July 25, 2024

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

Re: K241361
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: May 10, 2024
Received: May 14, 2024

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.

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, Ph.D.
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)*
K241361

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 but not limited to: orthopedic, spine, laparoscopic, urologic, sinuscopic, plastic surgical procedures, 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) Summary

Date Prepared	July 11, 2024
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 Endoscopic Imaging System
Classification Name	21 CFR 876.1500: Endoscope and accessories, 21 CFR 892.1600: Angiographic x-ray systems
Product Code	GCJ, IZI
Common Name	Endoscopic Imaging System
Regulatory Class	Class II
Primary Predicate Device	K233451 Arthrex Synergy Vision Endoscopic Imaging System
Additional Predicate Device	K221611 Stryker 780 nm L11 LED Light Source with AIM
Purpose of Submission	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 device modifications since the previous clearance (K233451).
Device Description	The Arthrex Synergy Vision Endoscopic Imaging System includes a camera control unit (CCU) console, camera heads, endoscopes, laparoscopes, 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.
Indications for Use	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 but not limited to: orthopedic, spine, laparoscopic, urologic, sinuscopic, plastic surgical procedures, 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.
Performance Data	Software testing was performed in accordance with recommendations in FDA guidance document "Content of Premarket Submissions for Device Software Functions" (issued June 2023) and IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes (FDA Recognition Number: 13-79). Design verification testing included engineering analysis and functional testing to evaluate the system's NIR fluorescence imaging modality and characterize its ability to detect pafolacianine. The test results confirm the Arthrex Synergy Vision Endoscopic Imaging System is compatible for use with pafolacianine for NIR imaging. Comparison testing with the additional predicate device (K221611) was conducted to support substantial equivalence. The test results demonstrate that the Arthrex Synergy Vision Endoscopic Imaging System is equivalent or better to the performance of the additional predicate device (K221611) in visualizing pafolacianine.
Technological Comparison	

Device	***Arthrex Synergy Vision Endoscopic Imaging System (This Submission)***	***Arthrex Synergy Vision Endoscopic Imaging System K233451 (Primary Predicate)***	***Stryker 780 nm L11 LED Light Source with AIM K221611 (Additional Predicate)***	***Comparison***
Classification	Class II	Class II	Class II	Equivalent
Product Code	GCJ, IZI	GCJ, IZI	OWN	The subject device and primary predicate have the same product code.
21 CFR	876.1500 Endoscope and Accessories	876.1500 Endoscope and Accessories	876.1500 Endoscope and Accessories	Equivalent
Combination Product	No	No	No	Equivalent

	Indications For Use	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 but not limited to: orthopedic, spine, laparoscopic, urologic, sinuscopic, plastic surgical procedures, 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	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 but not limited to: orthopedic, spine, laparoscopic, urologic, sinuscopic, plastic surgical procedures, 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	780 nm L11 LED Light Source with AIM and SafeLight Cable: Upon intravenous administration of SPY AGENT GREEN (indocyanine green for injection, USP), the 780 nm L11 LED Light Source with AIM and SafeLight Cable are used with SPY AGENT GREEN to provide real-time endoscopic visible and near infrared fluorescence imaging. The 780 nm L11 LED Light Source with AIM and SafeLight Cable enable surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion in adults and pediatric patients aged one month and older, and visualization of at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and	The subject device and additional predicate device are indicated for use with pafolacianine consistent with its approved label.

	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	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.	common hepatic duct) in adults and pediatric patients 12 to 17 years of age, using near-infrared imaging. Fluorescence imaging of biliary ducts with the 780 nm L11 LED Light Source with AIM and SafeLight Cable is intended for use with standard-of-care white light and, when indicated, intraoperative cholangiography. The devices are not intended for standalone use for biliary duct visualization. Additionally, the 780 nm L11 LED Light Source with AIM and SafeLight Cable enable surgeons to perform minimally invasive cranial neurosurgery in adults and pediatric patients and endonasal skull base surgery in adults and pediatric patients >6 years of age using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related	

		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.		tissue perfusion using near infrared imaging. Upon interstitial administration of SPY AGENT GREEN, the 780 nm L11 LED Light Source with AIM and SafeLight Cable are 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 780 nm L11 LED Light Source with AIM and SafeLight Cable are used to perform intraoperative fluorescence imaging of tissues that have taken up the drug. The 780 nm L11 LED Light Source with AIM is also intended to transilluminate the ureter during open or laparoscopic surgical procedures.	

System Components	Camera Control Unit, Camera Head, Light Source, Scopes	Camera Control Unit, Camera Head, Light Source, Scopes	Camera System, Light Source, SafeLight Cable, Laparoscopes, IRIS Ureteral Kit	The subject device and primary predicate have the same system components.
Imaging Modes	White Light, NIR Fluorescence	White Light, NIR Fluorescence	White Light, NIR Fluorescence, NIR Trans-Illumination	The subject device and predicates provide white light and NIR fluorescence imaging and visualization.
Safety Standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-18, IEC 60825-1, IEC TR 60601-4-2	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-18, IEC 60825-1, IEC TR 60601-4-2	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-18, IEC 60601-1-6, IEC 60825-1	The subject device and predicate devices are compliant with the same safety standards.
Power Rating	100-240V ~50/60 Hz	100-240V ~50/60 Hz	100-240V ~50/60 Hz	Equivalent
Light Source	Integrated (Visible), External (NIR)	Integrated (Visible), External (NIR)	Integrated (Visible), External (NIR)	Equivalent
Image Sensor	CMOS	CMOS	CMOS	Equivalent
Image Resolution	3840 x 2160	3840 x 2160	3840 x 2160	Equivalent
Frame Rate	60 FPS	60 FPS	60 FPS	Equivalent
Fluorescence Imaging Excitation Source	NIR Laser	NIR Laser	NIR Laser	Equivalent
Excitation Wavelength	785 nm	785 nm	780 nm	The subject device has a similar excitation wavelength than the additional predicate device.
Detection Bandwidth	810 to 940 nm	810 to 940 nm	795 to 900 nm	The subject device has a wider detection bandwidth than the additional predicate device.

Excitation Light Source Intensity		95 W/m^2	95 W/m^2	Not Available	The subject device is equivalent to the primary predicate device.
Lateral Resolution		800 LLLP	800 LLLP	Not Available	The subject device is equivalent to the primary predicate device.
LED Maximum Light Intensity		535 Lumens	535 Lumens	Not Available	The subject device is equivalent to the primary predicate device.
Contrast Agent		Indocyanine Green (ICG), Pafolacianine (CYTALUX)	Indocyanine Green (ICG)	Indocyanine Green (ICG), Pafolacianine (CYTALUX)	The subject device and additional predicate are compatible for use with pafolacianine for NIR fluorescence imaging.
NIR Scope	***Viewing Angle***	0°, 30°, 45°	0°, 30°, 45°	0°, 30°	The subject device has a greater angle of view than the additional predicate device.
	Diameter	5.5 mm, 10 mm	5.5 mm, 10 mm	5.4 mm, 10 mm	Equivalent
	Length	302 – 333 mm	302 – 333 mm	300 – 330 mm	The subject device is slightly longer than the additional predicate device.
	Field of View	75°	75°	70° – 80°	The subject device field of view is within range of the additional predicate device.

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.