August 21, 2018

IntraVu, Inc.
% Mr. Dave Yungvirt
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
Millburn, New Jersey 07041

Re: K181982
Trade/Device Name: MIDAScope and Introducer Kit, and MIDASystem
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, GCJ
Dated: July 23, 2018
Received: July 25, 2018

Dear Mr. 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,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K181982

Device Name
MIDAScope™ and Introducer Kit, and MIDASystem™

Indications for Use *(Describe)*
The MIDAScope™ and Introducer Kit, and MIDASystem™ are 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.

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510(K) SUMMARY

510(k) Applicant

IntraVu, Inc.
610 Price Avenue
Redwood City, CA 94063
Phone: (650) 395-6067

Contact Person

Plamena Entcheva-Dimitrov, PhD
Preferred Regulatory Consulting Inc.
Phone: (650) 533-2253
Email: entcheva@preferredregulatoryconsulting.com

Date of Summary

20 Aug 2018

Device Overview

Device Proprietary Name	MIDAScope™ and Introducer Kit, and MIDASystem™
Product Class	II
Regulation Name	Arthroscope
Regulation Number	888.1100
Product Code	HRX GCJ
Panel	Orthopedic

Predicate Device

510(k) Number	Product Name	Manufacturer
K162475	mi-eye 2 and mi-eye 2 Monitor (primary predicate)	Trice Medical, Inc.
K141326	NeedleView CH™ Scope Kits	BioVition Technologies, LLC
K152511	Neo-Arthroscope™ - Single Use Digital Video Arthroscopic System (reference device)	Prosurg, Inc.

Device Description

The MIDAScope™ is a miniaturized, sterile, single-use disposable scope. The image is acquired by an image sensor located at the distal tip. Illumination is provided by an LED and fibers when the disposable scope is connected to the reusable MIDASystem™ via an electrical cable. The scope is available in different lengths to accommodate different treatment locations. The scope is introduced into the joint space using the IntraVu disposable Introducer Kit, consisting of a cannula, trocar and stopcock, which are provided sterile in the same package as the scope.

The MIDASystem™ is a reusable device consisting of an integrated LCD display, and software that receives, processes and displays the images collected by the scope.

Intended Use

The device is intended to make visible the interior of a joint. The arthroscope and accessories also is intended to perform surgery within a joint.

Indications for Use

The MIDAScope™ and Introducer Kit, and MIDASystem™ are 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.

Comparison to Predicate Device

The MIDASystem and Introducer Kit and MIDAScope and predicate devices have the same intended use and thus fulfill the requirements of 513(i) of the FD&C Act (21 U.S.C. § 360c(i)). Subject device and predicates are similar in design, principle of operation, components, users and use environment. The subject scope and its predicates are sterilized with ethylene oxide to yield $SAL10^{-6}$. The subject system is reusable as are the predicate systems. The packaging of the MIDAScope (with the Introducer Kit), and MIDASystem and its predicates is similar and passed testing following the same internationally recognized standards. The subject device and the predicate devices were tested according to the same internationally recognized standards for electromagnetic compatibility, for electrical safety, and for biocompatibility and were shown to be safe and passed the standards' requirements.

Risks associated with the subject device and the predicates are similar. There are no significant technological differences between MIDASystem and MIDAScope (with the Introducer Kit) and the predicate devices.

Therefore, in conclusion, the subject devices MIDAScope (with the Introducer Kit), and MIDASystem are substantially equivalent to the predicates.

Performance Testing

Performance testing of the MIDAScope and Introducer Kit, and MIDASystem included structural and functional performance, software validation, electrical and EMC, biocompatibility, packaging and sterilization studies. Devices were subjected to environmental conditioning and simulated distribution to assure devices will perform as intended during marketing distribution. All tests met the pre-determined acceptance criteria at baseline and after aging. The following FDA-recognized standards were followed and the acceptance criteria set forth in them were met:

Scope performance:	ISO8600-1, ISO8600-3, and ISO8600-4
Biocompatibility:	ISO10993-1
Packaging validation:	ISO11607-1, ISO11607-2, ASTM D4169, ASTM F2096, ASTM F88/F88M
Sterilization validation:	ISO11135, ISO10993-7, ISO11737-1
Aging:	ASTM F1980
Environmental conditions:	ASTM D4332
Electrical and EMC testing:	IEC60601-1 and IEC60601-1-2

Safety and Effectiveness and Conclusion

Based on the evaluation of intended use, performance characteristics and meeting FDA-recognized standards for safety and performance, the MIDAScope™ and Introducer Kit, and the MIDASystem™ are substantially equivalent to the predicate device. The labeling of the MIDAScope and Introducer Kit, and MIDASystem contains instructions for use and any necessary cautions and warnings to assure safe and effective use of the device.