December 2, 2024

IntraVu, Inc.
Jenna Rapoport
VP, Quality
610 Price Ave
Redwood City, California 94063

Re: K243020
Trade/Device Name: MIDASVu
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, GCJ
Dated: August 27, 2024
Received: September 27, 2024

Dear Jenna Rapoport:

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,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2024.12.02 14:41:29 -05'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic 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)*

K243020

Device Name

MIDASVu

Indications for Use *(Describe)*

The MIDASVu is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination and visualization of interior cavity joints and other body cavities through a natural or surgical opening.

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."

MIDASVU

510(K) SUMMARY

Date	November 26, 2024
Submitter:	IntraVu Inc.
Address:	610 Price Avenue Redwood City, CA 94063
Contact Person:	Jenna Rapoport
Telephone:	650-771-9373
Email:	jenna@intravu.com
Device Trade Name:	MIDASVu
Common Name:	Arthroscope
Classification Name and Number:	Arthroscope 21 CFR 888.1100
Device Classification:	II
Product Code:	HRX
Legally Marketed Predicate Device:	MIDAScope and Introducer Kit, and MIDASystem (K181982) Product Code HRX, 21 CFR 888.1100
Description of the MIDASVu	MIDASVu is an advanced imaging system comprised of sterile, single-use scopes (0° and 30° viewing angle) and a reusable tablet. The scopes include camera and image capture features with LED light source. The distal tip of the scopes contains the camera, illumination, and imaging optics. The scopes are available in three lengths: 60mm, 90mm, and 120mm. The scopes and tablet work in concert as a system to acquire, display and record an intra-articular image as well as store images and video taken during the procedure.
Indications for Use of the MIDASVu	MIDASVu is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination and visualization of interior cavity joints and other body cavities through a natural or surgical opening.

Performance Data: The MIDASVu underwent non-clinical testing to confirm safety, effectiveness, and performance. Electrical safety and EMC testing met IEC 60601 standards, while software validation ensured intended functionality. Biocompatibility testing per ISO 10993 confirmed material safety, and performance and environmental tests verified durability under stress. Software and cybersecurity measures were validated. Results demonstrate the device is as safe and effective as the predicate for its intended use.

Results of Clinical Studies: None

Summary of Technological Characteristics:

	IntraVu, Inc: MIDAScope and Introducer Set, and MIDASystem (K181982)	**IntraVu, Inc: MIDASVu**
Components	Disposable scope + reusable system	Same
Usage	Single use, disposable scope and reusable system	Same
Scope		
Imaging Optics	Scope contains camera, illumination (LED light source) and imaging optics	Same
Scope Shaft	Rigid stainless-steel shaft	Same
Sterility	Sterile (ethylene oxide), SAL 10^{-6}	Same
Rigidity	Rigid	Same
Maximum Insertion Portion width	1.5 mm	Similar
Working Lengths	60 mm, 90 mm, and 120 mm	Same
Field of View (FOV)	90° in air	Similar
Direction of View	0°	Different, due to addition of 30° scope
Optics and Image Acquisition	A lens is located on the distal tip of the scope, which forms the image onto the CMOS sensor (400 x 400 pixels) and the digital signal is transmitted via electrical wires to image processing hardware. Light fibers run in the shaft to provide illumination from an LED that is housed inside the disposable handle.	Same
Scope to System Connection	The MIDAScope is connected via a proximal (permanently attached) electrical cable and proximal electrical connector to the MIDASystem for viewing.	Same

	IntraVu, Inc: MIDAScope and Introducer Set, and MIDASystem (K181982)	IntraVu, Inc: MIDASVu
Tablet		
Electrical Power	The reusable MIDASystem with integrated LCD monitor provides power to the scope via a cable from the scope to the system.	Same
Display Type	HD touch screen; color LCD	Same
Resolution	1024 x 768 (124 pixels per inch)	Same
Media Capture	None	Different, added feature
Data Transfer	None	Different, added feature

Conclusion: The IntraVu's MIDASVu is substantially equivalent to the predicate device, IntraVu's MIDAScope and Introducer Kit, and MIDASystem (510(k) Number: K181982). Both devices share the same intended use, fundamental design, and core technology. The MIDASVu includes minor enhancements that do not affect the established safety and efficacy of the device. Non-clinical testing, including performance testing and safety assessments, demonstrated that the MIDASVu performs comparably to the predicate device and meets all applicable requirements. Therefore, the MIDASVu is as safe and effective as the predicate for its intended use.