Arthex Inc.
Troy Brooks
Regulatory Affairs Team Lead
1370 Creekside Boulevard
Naples, Florida 34108-1945

February 24, 2023

Re: K223759
Trade/Device Name: Arthrex SynergyID Endoscopic Imaging System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ, IZI
Dated: February 16, 2023
Received: February 17, 2023

Dear Troy Brooks:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Colin K. Chen -S

Colin Kejing Chen
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223759

Device Name
Arthrex SynergyID Endoscopic Imaging System

Indications for Use *(Describe)*
The Arthrex SynergyID 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 SynergyID 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 SynergyID 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 SynergyID 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.

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510(k) Summary

Date Prepared	January 27, 2023
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Troy Brooks, RAC Regulatory Affairs Team Lead 1-239-643-5553 Troy.Brooks@Arthrex.com
Name of Device	Arthrex Synergy^{ID} Endoscopic Imaging System
Common Name	Endoscopic Video Imaging System
Product Code	GCJ, IZI
Classification Name	21 CFR 876.1500: Endoscope and accessories 21 CFR 892.1600: Angiographic x-ray systems
Regulatory Class	II
Primary Predicate Device	K202582 - Arthrex Synergy^{ID} Endoscopic Imaging System, Arthrex Inc.
Additional Predicate Devices	K182606 - PINPOINT Endoscopic Fluorescence Imaging System, Novadaq Technologies K201526 - TIPCAM1 Rubina Video Endoscope System, Karl Storz Endoscopy America K201134 - Arthrex NanoScope System, Arthrex Inc.
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for expanded indications for use for the existing Arthrex Synergy^{ID} Endoscopic Imaging System cleared under K202582.
Device Description	The Arthrex Synergy^{ID} Endoscopic Imaging System includes a non-sterile camera control unit (CCU) console, camera heads, a laser light source, and laparoscopes. The system integrates ultra-high-definition camera technology, 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^{ID} Endoscopic Imaging System CCU 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^{ID} 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^{ID} 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^{ID} 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^{ID} Endoscopic Imaging System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

Technological Comparison

Device	Arthrex Synergy^{ID} Endoscopic Imaging System Subject Device	Arthrex Synergy^{ID} Endoscopic Imaging System K202582 Primary Predicate	Novadaq PINPOINT Endoscopic Fluorescence Imaging System K182606 Additional Predicate	Karl Storz TIPCAM1 Rubina Video Endoscope System K201526 Additional Predicate	Arthrex NanoScope System K201134 Additional Predicate	Comparison
Classification	Class II	Class II	Class II	Class II	Class II	Equivalent
Product Code	GCJ, IZI	GCJ, IZI	GCJ, IZI	GCJ, FGB, HET	GCJ, HRX	Equivalent
21 CFR	876.1500 Endoscope and Accessories	876.1500 Endoscope and Accessories	876.1500 Endoscope and Accessories	876.1500 Endoscope and Accessories	876.1500 Endoscope and Accessories	Equivalent
Combination Product	No	No	No	No	No	Equivalent
Indications For Use	The Arthrex Synergy^{ID} Endoscopic Imaging System is intended to be used as an endoscopic video camera to provide visual 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^{ID} 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	The Arthrex Synergy^{ID} Endoscopic Imaging System is intended to be used as an endoscopic video camera in a variety of endoscopic surgical procedures, including but not limited to: orthopedic, laparoscopic, urologic, sinuscopic, and plastic surgical procedures. The device is also intended to be used as an accessory for microscopic surgery. The Arthrex Synergy^{ID} 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	Upon intravenous administration of TRADENAME (ICG drug product), the PINPOINT Endoscopic Fluorescence Imaging System is used with TRADENAME to perform intraoperative fluorescence angiography, and it is also indicated for use in fluorescence imaging of biliary ducts, and when indicated, during intraoperative cholangiography. The PINPOINT Endoscopic Fluorescence Imaging System is indicated for use to provide real time endoscopic visible and near-infrared fluorescence imaging. The PINPOINT System enables surgeons to perform minimally invasive surgery using standard endoscope visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major	The TIPCAM1 Rubina Video Endoscope System is intended to be used together with the camera control unit during diagnostic and/or surgical procedures when endoscopic video assistance is required. For use in all endoscopy and endoscopic surgery within the peritoneal and thoracic cavity, including gynecological and urological anatomy.	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, sinuscopic, and plastic surgical procedures. The device is also intended to be used as an accessory for microscopic surgery.	The subject device includes the following additional indications for use: - fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes - use as an endoscopic video camera (i.e. visual imaging) in diagnostic and surgical procedures for spine and within the thoracic cavity

	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^{ID} 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^{ID} Endoscopic Imaging System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.	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^{ID} 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.	extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near-infrared imaging. Fluorescence imaging of biliary ducts with the PINPOINT 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 of TRADENAME (ICG drug product), the PINPOINT System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.			
System Components	Camera Control Unit Light Source Camera Heads Scopes	Camera Control Unit Light Source Camera Heads Scopes	Video Processor Illuminator (VPI) Camera Head Scopes	Camera Control Unit Camera/Scope (integrated)	Console Camera/Scope (integrated)	Equivalent to the primary predicate K202582. Similar to predicates K182606 and K201526.

Imaging Modes	White Light NIR Fluorescence	White Light NIR Fluorescence	White Light NIR Fluorescence	White Light	White Light	Equivalent per white light indications and NIR fluorescence indications.
Safety Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-18 IEC 60825-1	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-18 IEC 60825-1	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-18 IEC 60825-1	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-18	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-18	Equivalent
Light Source	Integrated (Visible) External (NIR)	Integrated (Visible) External (NIR)	Integrated	Integrated	Integrated	Equivalent to primary predicate K202582.
Image Sensor	CMOS	CMOS	CMOS	CMOS	CMOS	Equivalent
Image Resolution	3840 x 2160	3840 x 2160	1920 x 1080	3840 x 2160	400 x 400	Equivalent to predicates K202582 and K201526.
Frame Rate	60 FPS	60 FPS	60 FPS	60 FPS	30 FPS	Equivalent to predicates K202582, K182606 and K201526.
Fluorescence Imaging Excitation Source	NIR laser	NIR laser	NIR laser	N/A	N/A	Equivalent
Excitation Wavelength	785nm	785nm	805nm	N/A	N/A	Equivalent to primary predicate K202582. Similar to predicate K182606.
Detection Bandwidth	810 to 940 nm	810 to 940 nm	825 to 850 nm	N/A	N/A	Equivalent to primary predicate K202582. Similar to predicate K182606. See Note 1.
Excitation Light Source Intensity	95 W/m^2	95 W/m^2	Light source is pulsed (20 pulses/s, 2 mJ/pulse)	N/A	N/A	Equivalent to primary predicate K202582. Similar to predicate K182606. See Note 2 and Note 3.
Maximum Light Intensity	535 lumens	535 lumens	Light source is pulsed (20 pulses/s, 2 mJ/pulse)	N/A	N/A	
Maximum Output Power	1.37W	1.37W	Light source is pulsed (20 pulses/s, 2 mJ/pulse)	N/A	N/A	
Depth of Observation	5 – 10mm	5 – 10mm	Not available	N/A	N/A	Equivalent to primary predicate K202582. See Note 3.
Lateral Resolution	800 LLLP	800 LLLP	Not available	N/A	N/A	
Contrast Agent	Indocyanine Green (ICG)	Indocyanine Green (ICG)	Indocyanine Green (ICG)	N/A	N/A	Equivalent
NIR Scope Viewing Angle	0°, 30°, 45°	0°, 30°, 45°	0°, 30°, 45°	N/A	N/A	Equivalent

NIR Scope Diameter	5.5mm, 10mm	5.5mm, 10mm	5.5mm, 10mm	N/A	N/A	Equivalent
NIR Scope Length	302 – 333mm	302 – 333mm	300 – 420mm	N/A	N/A	Equivalent to primary predicate K202582. Within range of predicate K182606.
NIR Scope Field of View	75°	75°	70° - 75°	N/A	N/A	Equivalent
(Visible) Scope Viewing Angle	Endoscopes: 0°, 30°, 45°, 70° ---------- Spine Endoscopes: 15°, 30°	Endoscopes: 0°, 30°, 45°, 70°	N/A	0°, 30°	0°	Endoscopes: See Note 4. ---------- Spine Endoscopes : See Note 5.
(Visible) Scope Diameter	Endoscopes: 1.9mm – 10mm ---------- Spine Endoscopes: 6.3mm - 10mm	Endoscopes: 1.9mm – 10mm	N/A	10mm	1.9mm	Endoscopes: See Note 4. ---------- Spine Endoscopes : See Note 5.
(Visible) Scope Length	Endoscopes: 58mm – 459mm ---------- Spine Endoscopes: 130 - 181mm	Endoscopes: 58mm – 459mm	N/A	317 - 320mm	95mm	Endoscopes: See Note 4. ---------- Spine Endoscopes : See Note 5.
(Visible) Scope Field of View	Endoscopes: 75°- 105° ---------- Spine Endoscopes: 80°	Endoscopes: 75°- 105°	N/A	82°	120°	Endoscopes: See Note 4. ---------- Spine Endoscopes : See Note 5.

Note 1: Detection Bandwidth for the subject device: NIR Sensor Spectral Response peak of 840nm, 50% response: 810nm - 940nm. Because the subject device has wider detection bandwidth than the predicate K182606, this difference does not impact safety and effectiveness.

Note 2: The subject device has continuous wave laser whereas the predicate K182606 laser is pulsed. This difference does not impact safety and effectiveness as it is a system design decision only. Additionally, the existing Synergy^{ID} Endoscopic Imaging System (K202582) was deemed to be substantially equivalent to the PINPOINT Endoscopic Fluorescence Imaging System (K150956).

Note 3:
Subject Device:
Excitation light source intensity: ~95W/m^2 at Light Guide Exit
Maximum light intensity: 535 lumens measured at Endoscope tip, 10mm 0 deg scope
Maximum output power: 1.37W
Dept of observation: 5-10mm
Lateral Resolution: NIR Resolution > 800 LPPH (Lines Per Picture Height) measured using an infrared resolution chart

Predicate K182606:
Dept of observation: Information is not available
Lateral Resolution: Information is not available

Note 4: These endoscopes are existing accessories to the Synergy^{ID} Endoscopic Imaging System (K202582). The FDA clearance applicable to these scopes is K941541 and K080560. Safety and effectiveness of the scopes for use in diagnostic and surgical procedures has been previously established as cleared by the FDA under K941541 and K080560.

Note 5: The spine endoscopes are accessories to the Synergy^{ID} Endoscopic Imaging System. The FDA clearance applicable to the spine endoscopes is K130778. Safety and effectiveness of the spine endoscopes for visualization during spinal endoscopic procedures has been previously established as cleared by the FDA under K130778. As demonstrated within the submission, Arthrex has verified compatibility of the spine endoscopes with the Synergy^{ID} Endoscopic Imaging System.

Performance Data	Conformance to the following standards was demonstrated: Biocompatibility: ISO 10993-5:2009 ISO 10993-10:2010 Electrical Safety and EMC: AAMI/ANSI ES60601-1:2005(R) 2012 and A1:2012 IEC 60601-1-2:2014 Software Validation and Verification Testing: Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern. Activities included software validation/verification, regression testing, unit testing, code reviews and checks and integration testing. Bench Testing: Verification activities including engineering evaluation and functional analysis were conducted to demonstrate the accessory spine endoscopes are compatible with the Arthrex Synergy^{ID} Endoscopic Imaging System. All verification activities conducted were successful and confirmed the accessory spine endoscopes are compatible with the Arthrex Synergy^{ID} Endoscopic Imaging System.
Conclusion	Based on the intended use, technological characteristics, and conducted performance testing Arthrex has determined that the Synergy^{ID} Endoscopic Imaging System is as safe and as effective as the predicate devices. Any differences between the proposed device and predicate devices are considered minor and do not raise different questions concerning safety and effectiveness.