January 18, 2024

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

Re: K233451
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: October 19, 2023
Received: October 20, 2023

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, 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.

Submission Number *(if known)*

K233451

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.

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.

K233451 510(k) Summary

Date Prepared	October 19, 2023
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Lai Saeteurn Title: Regulatory Affairs Specialist II Phone: 239-643-5553 Email: Lai.Saeteurn@Arthrex.com
Trade Name	Arthrex Synergy Vision Endoscopic Imaging System
Common Name	21 CFR 876.1500: Endoscope and accessories 21 CFR 892.1600: Angiographic x-ray systems
Product Code	GCJ, IZI
Classification Name	Laparoscope, General & Plastic Surgery
Regulatory Class	Class II
Primary Predicate Device	K223759 Arthrex SynergyID Endoscopic Imaging System
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Synergy Vision Endoscopic Imaging System.
Device Description	The Arthrex Synergy Vision Endoscopic Imaging System includes a non-sterile camera control unit (CCU) console, camera heads, a laser light source, and endoscope. The system integrates ultra-high-definition camera technology, light emitting diode (LED) lighting, and an image management system into a single console with a tablet interface. The system provides real-time visible and near-infrared light illumination and imaging. The Arthrex Synergy Vision Endoscopic Imaging System interacts with the laser light source to be able to provide near-infrared (NIR) imaging to visualize the presence of Indocyanine Green (ICG). The ICG fluoresces when illuminated through a laparoscope with NIR excitation light from the laser light source and the fluorescence 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.
Performance Data	Non-clinical testing was developed and performed on the Arthrex Synergy Vision Endoscopic Imaging System to confirm the device meets product requirements and device specifications. These tests included design verification, software testing, biocompatibility testing, electrical safety, and electromagnetic compatibility (EMC) testing. The testing methods are the same between the subject device and predicate device. Biological testing and toxicological risks assessments were performed in accordance with ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (FDA Recognition Number: 2-258); ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (FDA Recognition Number: 2-245); ISO 10993-12:2021, Biological evaluation of

	medical devices - Part 12: Sample preparation and reference materials (FDA Recognition Number: 2-289); ISO 10993-17:2002, Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (FDA Recognition Number: 2-237); and ISO 10993-18:2020, Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (FDA Recognition Number: 2-298). Electrical safety and EMC testing was performed in accordance with IEC 60601-1 Edition 3.2 2020-08, CONSOLIDATED VERSION Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (FDA Recognized Number: 19-49); IEC 60601-1-2 Edition 4.1 2020-09, CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (FDA Recognized Number: 19-36); IEC 60601-1-6:2010, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (FDA Recognition Number: 5-89), IEC 60601-2-18:2009, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment (FDA Recognition Number: 9-114); and IEC TR 60601-4-2:2016, Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems (FDA Recognition Number: 19-19). Software testing was performed in accordance with recommendations in FDA guidance document “Content of Premarket Submissions for Device Software Functions” (issued June 2023). Design verification testing included inspection, engineering analysis, and functional testing of the subject device, both as a system and as individual components. The test results confirm the subject device met Arthrex product requirements and design specifications for the device.

	Biological testing and toxicological risks assessments were conducted and test results confirm the subject device is biocompatible for its intended use. Electrical safety and EMC testing was conducted on the subject device. The test results confirm the subject device conforms with electrical safety and EMC standards. Software testing was conducted and documentation was provided in this submission. The test results confirm the Arthrex software functions met product requirements and design specifications for the device
Technological Comparison	The Arthrex Synergy Vision Endoscopic Imaging System has the same intended use and indications for use as the predicate device. The subject device and predicate device have the same technological characteristics (i.e., principle of operation, accessories/components, user interface, basic software design, cleaning/reprocessing requirements, wireless technology, electrical safety, and EMC) with differences in user interface workflow/layout, internal hardware components, and additional device accessories.
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 electrical safety, electromagnetic compatibility, 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/indications for use, similar 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 device. Any differences between the subject device and predicate device are considered minor and do not raise different questions concerning safety and effectiveness.