Arthrex Inc.
Troy Brooks
Principal Regulatory Affairs Specialist
1 Arthrex Way
Naples, Florida 34108

July 22, 2021

Re: K202582
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: June 17, 2021
Received: June 21, 2021

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,

Neil R.P. Ogden
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)*
K202582

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 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 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.

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	July 22, 2021
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Troy Brooks, RAC Principal Regulatory Affairs Specialist 1-972-369-2712 Troy.Brooks@Arthrex.com
Name of Device	Arthrex Synergy^{ID} Endoscopic Imaging System
Common Name	Endoscopic Video Camera 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
Predicate Device	K150956 – Pinpoint Endoscopic Fluorescence Imaging System (Primary Predicate) K153218 – Arthrex UHD4 System
Purpose of Submission	This 510(k) premarket notification is submitted to add near-infrared fluorescence imaging, visualization of blood vessels, blood flow, related tissue perfusion and at least one major of the major extra hepatic bile duct indications for use. This 510(k) is also submitted to incorporate an external laser engine light source to provide the NIR excitation light for fluorescence visibility.
Device Description	The Arthrex Synergy^{ID} Endoscopic Imaging System comprises a non-sterile camera control unit (CCU) console, camera head, and light engine source. The system integrates ultra-high-definition camera technology, LED lighting, and an image management system into a single console with a tablet interface in an identical manner as the Arthrex UHD4 System cleared under **K153218.** The Arthrex Synergy^{ID} Endoscopic Imaging System camera control unit interacts with the near-infrared 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 the laparoscope with NIR excitation light from the external laser engine and the fluorescence response is then imaged with the camera, processed and displayed on an Arthrex UHD4 System monitor.
Indications for Use	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 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.

Substantial Equivalence Summary	The Synergy^{ID} System shares the same design features, materials, and intended use as the predicate, The Arthrex Synergy UHD4 System, cleared under **K153218.** Similarly, to the Arthrex Synergy UHD4, The Synergy^{ID} Endoscopic Imaging System integrates ultra-high-definition camera technology, LED lighting, and an image management system into a single console with a tablet interface. The Synergy^{ID} Endoscopic imaging system also interacts with an optimized camera head, endoscopes, and a flexible 0°- and 90°-degree light guide cable to support near-infrared illumination and imagining. The Synergy^{ID} Endoscopic Imaging System-camera control unit (CCU) interacts with the laser light source to provide near-infrared (NIR) imaging. The principle of operation the Synergy^{ID} recognizes the near-infrared illumination and imaging is equivalent to predicate, Pinpoint Fluorescence Endoscopic System cleared under **K150956**. Accordingly, Arthrex believes that the Arthrex Synergy^{ID} Endoscopic Imaging System is substantially equivalent to the original clearance Arthrex Synergy UHD4 cleared under **K153218** clearance and to the Pinpoint Endoscopic Fluorescence system cleared under **K150956**.
Conclusion	The proposed Arthrex Synergy^{ID} Endoscopic Imaging System is substantially equivalent to the predicate device in which the basic design feature, intended use, principle of operation, major technical characteristics, product performance and functionality are the same as the Arthrex UHD4 System cleared under **K153218** and the Pinpoint Endoscopic Fluorescence System cleared under **K150956.** The Arthrex Synergy^{ID} principle of operation for visualization under white visible light, image management and accessory interaction remains identical as it was originally cleared under **K153218.** The Arthrex Synergy^{ID} incorporates an external engine light source which provides the NIR (near infrared) excitation light to cause the fluorescence illumination. The principle of operation of this external light source is identical to Pinpoint endoscopic fluorescence system video processor illuminator (VIP) cleared under **K150956**. The differences between the proposed Arthrex Synergy^{ID} Endoscopic Imaging System and the predicate devices listed above are primarily technological features that do not affect the performance, principle of operation or impede the system from executing its intended use. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex Inc. has determined that the proposed device is substantially equivalent to the currently marketed predicate device.