October 16, 2025

Arthrex, Inc.
Lai Saeteurn
Official Correspondent
1370 Creekside Blvd.
Naples, Florida 34108

Re: K251994
Trade/Device Name: Arthrex Synergy Vision Imaging System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ, OWN, IZI
Dated: June 27, 2025
Received: June 27, 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

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)*
K251994

Device Name
Arthrex Synergy Vision Imaging System

Indications for Use *(Describe)*
The Arthrex Synergy Vision imaging system is intended to provide visible light imaging in a variety of 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 imaging system is indicated for use to provide real-time visible and near-infrared fluorescence imaging. Upon intravenous administration and use of ICG consistent with its approved label, the system enables surgeons to perform open and 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 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. Additionally, the system is indicated for fluorescence imaging of blood flow and tissue perfusion before, during, and after vascular, gastrointestinal, organ transplant, plastic, micro- and reconstructive surgical procedures.
Upon interstitial administration and use of ICG consistent with its approved label, the Arthrex Synergy Vision 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 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 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.

The Arthrex 4K Open Scope 0° NIR is intended to be used as an accessory with the Synergy Vision imaging system to provide visible light imaging and near-infrared fluorescence imaging during open surgical 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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510(k) Summary

Date Prepared	October 14, 2025
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Lai Saeteurn Phone: 239-643-5553 Email: Lai.Saeteurn@Arthrex.com
Trade Name	Arthrex Synergy Vision Imaging System
Classification Name	21 CFR 876.1500: Endoscope and accessories, 21 CFR 892.1600: Angiographic x-ray systems
Product Code	GCJ, IZI, OWN
Common Name	Laparoscope, General & Plastic Surgery, Confocal Optical Imaging
Regulatory Class	Class II
Primary Predicate Device	K250728 Arthrex Synergy Vision Endoscopic Imaging System
Additional Predicate Device	K200737 Novadaq Technologies ULC SPY Portable Handheld Imaging (SPY-PHI) System
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to expand indications for the Synergy Vision Imaging System and to introduce a new device model designed to support the proposed indications.
Device Description	The Synergy Vision Imaging System includes a camera control unit (CCU) console, camera head, scope, and a laser light source. The system provides real-time visible light and near-infrared (NIR) illumination and imaging. The Synergy Vision 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 scope 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.
Indications for Use	The Synergy Vision imaging system is intended to provide visible light imaging in a variety of 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 Synergy Vision imaging system is indicated for use to provide real-time visible and near-infrared fluorescence imaging. Upon intravenous administration and use of ICG consistent with its approved label, the system enables surgeons to perform open and 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 Synergy Vision 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. Additionally, the system is indicated for fluorescence imaging of blood flow and tissue perfusion before, during, and after vascular, gastrointestinal, organ transplant, plastic, micro- and reconstructive surgical procedures. Upon interstitial administration and use of ICG consistent with its approved label, the Synergy Vision 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 Synergy Vision imaging system is used to perform intraoperative fluorescence imaging of tissues that have taken up the drug. The NanoNeedle Scope when used with the Synergy Vision 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 NanoNeedle Scope is indicated for laparoscopy and orthopedic procedures. The 4K Open Scope 0° NIR is intended to be used as an accessory with the Synergy Vision imaging system to provide visible light imaging and near-infrared fluorescence imaging during open surgical procedures.
Performance Data	Design verification activities included engineering analysis and functional testing. The results confirmed that the subject device

met all applicable Arthrex product requirements and design specifications.

A design validation study was conducted using a porcine model to evaluate system performance during fluorescence imaging in open-field surgical procedures. The study included a comparative assessment with the additional predicate device and demonstrated that the Synergy Vision imaging system performed equivalently or better in visualizing ICG.

An assessment was performed to confirm that the subject device presents an equivalent or lesser challenge to the effectiveness of the cleaning and sterilization processes when compared to a validated master device.

A biocompatibility assessment determined that no additional testing was required to support the intended use of the subject device.

No modifications were made to the device that would impact electromagnetic safety or compatibility; therefore, existing EMT and EMC test reports from prior Arthrex submissions were used to support this submission.

No software changes were reported; therefore, no new software testing or documentation was required or provided in this submission.

Technological Comparison

	Arthrex Synergy Vision System (This Submission)	***Arthrex Synergy Vision Endoscopic Imaging System K250728 (Primary Predicate)***	***Novadaq Technologies ULC SPY Portable Handheld Imaging (SPY-PHI) System K200737 (Additional Predicate)***
System Components	Camera Control Unit, Camera Head, Light Source, Light Guide Cable, Scope	Camera Control Unit, Camera Head, Light Source, Light Guide Cable, Scope	Camera Control Unit, Scope (with integrated light guide cable)
Imaging Modes	White Light, Near-Infrared	White Light, Near-Infrared	White Light, Near-Infrared (SPY, Overlay, Color Segmented Fluorescence)
Light Source	Visible (Integrated), NIR (External)	Visible (Integrated), NIR (External)	Visible (Integrated), NIR (Integrated)
Excitation Wavelength	785 nm	785 nm	805 nm
Detection Bandwidth	810 – 940 nm	810 – 940 nm	Not Available
Excitation Light Source Intensity	95 W/m^2	95 W/m^2	Not Available

Power Rating		100-240 V~ 50/60 Hz	100-240 V~ 50/60 Hz	100-240 V~ 50/60 Hz
Laser Safety Class		Class I	N/A	Class 3R
Scope	Type	Rigid Rod Lens	Rigid Rod Lens, Chip on Tip (Nano)	Not Available
	Image Sensor	CMOS	CMOS	CMOS
	Angle of View	0°	0°, 30°, 45° 0° (Nano)	Not Available
	Field of View	42°	75°, 120° (Nano)	Not Available
	Diameter	10 mm	5.5 mm, 10 mm 1.9 mm (Nano)	Not Available
	Length	20.75 mm	302 – 333 mm 125, 180, 250 mm (Nano)	Not Available
	Resolution	3840 x 2160	3840 x2160, 400 x 400 (Nano), 720 x 720 (Nano)	1920 x 1080
Contrast Agent		Indocyanine Green	N/A	Indocyanine Green
Reprocessing Method		Cleaning/Disinfection (Console, Laser), Steam (Camera Head), Steam or Hydrogen Peroxide (Scope)	Cleaning/Disinfection (Console, Laser), Ethylene Oxide (Nano), Steam or Hydrogen Peroxide (Scope)	Cleaning/Disinfection
Single Use		No	Yes (Nano)	No

Conclusion

All verification and validation activities were successfully completed and confirm that the Synergy Vision imaging system meets product requirements, design specifications, and user needs established for the device, including compliance with FDA-recognized standards for EMT safety, EMC, reprocessing of reusable devices, and software validation testing in accordance with relevant FDA guidance documents.

The Synergy Vision imaging system did not require 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 Synergy Vision 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.