



May 5, 2025

Arthrex, Inc.
Lai Saeteurn
Senior Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108

Re: K250728

Trade/Device Name: Arthrex Synergy Vision Endoscopic Imaging System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ, IZI
Dated: March 10, 2025
Received: March 11, 2025

Dear Lai Saeteurn:

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,

Jessica Carr -S

Jessica Carr, PhD

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

510(k) Number (if known)

K250728

Device Name

Arthrex Synergy Vision Endoscopic Imaging System

Indications for Use (Describe)

The Arthrex Synergy Vision Endoscopic Imaging System is intended to be used as an endoscopic video camera to provide visible light imaging in a variety of endoscopic diagnostic and surgical procedures, including laparoscopy, orthopedic, plastic surgery, sinuscopy, spine, urology, and procedures within the thoracic cavity. The device is also intended to be used as an accessory for microscopic surgery.

The Arthrex Synergy Vision Endoscopic Imaging System is indicated for use to provide real time endoscopic visible and near-infrared fluorescence imaging. Upon intravenous administration and use of ICG consistent with its approved label, the system enables surgeons to perform minimally invasive surgery using standard endoscope visible light as well as visualization of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near-infrared imaging. Fluorescence imaging of biliary ducts with the Arthrex Synergy Vision Endoscopic Imaging System is intended for use with standard of care white light, and when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.

Upon interstitial administration and use of ICG consistent with its approved label, the Arthrex Synergy Vision Endoscopic Imaging System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

Upon administration and use of pafolacianine consistent with its approved label, the Arthrex Synergy Vision Endoscopic Imaging System is used to perform intraoperative fluorescence imaging of tissues that have taken up the drug.

The Arthrex NanoNeedle Scope when used with the Synergy Vision Endoscopic Imaging System is intended to be used as an endoscopic video camera to provide visible light imaging in a variety of endoscopic diagnostic and surgical procedures, including laparoscopy, orthopedic, plastic surgery, sinuscopy, spine, urology, and procedures within the thoracic cavity. The device is also intended to be used as an accessory for microscopic surgery. For pediatric patients, the Arthrex NanoNeedle Scope is indicated for laparoscopy and orthopedic procedures.

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.

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K250728

510(k) Summary

<i>Date Prepared</i>	April 21, 2025
<i>Submitter</i>	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
<i>Contact Person</i>	Name: Lai Saeteurn Phone: 239-643-5553 Email: Lai.Saeteurn@Arthrex.com
<i>Trade Name</i>	Arthrex Synergy Vision Endoscopic Imaging System
<i>Classification Name</i>	21 CFR 876.1500: Endoscope and accessories, 21 CFR 892.1600: Angiographic x-ray systems
<i>Product Code</i>	GCI, IZI
<i>Common Name</i>	Laparoscope, General & Plastic Surgery
<i>Regulatory Class</i>	Class II
<i>Primary Predicate Device</i>	K241361 Arthrex Synergy Vision Endoscopic Imaging System
<i>Additional Predicate Device</i>	K243008 Arthrex NanoScope System
<i>Purpose of Submission</i>	This Traditional 510(k) premarket notification is submitted to expand indications for the Arthrex Synergy Vision Endoscopic Imaging System. Arthrex is also reporting minor software updates and additional device models made since the previous clearance (K241361).
<i>Device Description</i>	The Arthrex Synergy Vision Endoscopic Imaging System includes a camera control unit (CCU) console, camera heads, endoscopes, and a laser light source. The system provides real-time visible light and near-infrared (NIR) illumination and imaging. The Arthrex Synergy Vision Endoscopic Imaging System uses an integrated LED light to provide visible light illumination and imaging of a surgical site. For NIR imaging, the system interacts with the laser light source to visualize the presence of a fluorescence contrast agent, indocyanine green (ICG) and pafolacianine. The contrast agent fluoresces when illuminated through the laparoscope with NIR excitation light from the laser light source and the fluorescent response is then imaged with the camera, processed, and displayed on a monitor.
<i>Indications for Use</i>	The Arthrex Synergy Vision Endoscopic Imaging System is intended to be used as an endoscopic video camera to provide visible light imaging in a variety of endoscopic diagnostic and surgical procedures, including laparoscopy, orthopedic, plastic surgery, sinuscopy, spine, urology, and procedures within the

	thoracic cavity. The device is also intended to be used as an accessory for microscopic surgery. The Arthrex Synergy Vision Endoscopic Imaging System is indicated for use to provide real time endoscopic visible and near-infrared fluorescence imaging. Upon intravenous administration and use of ICG consistent with its approved label, the system enables surgeons to perform minimally invasive surgery using standard endoscope visible light as well as visualization of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near-infrared imaging. Fluorescence imaging of biliary ducts with the Arthrex Synergy Vision Endoscopic Imaging System is intended for use with standard of care white light, and when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization. Upon interstitial administration and use of ICG consistent with its approved label, the Arthrex Synergy Vision Endoscopic Imaging System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes. Upon administration and use of pafolacianine consistent with its approved label, the Arthrex Synergy Vision Endoscopic Imaging System is used to perform intraoperative fluorescence imaging of tissues that have taken up the drug. The Arthrex NanoNeedle Scope when used with the Synergy Vision Endoscopic Imaging System is intended to be used as an endoscopic video camera to provide visible light imaging in a variety of endoscopic diagnostic and surgical procedures, including laparoscopy, orthopedic, plastic surgery, sinuscopy, spine, urology, and procedures within the thoracic cavity. The device is also intended to be used as an accessory for microscopic surgery. For pediatric patients, the Arthrex NanoNeedle Scope is indicated for laparoscopy and orthopedic procedures.
Performance Data	Design verification testing included inspection, engineering analysis and functional testing of the subject device. The test results confirm the subject device met Arthrex product requirements and design specifications for the device. The biocompatibility and sterility data for the subject device was leveraged from the biocompatibility testing and sterilization validation of the additional predicate devices, as there were no

modifications made to the subject device since prior clearances that would affect the biocompatibility or sterility of the device.

EMT and EMC testing was conducted on the subject device. The test results confirm the subject device conforms with EMT safety and EMC standards.

Software testing was conducted and documentation was provided in this submission. The test results confirm the Arthrex software updates met product requirements and design specifications established for the device.

Technological Comparison

Device & Predicate Devices		Arthrex Synergy Vision Endoscopic Imaging System K250728	Arthrex Synergy Vision Endoscopic Imaging System K241361	Arthrex NanoScope System K243008
System Components		Camera Control Unit, Camera Head, Light Source, Endoscope	Camera Control Unit, Camera Head, Light Source, Endoscope	Camera Control Unit, Endoscope
Imaging Modes		White Light, NIR Fluorescence	White Light, NIR Fluorescence	White Light
Power Rating		100-240V ~50/60 Hz	100-240V ~50/60 Hz	100-240V ~50/60 Hz
Light Source		Integrated (Visible), External (NIR)	Integrated (Visible), External (NIR)	Integrated (Visible)
Image Resolutions		3840 x 2160, 400 x 400 (Nano), 720 x 720 (Nano)	3840 x 2160	400 x 400
Frame Rate		60 fps, 30 fps (Nano)	60 fps	30 fps
Scope	Type	Rigid Rod Lens, Chip on Tip (Nano)	Rigid Rod Lens	Chip on Tip
	Image Sensor	CMOS	CMOS	CMOS
	Angle of View	0°, 30°, 45° 0° (Nano)	0°, 30°, 45°	0
	Field of View	75°, 120° (Nano)	75°	120°
	Diameter	5.5 mm, 10 mm 1.9 mm (Nano)	5.5 mm, 10 mm	1.9 mm
	Length	302 – 333 mm 125, 180, 250 mm (Nano)	302 – 333 mm	125, 180, 250 mm
Fluorescence Imaging Excitation Source		NIR Laser	NIR Laser	--
Excitation Wavelength		785 nm	785 nm	--
Detection Bandwidth		810 – 940 nm	810 – 940 nm	--
Excitation Light Source Intensity		95 W/m ²	95 W/m ²	--

Conclusion

All verification activities were successfully completed to confirm the subject device meets product requirements and design specifications established for the device, including compliance with FDA-recognized standards for EMT safety, EMC, biological safety, and recommendations per FDA guidance document for software testing.

The Arthrex Synergy Endoscopic Imaging System did not require animal testing or human clinical studies to support the determination of substantial equivalence.

Based on the same intended use, the same or similar indications for use and technological characteristics, and successful completion of non-clinical testing, the Arthrex Synergy Vision Endoscopic Imaging System is as safe and effective as the legally marketed predicate devices. Any differences between the subject device and predicate devices are considered minor and do not raise different questions concerning safety and effectiveness.