



December 23, 2025

Medimaging Integrated Solution, Inc (MiiS)
Sandy Chou
Regulatory Affairs
3f, # 24-2, Industry E. Rd. Iv, Hsinchu Science Park
Hsinchu, 30077
Taiwan

Re: K253217

Trade/Device Name: MiiS Horus Arthroscope (EJA 100); MiiS Horus Endoscope Display System - Tablet (EDS 500); MiiS Horus Endoscope Display System -Video Box (EVS 700)

Regulation Number: 21 CFR 888.1100

Regulation Name: Arthroscope

Regulatory Class: Class II

Product Code: HRX

Dated: September 25, 2025

Received: September 29, 2025

Dear Sandy Chou:

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: 2025.12.23 13:11:21
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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

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.

K253217

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Please provide the device trade name(s).

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MiiS Horus Arthroscope (EJA 100);
MiiS Horus Endoscope Display System -Tablet (EDS 500);
MiiS Horus Endoscope Display System -Video Box (EVS 700)

Please provide your Indications for Use below.

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MiiS Horus Arthroscope:

The MiiS Horus Arthroscope is a sterile and single-use device designed for operation with its compatible display system.

It is intended for use in diagnostic and operative arthroscopic and endoscopic procedures to provide visualization of an interior cavity of the body through a surgical opening.

The device is intended for use in a hospital or medical office environment and is designed for use in adults.

MiiS Horus Endoscope Display System -Tablet:

The MiiS Horus Endoscope Display System -Tablet is intend for use with compatible endoscopes to provide visualization for endoscopic diagnosis, treatment, and video observation.

MiiS Horus Endoscope Display System -Video Box:

The MiiS Horus Endoscope Display System -Video Box is intend for use with compatible endoscopes to provide visualization for endoscopic diagnosis, treatment, and video observation.

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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K253217

510(k) Summary

Prepared: September 25, 2025

Submitter/Owner's Name/ Address: Medimaging Integrated Solution Inc. (MiiS)
3F., No. 24-2, Industry E. Rd. IV, Hsinchu Science Park, Hsinchu, 30077,
Taiwan, R.O.C.

Contact Person: Sandy Chou

Telephone: +886-3-5798860 Ext: 1701

Fax: +886-3-5798011

Address: ra@miis.com.tw

Device Identification:

Trade/Device Name: Arthroscope: MiiS Horus Arthroscope (EJA 100)

Tablet: MiiS Horus Endoscope Display System -Tablet (EDS 500)

Video Box: MiiS Horus Endoscope Display System -Video Box (EVS 700)

Common Name: Arthroscope

Regulation Name: Arthroscope

Regulation Number: 21 CFR 888.1100

Regulatory Class: Class II

Product Code: HRX

Predicate Device:

K201134

Trade/Device Name: Arthrex NanoScope System

Regulation Number: 21 CFR 876.1500 and 888.1100

Regulatory Class: Class II

Product Code: GCJ, HRX

Description of Device:

MiiS Horus Arthroscope is a sterile and single-use device designed to be operated with its compatible display system. The device provides visualization for endoscopic procedures of an interior cavity of the body through a surgical opening.

The Arthroscope needs to connect with its compatible display system MiiS Horus Endoscope Display System -Tablet or MiiS Horus Endoscope Display System -Video Box and the signal captured was then transmitted to the cable-connected display system. Both the Tablet and Video box are reusable devices.

MiiS Horus Endoscope Display System –Tablet is a tablet which showing live image or snapshot from Arthroscope.

MiiS Horus Endoscope Display System -Video Box is a standalone imaging transfer system; it can be connected to computer to project live imaging. If needed, the pictures or videos can be storage to Tablet or computer.

Indications for Use

MiiS Horus Arthroscope:

The MiiS Horus Arthroscope is a sterile and single-use device designed for operation with its compatible display system.

It is intended for use in diagnostic and operative arthroscopic and endoscopic procedures to provide visualization of an interior cavity of the body through a surgical opening.

The device is intended for use in a hospital or medical office environment and is designed for use in adults.

MiiS Horus Endoscope Display System -Tablet:

The MiiS Horus Endoscope Display System -Tablet is intend for use with compatible endoscopes to provide visualization for endoscopic diagnosis, treatment, and video observation.

MiiS Horus Endoscope Display System -Video Box:

The MiiS Horus Endoscope Display System -Video Box is intend for use with compatible endoscopes to provide visualization for endoscopic diagnosis, treatment, and video observation.

Substantial Equivalence Summary

The MiiS Horus Arthroscope and compatible display system is substantially equivalent in intended use, technical specifications, performance and principles of operation to the predicate device; Arthrex Nanoscope System (K201134).

The indications for use for the MiiS Horus Arthroscope and compatible display system represent a subset of the cleared indications for the predicate Arthrex Nanoscope System. As a subset of the indications for the cleared device, this difference does not raise any new risks or issues related to safety or efficacy.

Below is a summary table that provides a top-level overview of the substantial equivalent comparison between proposed and predicate devices.

Item	Subject Device MiiS Horus Arthroscope (EJA 100)	Predicte Device Arthrex NanoScope System (K201134)
Submitter	Medimaging Integrated Solution Inc.	Arthrex Inc.
Model name	Arthroscope: MiiS Horus Arthroscope Tablet: MiiS Horus Endoscope Display System -Tablet	Arthrex NanoScope System

Item	Subject Device MiiS Horus Arthroscope (EJA 100)	Predicted Device Arthrex NanoScope System (K201134)
	Video Box: MiiS Horus Endoscope Display System -Video Box	
K Number	---	K201134
Product code & Classification	HRX Class II	HRX Class II
Principle System Components (Sterile, Disposable, Single Use)	MiiS Horus Arthroscope	Nanoscope
Principle System Components (Reusable)	MiiS Horus Endoscope Display System -Tablet MiiS Horus Endoscope Display System -Video Box	Nanoscope Control Unit
Intended use	<p>MiiS Horus Arthroscope: The MiiS Horus Arthroscope (EJA 100) is a sterile and single-use device designed for operation with its compatible display system. It is intended for use in diagnostic and operative arthroscopic and endoscopic procedures to provide visualization of an interior cavity of the body through a surgical opening. The device is intended for use in a hospital or medical office environment and is designed for use in adults.</p> <p>MiiS Horus Endoscope Display System -Tablet: The MiiS Horus Endoscope Display System -Tablet (EDS 500) is intended for use with compatible endoscopes to provide visualization for endoscopic diagnosis, treatment, and video observation.</p> <p>MiiS Horus Endoscope Display System -Video Box: The MiiS Horus Endoscope Display System -Video Box (EVS 700) is intended for use with compatible</p>	<p>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, sinusopic, and plastic surgical procedures. The device is also intended to be used as an accessory for microscopic surgery.</p>

Item	Subject Device MiiS Horus Arthroscope (EJA 100)	Predicate Device Arthrex NanoScope System (K201134)
	endoscopes to provide visualization for endoscopic diagnosis, treatment, and video observation.	
Technical Features		
Lens Specification	FOV: 120° DOV: 0° (EJA 100-0D)/ 30° (EJA 100-30D) DOF: 3-50 mm	FOV: 120° DOV: 0° DOF: 3 mm × 100 mm
Resolution	720x720	400x400
Illuminance	>100 Lux at 50 mm	49 Lux at 50 mm
Mechanical Specification	Working length: 125 mm Scope outer diameter: 2.2 mm (EJA 100-0D)/3.4 mm (EJA 100-30D)	Working length: 125 mm Scope outer diameter: 1.9 mm
LED Light source	At distal tip	Fiber at distal tip with LED in the handle
Bench test	ISO 8600-1 ISO 8600-3 ISO 8600-4	ISO 8600-1 ISO 8600-3 ISO 8600-4
Sterilization	EO Sterilization	EO Sterilization
Electrical Safety		
EMC	IEC 60601-1-2	IEC 60601-1-2
Safety	IEC 60601-1 IEC 60601-2-18	IEC 60601-1 IEC 60601-2-18
Materials		
Biocompatibility of Materials Meets ISO 10993-1 requirements	Meets ISO 10993-1 requirements for tissue/bone/dentin contact of limited duration (<24 hrs)	Meets ISO 10993-1 requirements for tissue/bone/dentin contact of limited duration (<24 hrs)

Summary of the technological characteristics in comparison to the predicate devices

Similarities

“MiiS Horus Arthroscope” and its compatible display system (MiiS Horus Endoscope Display System - Tablet (EDS 500) or MiiS Horus Endoscope Display System - Video Box (EVS 700)) and the predicate device, Arthrex Inc. Arthrex NanoScope System (K201134), have the same intended use in arthroscopic diagnostics and procedures. Both devices share the same key mechanical specifications such as working length and field of view (FOV). For model EJA 100-

OD, the direction of view (DOV) is also the same. In addition, the subject and predicate device have successfully passed the same testing, including EMC, safety, bench, package integrity, transportation, aging, and biocompatibility tests. Both devices are sterilized using the same EO method and comply with EO/ECH residue limits.

Differences

The differences pertain to the scope's outer diameter and the 30° direction of view (DOV) of model EJA 100-30D. The outer diameter is slightly larger but remains within the range of commonly used arthroscope sizes. The larger diameter enhances optical performance and structural strength. The 30° DOV, which is commonly available inarthroscopes, has been verified to meet specifications and performance requirements. Regarding depth of field (DOF), the subject device has a range of 3–50 mm, compared to 3 mm × 100 mm for the predicate device. Bench testing shows MiiS Horus Arthroscope provides comparable image resolution and illuminance. These differences do not introduce any new risks or concerns regarding safety or effectiveness. Therefore, the MiiS Horus Arthroscope is considered substantially equivalent to its predicate devices.

Nonclinical Tests

The following tests have been performed in support of the substantial equivalence determination:

- Electrical safety per IEC/EN 60601-1
- Electromagnetic Compatibility per IEC/EN 60601-1-2
- Sterilization Validation per ISO 11135
- Package Integrity per ISO 11607-1
- Transportation test per ASTM D4169
- Aging test per ASTM F1980
- Biocompatibility test per ISO 10993-1
 - Cytotoxicity test per ISO 10993-5
 - Sensitization test per ISO 10993-10
 - Irritation test per ISO 10993-23
 - Acute systemic toxicity and Pyrogen test per ISO 10993-11
- Optical and Color performance testing
- Software validation
- Cybersecurity test
- Endoscopic Performance test per ISO 8600
- EO/ECH residue test per ISO 10993-7

- Light hazard (photobiological safety) test per IEC 62471

Clinical Tests

No clinical studies were performed.

Conclusion

The substantial equivalence comparison, together with bench performance testing, supports the conclusion that the MiiS Horus Arthroscope is substantially equivalent to the predicate device, the Arthrex NanoScope System (K201134).