & Co-Founder
WeMED Bio-Tech, Inc.
Contact Address

June 10, 2026

Re: K260414
Trade/Device Name: "Tech-Image" Video Endoscope System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ, HRX
Dated: May 8, 2026
Received: May 11, 2026

Dear Yin-Jiun Tseng:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Colin K. Chen -S
Digitally signed by Colin K. Chen -S
Date: 2026.06.10 16:44:50 -04'00'

Colin K. Chen, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260414

Please provide the device trade name(s).

"Tech-Image" Video Endoscope System

Please provide your Indications for Use below.

The "Tech-Image" Video Endoscope System is intended to be used as a single-use endoscopic video camera to provide visualization of the interior of the body's internal anatomy during various diagnostic and surgical endoscopic procedures. These applications include, but are not limited to: general surgery and minimally invasive surgery (e.g., orthopedic, spine, laparoscopic, and plastic surgical procedures).

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary

Tech-Image Video Endoscope System

U.S. FOOD AND DRUG ADMINISTRATION

Center for Devices and Radiological Health (CDRH)

Premarket Notification 510(k) Summary

SECTION I: GENERAL INFORMATION

A. Applicant Information

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B. Device Information

Item	Details
510(k) Submitter	Tech-Image CO., LTD.
Device Trade Name	"Tech-Image" Video Endoscope System
Device Common Name	Endoscope and accessories
Product Code	GCJ (21 CFR 876.1500)
Subsequent Product Code	HRX (21 CFR 888.1100)
Classification	Class II
Review Panel	General & Plastic Surgery
Regulation Medical Specialty	Gastroenterology/Urology
Submission Type	Traditional 510(k)
Predicate Device	K201134
Secondary Predicate	K203226

SECTION II: INTENDED USE

A. Intended Use Statement

The “Tech-Image” Video Endoscope System is intended to be used as a single-use endoscopic video camera by qualified physicians to provide real-time illumination and visualization of internal anatomical structures during various general surgical and minimally invasive endoscopic procedures in diagnostic and therapeutic interventions.

B. Indications for Use

The “Tech-Image” Video Endoscope System is intended to be used as a single-use endoscopic video camera to provide visualization of the interior of the body’s internal anatomy during various diagnostic and surgical endoscopic procedures. These applications include, but are not limited to: general surgery and minimally invasive surgery (e.g., orthopedic, spine, laparoscopic, and plastic surgical procedures).

C. Patient Population

Adult patients undergoing general or minimally invasive surgery (e.g., orthopedic, spine, laparoscopic, and plastic surgical procedures) requiring visualization of internal anatomical structures.

SECTION III: DEVICE DESCRIPTION

A. General Device Description

The "Tech-Image" Video Endoscope System is an integrated digital imaging platform designed for the real-time visualization of internal anatomical structures. The system consists of the CYTS-02 Video Display Device, a reusable 13.3-inch Full-HD LCD console, and the TISE Series Single-use Video Endoscopes. Utilizing advanced "Chip-on-Tip" CMOS technology and integrated LED illumination, the system captures high-resolution imaging data and supports external video output via a dedicated HDMI port. The TISE endoscopes are available in various configurations—including different diameters, viewing angles, and working lengths—to accommodate diverse clinical requirements. When used in conjunction with their corresponding sterile cannula accessories, the system facilitates precise access through surgically created openings during minimally invasive procedures, such as laparoscopy or arthroscopy. This single-use architecture effectively eliminates reprocessing risks and

cross-contamination, ensuring consistent optical performance and patient safety.

B. Manufacturing & Materials

Component	Material	Specification	Rationale
Shaft	SUS 304 Stainless Steel	ASTM A312	Biocompatible, corrosion-resistant, surgical standard
Optical Window			High durability, optical clarity, scratch-resistant
Seals/Gaskets	Silicone elastomer	ISO 9002 synthetic sapphire	ISO 10993 biocompatible for prolonged contact
Internal Lenses	Borosilicate Glass	Optical-grade	Precision optics, chemically stable

C. Sterilization

Sterilization Method：Ethylene Oxide (EO) gas per ISO 11135-1

- Sterilization Assurance Level (SAL)：10^{-6}

- Shelf Life：3 years when stored in protective packaging at room temperature

D. Non-Clinical Testing Summary

A series of non-clinical evaluations were performed to verify the safety and effectiveness of the “Tech-Image” Video Endoscope System and to demonstrate substantial equivalence to the primary predicate device (K201134). The following tests were conducted:

- **Electrical Safety and Electromagnetic Compatibility (EMC):** The system was tested and found to be in compliance with the **IEC 60601-1** standard for general electrical safety and the **IEC 60601-1-2** standard for electromagnetic compatibility. The results confirmed that the device performs safely in its

intended clinical environment.

- **Optical and Thermal Safety:** The distal LED illumination and imaging system were evaluated according to **IEC 60601-2-18**. Testing verified light output safety, color consistency, and thermal management. Measurements confirmed that the temperature of the endoscope tip remains within safe limits during continuous operation.
- **Performance Testing – Bench:** Side-by-side comparative testing was performed on the subject device and the predicate to evaluate key imaging parameters, including resolution (spatial frequency response), Signal-to-Noise Ratio (SNR), image distortion, Field of View (FOV), and Depth of Field (DOF). For models with larger outer diameters (up to 10.0mm), mechanical integrity and structural strength tests were conducted to ensure compatibility with standard surgical portals.
- **Biocompatibility:** In accordance with **ISO 10993-1** and FDA guidance, the patient-contacting components of the single-use endoscopes were categorized as "Externally Communicating Devices" with limited contact (< 24 hours) with tissue, bone, and/or blood. Testing included Cytotoxicity, Sensitization, and Irritation/Intracutaneous Reactivity. All results met the predetermined acceptance criteria.

SECTION IV: SUBSTANTIAL EQUIVALENCE & PREDICATE COMPARISON

A. Predicate Device

- 510(k) Number: K201134
- Device: Arthrex NanoScope System
- Product Code / Regulation: GCJ / 21 CFR 876.1500 (Primary) and HRX / 21 CFR 888.1100 (Subsequent)
- Clearance Date: September 4, 2020
- Rationale: K201134 is designated as the primary predicate for the “Tech-Image” Video Endoscope System due to its identical product codes

(Primary: GCJ; Subsequent: HRX) and fundamental intended use in diagnostic and surgical procedures, specifically within spinal and orthopedic applications. The system architecture is substantially equivalent, featuring a reusable video processing unit and single-use imaging components.

B. Secondary Predicate Device

- 510(k) Number: K203226
- Device: Richard Wolf PANOVIEW Ultra Telescopes
- Product Code / Regulation: GCM / 21 CFR 876.1500 (Primary) and GCJ / 21 CFR 876.1500 (Subsequent) / HET 21 CFR 884.1720
- Clearance Date: May 14, 2021
- Rationale: K203226 is designated as the secondary predicate for the "Tech-Image" Video Endoscope System to address a specific dimensional characteristic of the subject device — the outer diameter (OD) — that extends beyond the dimensional range of the primary predicate (K201134, OD: 1.9 mm). Both the subject device and K203226 share the same intended use (visualization of internal anatomical structures during minimally invasive endoscopic procedures), the same regulatory classification (Class II, 21 CFR 876.1500), and the same medical specialty (Gastroenterology & Urology). The OD range of the subject device (4.7–10.0 mm) falls entirely within the cleared OD of K203226 (10.0 mm). Therefore, the use of K203226 as a secondary predicate supports the conclusion that the subject device's dimensional specifications do not raise new questions of safety and effectiveness, and that the subject device is substantially equivalent to legally marketed predicates.

C. Substantial Equivalence Comparison Table

Features	Subject Device	Primary Predicate	Secondary Predicate	Result
Device Trade Name	**Tech-Image" Video Endoscope System**	**Arthrex NanoScope System**	**Richard Wolf PANOVIEW Ultra Telescopes**	
510 (k)		**K201134**	**K203226**	
Classification	**Class II**	**Class II**	**Class II**	**Identical**
Medical Specialty	**Gastroenterology & Urology**	**Gastroenterology & Urology**	**Gastroenterology & Urology**	**Identical**
Primary Product Code	**GCJ**	**GCJ**	**GCM**	**Same as Predicate**
Substantial Product Code	**HRX**	**HRX**	**GCJ HET**	**Same as Predicate**
Regulation No.	**21 CFR 876.1500 Endoscope and Accessories**	**21 CFR 876.1500 Endoscope and Accessories**	**21 CFR 876.1500 Endoscope and Accessories**	**Identical**
Review Panel	**General & Plastic Surgery**	**General & Plastic Surgery**	**General & Plastic Surgery**	**Identical**
Intended Use	The "Tech-Image" Video Endoscope System is intended to be used as a single-use endoscopic video camera by qualified physicians to provide real-time illumination and visualization of internal anatomical structures during various general surgical and minimally invasive endoscopic procedures in diagnostic and therapeutic interventions.	The Arthrex NanoScope System provides image processing and digital documentation for endoscopic procedures. The system utilizes a handpiece which provides distal LED illumination to the surgical site using a fiber optic bundle surrounding a high-resolution camera sensor.	The PANOVIEW Ultra telescopes (common name: telescopes) are rigid endoscopes which are used in invasive surgery or via natural orifices for diagnosis and therapy and serve to visualize the inside of the body. The products are used for interventions in different medical disciplines, such as surgery and laparoscopic interventions e.g. in urology and gynecology. The submitted devices can be grouped by working length (WL) and direction of view.	**Similar**
Indications for Use	The "Tech-Image" Video Endoscope System is intended to be used as a single-use endoscopic video camera to provide visualization of the interior of the body's internal anatomy during various diagnostic and surgical endoscopic procedures. These applications include, but are not limited to: general surgery and minimally invasive surgery (e.g., orthopedic, spine, laparoscopic, and plastic surgical procedures).	The Arthrex NanoScope System is intended to be used as an endoscopic video camera in a variety of endoscopic diagnostic and surgical procedures, including but not limited to: orthopedic, spine, laparoscopic, urologic, sinuscopic, and plastic surgical procedures. The device is also intended to be used as an accessory for microscopic surgery.	The products are used in invasive surgery or via natural orifices for diagnosis and therapy and serve to visualize the inside of the body. The products are used for interventions in different medical disciplines, such as surgery and laparoscopic interventions e.g. in urology and gynecology.	**Similar**
System Configuration	Single-Use Endoscope + Reusable control unit	Single-Use Endoscope + Reusable control unit (CCU/Console)	Reusable rigid endoscope telescope + external light source + external camera	**Same System Components Subject & Primary Predicate are single-use**
Biocompatibility	ISO 10993-1 compliant	ISO 10993-1 compliant	ISO 10993-1 compliant	**Identical**
Electrical Safety	IEC 60601-1	IEC 60601-1	N/A (passive optical device)	**Identical**
EMC	IEC 60601-1-2	IEC 60601-1-2	N/A (passive optical device)	**Identical**
Thermal Safety	IEC 60601-2-18	IEC 60601-2-18	IEC 60601-2-18	**Equivalent**
Sterilization	EO	EO	Steam sterilization (moist heat)	**Subject & Primary Predicate are EO**
Software Validation	IEC 62304		No software	**N/A**

Human Factors / Usability	IEC 62366-1	Per IEC 60601-1-6	N/A	**Similar to Predicate**
Performance Testing	ISO 8600	Bench Testing	ISO 8600-1/-3/-5	**Equivalent**
OD(Diameter)	4.7、8.6、10.0 mm	Scope diameter 1.9mm; utilizes accessory scope sheath of up to 3.4 mm diameter	10.0 mm	**Equivalent**
Working Length	218、273 mm	125 , 180, 250 mm	305, 440 mm	**Similar**
FOV	130°	120°	0°, 30°, 50°	**Similar**
Material	Stainless steel + ABS + PEEK…	-	Optical glass + stainless steel	**Similar**
Imaging Sensor	High-Res CMOS	CMOS	Rod lens optical system	**Similar**
Sensor Location	Distal Tip (Chip-on-Tip)	Distal Tip	N/A (not chip-on-tip)	**Similar**
Resolution	1080p	Standard/High Res	Optical eyepiece / monitor via attached camera	**Similar**
Light Source	Distal LED	Distal LED	External cold light source (fiber bundle)	**Similar**
Working Channel	Integrated (Optional)	N/A	N/A	**Similar**
Energy Source	AC Mains (via CCU)	AC Mains	External light source (passive device)	**Similar**

D. Substantial Equivalence Discussion

The collective data from the identified predicate devices establish a robust basis for the substantial equivalence of the “Tech-Image” Video Endoscope System. Detailed side-by-side comparisons and supporting performance data are documented comprehensively and we affirm that the subject device is as safe and effective as the legally marketed devices, raising no new questions of safety or effectiveness.