November 20, 2025

Integrated Endoscopy, Inc.
Albert Rego
Vice President Regulatory & Quality
16 Technology Drive Suite 165
Irvine, California 92618

RE: K242606
Trade/Device Name: Nuvis® Wireless HD Camera System (Nuvis-2K)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: November 19, 2025
Received: November 20, 2025

Dear Albert Rego:

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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2025.11.20 08:47:36 -05'00'

Colin Kejing 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

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.

510(k) Number *(if known)*
K242606

Device Name
Nuvis® Wireless HD Camera System

Indications for Use *(Describe)*
The Nuvis Wireless HD Camera System is indicated for use in diagnostic and operative endoscopic procedures, supplying visualization of an interior cavity of the body.

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.

Integrated Endoscopy, Inc.

Nuvis Wireless HD Camera System

K242606 510(K) Summary

I.	**SUBMITTER**	Integrated Endoscopy, Inc. 16 Technology Drive, Suite 165 Irvine, CA 92618
	ESTABLISHMENT Number:	3011401113
	Contact Person:	Albert Rego, Ph.D. Vice President Regulatory & Quality
	Phone:	949-632-8126 Email: albert@iescope.com
	Date Prepared:	November 19, 2025
II.	**DEVICE**	
	Trade Name:	Nuvis® Wireless HD Camera System
	Regulation Number and Name:	21 CFR 876.1500 Endoscope and accessories.
	Regulation Class:	Class II
	Product Code and Review Panel:	GCJ; General and Plastic Surgery
III.	**Predicate Device**	
	510(K) Number:	K213860
	Product Name:	ArthroFree Wireless Surgical Camera System
	Manufacturer:	Lazurite Holdings LLC

IV. DEVICE DESCRIPTION

The Nuvis Wireless HD Camera System (or "System" or "Nuvis-2K") consists of two wireless reusable camera heads that can be paired to a wireless base station. When the camera head is attached to an arthroscope/light source (using a C-mount coupler) AND the wireless base station is attached to a clinic supplied video system, arthroscopic examinations can be viewed and pertinent data recorded.

A tablet with NuvisCon Application (APP) can be connected to the wireless base station to enter patient and case data.

The System can transmit uncompressed video content from the camera head to the wireless base station up to 5 meters (15 feet) away.

Recorded video and snapped pictures are saved to an internal storage drive in the wireless base station.

V. INDICATIONS FOR USE

The Nuvis Wireless HD Camera System is indicated for use in diagnostic and operative endoscopic procedures, supplying visualization of an interior cavity of the body.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The comparison of features and operation principles between Nuvis Wireless HD Camera System and the ArthroFree Wireless Surgical Camera System are listed below:

Substantial Equivalence Comparison

	Subject Device	Predicate Device	Substantially Equivalent
510(K)	TBD	510(K) K213860	
Manufacturer	Integrated Endoscopy, Inc.	Lazurite Holdings LLC	
Device Name	NuVis Wireless HD Camera System	ArthroFree Wireless Surgical Camera System	YES
Product Code	GCJ	GCJ	YES
Regulation Number	876.1500	876.1500	YES
Indications for Use	The Nuvis Wireless Camera System is indicated for use in diagnostic and operative endoscopic procedures, supplying visualization of an interior cavity of the body	*The ArthroFree System is indicated for use in arthroscopy, general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery or wherever a laparoscope /endoscope/ arthroscope is indicated for use. The users of the camera are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons, neurosurgeons, and urologists.* *The ArthroFree System is indicated for use in diagnostic and operative endoscopic procedures, supplying illumination and*	YES. The NuVis Wireless HD Camera System Indications for Use are a sub-set of the predicate devices Indications for Use.

	supplying visualization of an interior cavity of the body.	*visualization of an interior cavity of the body.* Examples of common general endoscopic surgeries are listed below. • laparoscopic cholecystectomy • laparoscopic hernia repair • laparoscopic appendectomy • laparoscopic pelvic lymph node dissection • laparoscopically assisted hysterectomy • laparoscopic and thoracoscopic anterior spinal fusion • anterior cruciate ligament reconstruction • knee arthroscopy • shoulder arthroscopy • small joint arthroscopy • decompression fixation • wedge resection • lung biopsy • pleural biopsy • dorsal sympathectomy • pleurodesis • internal mammary artery dissection for coronary artery bypass • coronary artery bypass grafting where endoscopic visualization is indicated • examination of the evacuated cardiac chamber during performance of valve replacement	
System Components	-Wireless Camera Head with Battery & Battery Charger -Receiver (wireless base station) -Sterilization Tray -Cables	-Wireless Camera Head Battery & Battery Charger -Receiver -Sterilization Tray -Cables	YES.
Camera Battery	Rechargeable	Rechargeable	YES
Reusable	Yes	Yes	YES
Cleanable	Yes	Yes	YES
Camera Head Control Buttons	Yes	Yes	YES
Sterilization (camera head)	Established Sterilization Method: Vaporized Hydrogen Peroxide	Established Sterilization Method: Vaporized Hydrogen Peroxide	YES
Principle of Operation	Wireless o FCC (Federal Communications Commission) Compliance o Wireless Co-Existence	Wireless o FCC (Federal Communications Commission) Compliance o Wireless Co-Existence	YES
Transmission distance	5 meters (15 feet)	Within 10 feet	YES

Compliance			
Electrical Safety	IEC 60601-1 IEC 60601-2-18	IEC 60601-1 IEC 60601-2-18	YES
EMC Compliance	IEC 60601-1-2	IEC 60601-1-2	YES
Rechargeable Batteries	IEC 62133-2 compliant	IEC 62133-2 compliant	YES
Usability	IEC 60601-1-6 EN 62366	IEC 60601-1-6	YES
Wireless Compliance	FCC Wireless Co-Existence	FCC Wireless Co-Existence	YES
Software			
Documentation Level	Basic (per "Content of Premarket Submissions for Device Software Functions" Guidance issued on June 14, 2023)	Moderate (per "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005)	YES. The FDA Software classifications were revised in 2023.

VIII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Nuvis Wireless HD Camera System has comparable technological characteristics (e.g., design, principle of operation, and energy source) as the predicate device (Lazurite ArthroFree Wireless Surgical Camera System).

IX. PERFORMANCE DATA SUMMARY

Performance Tests included:

Test	Test Summary
Electrical/thermal	IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance was conducted by a third party and passed.
Electromagnetic Compatibility	IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests was conducted by a third party and passed.
Essential Performance	IEC 60601-2-18 Endoscopic basic safety and essential performance was conducted by a third party and passed
Cleaning Validation	Cleaning Validation (ANSI/AAMI ST98: 2022) was conducted by a third party and passed.
Sterilization Validation	Sterilization Validation (ISO 22441: 2022 Sterilization of health care products-Low temperature vaporized Hydrogen Peroxide) was conducted by a third party and passed.
Camera Resolution Tests	Air Force Resolution Chart images obtained from the system were checked for Resolution, and the resolution was found to be at least 1920x1080 p.
Wireless Range Tests	With the camera head transmitter partially and fully covered, the wireless base station could receive data from the enabled camera head at a distance of 15 feet.
Battery Life/Durability Tests	The camera head rechargeable battery was charged to various charging levels and the length of time for imaging was measured. The length of time for imaging at various camera head charging levels was acceptable.
Wireless Co-existence	ANSI C63.27 Wireless Co-existence was conducted by a third party and passed.
Software	IEC 62304 Software Life Cycle Process was reviewed by a third party and passed.
Transportation	ISTA 3 Transportation/Packaging Tests was conducted by a third party and passed.
Usability	IEC 62366-1 Usability was reviewed by a third party and passed.
Communications	FCC Part 15 Compliance testing was conducted by a third party and passed.

FDA Recognized Consensus Standards Utilized

FDA Recognition Number	Description
19-49	IEC 60601-1 Ed. 3.2 en:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
19-36	IEC 60601-1-2 Edition 4.1 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
9-114	IEC 60601-2-18 Ed. 3.0 b:2009 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
5-129	IEC 62366-1 Ed. 1.1 b:2020 Medical devices - Part 1: Application of usability engineering to medical devices
13-79	IEC 62304 Ed. 1.1 b:2015 Medical device software - Software life cycle processes
5-126	ISTA 3A 2018 Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less
19-48	IEEE/ANSI C63.27-2021 American National Standard for Evaluation of Wireless Coexistence
19-22	AAMI TIR69:2017/(R2020) Risk management of radio-frequency wireless coexistence for medical devices and systems for wireless co-existence.
14-583	ANSI/AAMI ST98: 2022; Cleaning Validation of Health Care Products—Requirements for Development and Validation of a Cleaning Process for Medical Devices
14-578	EN ISO 17664-1:2021 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices (ISO 17664-1:2021)
14-586	ISO 22441: 2022 Sterilization of health care products-Low temperature vaporized hydrogen peroxide-Requirements for the development, validation and routine control of a sterilization process for medical devices
5-125	EN ISO 14971:2019 Medical devices – Application of risk management to medical devices (ISO 14971:2019)

FDA Guidance Documents Utilized

"Electronic Submission Template for Medical Device 510(k) Submissions" Guidance for Industry and Food and Drug Administration Staff. Document issued on October 2, 2023.

"Content of Premarket Submissions for Device Software Functions" Guidance for Industry and Food and Drug Administration Staff. Document issued on June 14, 2023.

"Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" Guidance for Industry and Food and Drug Administration Staff. Document issued on: March 17, 2015.

"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" Guidance for Industry and Food and Drug Administration Staff. Document issued on September 27, 2023.

"Radio Frequency Wireless Technology in Medical Devices" Guidance for Industry and Food and Drug Administration Staff. Document issued on: August 14, 2013.

"Electromagnetic Compatibility (EMC) of Medical Devices" Guidance for Industry and Food and Drug Administration Staff. Document issued on June 6, 2022.

XI CONCLUSION

The Nuvis Wireless HD Camera System has the same intended use as the predicate device (Lazurite ArthroFree Wireless Surgical Camera System) and similar technological characteristics to the predicate device, including comparable design, principle of operation, and energy source. The subject device incorporates additional features (tablet availability, storage ability, and increased battery life) that enhance convenience and functionality without altering the intended use or safety profile relative to the predicate device.

Based on the comparison of technological characteristics and performance data, the Nuvis Wireless HD Camera System (subject device) is substantially equivalent to the Lazurite ArthroFree Wireless Surgical Camera System (K213860).