May 28, 2026

Stryker Endoscopy
Mark William
Senior Staff Regulatory Affairs Specialist
Contact Address

Re: K261037
Trade/Device Name: 780 nm SPY Portable Handheld Imaging (SPY-PHI) System
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic X-Ray System
Regulatory Class: Class II
Product Code: IZI
Dated: March 30, 2026
Received: March 30, 2026

Dear Mark William:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2026.05.28 17:34:34 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K261037

Device Name
780 nm SPY Portable Handheld Imaging (SPY-PHI) System

Indications for Use *(Describe)*

Upon intravenous administration of SPY AGENT GREEN (indocyanine green for injection, USP), the 780 nm SPY-PHI System is used with SPY AGENT GREEN to perform intraoperative fluorescence angiography. The 780 nm SPY-PHI System is indicated for use in adult and pediatric patients one month of age and older.

The 780 nm SPY-PHI System is indicated for fluorescence imaging of blood flow and tissue perfusion before, during, and after: vascular, gastrointestinal, organ transplant, and plastic, micro- and reconstructive surgical procedures.

Upon interstitial administration of SPY AGENT GREEN, the 780 nm SPY-PHI System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

Upon intradermal administration of SPY AGENT GREEN, the 780 nm SPY-PHI System is indicated for fluorescence imaging of lymph nodes and delineation of lymphatic vessels during lymphatic mapping in adults with breast cancer for which this procedure is a component of intraoperative management.

Upon administration and use of pafolacianine consistent with its approved label, the 780 nm SPY-PHI 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.

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510(k) Summary K261037

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R Part 807.92(a)

Submitter:

Applicant	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138
Contact Person	Mark William Senior Staff Regulatory Affairs Specialist Phone: (732) 353-9168 Email: Mark.william@stryker.com
Date Prepared	March 30th, 2026

Subject Device:

Name of Device	780 nm SPY Portable Handheld Imaging (SPY-PHI) System
Common or Usual Name	Fluorescence Angiographic System
Classification Name	System, X-Ray, Angiographic (21 C.F.R. 892.1600)
Regulatory Class	II
Product Code	Class II
Subsequent Product Code	IZI
510(k) Review Panel	Radiology

Predicate Device:

Primary Predicate Device	SPY Portable Handheld Imaging (SPY-PHI) System	K230727
Secondary Predicate Device	1788 4K Advanced Imaging Modality (AIM) Platform	K231854
Reference Device	Medtronic VS3-Iridium System (VS3-IR)	K210265, K223020

NOTE: The predicate and reference devices have not been subject to a design-related recall.

Device Description:

The 780 nm SPY-PHI System is a 4K real-time visible white-light and near-infrared illumination and imaging system used during open-field surgical procedures. Near-infrared illumination is used for fluorescence imaging using SPY AGENT™ GREEN (indocyanine green for injection, USP) or CYTALUX™ (pafolacianine) injection, approved under NDA 211580 and NDA 214907, respectively. The 780 nm SPY-PHI System includes the following devices:

1. 780 nm SPY-PHI Camera System (780 nm SPY-PHI Camera Control Unit and 780 nm SPY-PHI Imager); and,
2. 780 nm SPY-PHI Light Source

Indications for Use:

Upon intravenous administration of SPY AGENT GREEN (indocyanine green for injection, USP), the 780 nm SPY-PHI System is used with SPY AGENT GREEN to perform intraoperative fluorescence angiography. The 780 nm SPY-PHI System is indicated for use in adult and pediatric patients one month of age and older.

The 780 nm SPY-PHI System is indicated for fluorescence imaging of blood flow and tissue perfusion before, during, and after: vascular, gastrointestinal, organ transplant, and plastic, micro- and reconstructive surgical procedures.

Upon interstitial administration of SPY AGENT GREEN, the 780 nm SPY-PHI System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

Upon intradermal administration of SPY AGENT GREEN, the 780 nm SPY-PHI System is indicated for fluorescence imaging of lymph nodes and delineation of lymphatic vessels during lymphatic mapping in adults with breast cancer for which this procedure is a component of intraoperative management.

Upon administration and use of pafolacianine consistent with its approved label, the 780 nm SPY-PHI System is used to perform intraoperative fluorescence imaging of tissues that have taken up the drug.

Comparison of Technological Characteristics with the Predicate Devices:

Item	Subject Device	Predicate Devices	
	780 nm SPY-PHI System	Primary	Secondary
		SPY-PHI System	1788 4K AIM Platform
Manufacturer	Stryker	Novadaq Technologies ULC (a part of Stryker)	Stryker
Submission Reference(s)	Current Submission	K230727	K231854
Intended Use	Visible white light and near-infrared illumination and imaging during open-field surgical procedures.	Same as subject device	Visible white light and near-infrared illumination and imaging during endoscopic procedures.
Indications for Use Statement	NOTE 1	NOTE 2	NOTE 3
Imaging System Type	Open-Field	Same as subject device	Endoscopic
Compatible Imaging Agents	SPY AGENT GREEN pafolacianine	SPY AGENT GREEN	Same as subject device

Item		Subject Device	Predicate Devices	
		780 nm SPY-PHI System	Primary	Secondary
			SPY-PHI System	1788 4K AIM Platform
Imaging Modes		• White Light • Near-infrared Fluorescence (SPY Modes) 1. Overlay Mode 2. Contrast 3. Color Segmented Fluorescence (CSF)	Same as subject device	• White Light • Near-infrared Fluorescence (SPY Modes) 1. ENV 2. Overlay Mode 3. Contrast 4. Color Segmented Fluorescence (CSF) • Cyan Spectral Imaging (CSI) • Near-infrared Trans-illumination (IRIS)
Principles of Operation		Via a handheld imager, light is projected from a light source onto image sensors which acquire a continuous stream of image data. The image data is processed to provide a video stream that is then sent to a display for viewing.	Same as subject device.	Via an endoscope, light is projected by a light source onto one or more image sensor(s) which acquire a continuous stream of image data. The image data is processed to provide a video stream that is then sent to a display for viewing.
Safety Standards		IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60825-1 IEC 60601-4-2 IEC 62471	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60825-1 IEC 60601-4-2 CIE S009/E:2002	IEC 60601-1 IEC 60601-2-18 IEC 60601-1-2 IEC 60825-1 IEC 60601-4-2 IEC 62471
System Architecture / Components		• 780 nm SPY-PHI Camera System, inclusive of: - 780 nm SPY-PHI Imager (with integrated light cable) - 780 nm SPY-PHI Camera Control Unit • 780 nm SPY-PHI Light Source	• SPY-PHI Imager (with integrated light cable) • Video Processor/ Illuminator	• 1788 4K Camera System, inclusive of: - 1788 4K Camera Heads - 1788 4K Coupler - 1788 4K Camera Control Unit • L12 LED Light Source and SafeLight Cable
Imager	Sensor	3-chip rolling shutter CMOS sensor	1-chip global shutter CMOS sensor	Same as subject device

Item		Subject Device	Predicate Devices	
		780 nm SPY-PHI System	Primary	Secondary
			SPY-PHI System	1788 4K AIM Platform
	Immunity Mechanism	Room light immunity through liquid crystal shutter (LC shutter) for all imaging modes	Room light immunity through room light subtraction software algorithm (in Overlay mode) and movable optical filter (in Contrast mode)	Same as subject device.
Camera Control Unit	Image Processing/ Video Output	Digital	Same as subject device	Same as subject device
	Frame Rate	60 Hz	Same as subject device	Same as subject device
Light Source	Light Source/ Laser	RGB LEDs Infrared Laser	Same as subject device	Same as subject device
	Wavelengths	White Light: 400 nm – 700nm Near-infrared: 780 nm	White Light: 400 nm – 700 nm Near-infrared: 805 nm	White Light: 400 nm – 680 nm Near-infrared: 780 nm (used for NIR fluorescence) 830 nm (used for NIR transillumination)
	Laser Safety	Class 3R	Same as subject device	Class 1M

NOTE 1:
Upon intravenous administration of SPY AGENT GREEN (indocyanine green for injection, USP), the 780 nm SPY-PHI System is used with SPY AGENT GREEN to perform intraoperative fluorescence angiography. The 780 nm SPY-PHI System is indicated for use in adult and pediatric patients one month of age and older.
The 780 nm SPY-PHI System is indicated for fluorescence imaging of blood flow and tissue perfusion before, during, and after: vascular, gastrointestinal, organ transplant, and plastic, micro- and reconstructive surgical procedures.
Upon interstitial administration of SPY AGENT GREEN, the 780 nm SPY-PHI System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.
Upon intradermal administration of SPY AGENT GREEN, the 780 nm SPY-PHI System is indicated for fluorescence imaging of lymph nodes and delineation of lymphatic vessels during lymphatic mapping in adults with breast cancer for which this procedure is a component of intraoperative management.
Upon administration and use of pafolacianine consistent with its approved label, the 780 nm SPY-PHI System is used to perform intraoperative fluorescence imaging of tissues that have taken up the drug.

NOTE 2:
Upon intravenous administration of SPY AGENT GREEN (indocyanine green for injection, USP), the SPY-PHI System is used with SPY AGENT GREEN to perform intraoperative fluorescence angiography. The SPY-PHI System is indicated for use in adult and pediatric patients one month of age and older.

The SPY-PHI System is indicated for fluorescence imaging of blood flow and tissue perfusion before, during, and after: vascular, gastrointestinal, organ transplant, and plastic, micro- and reconstructive surgical procedures.
Upon interstitial administration of SPY AGENT GREEN, the SPY-PHI System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.
Upon intradermal administration of SPY AGENT GREEN, the SPY-PHI System is indicated for fluorescence imaging of lymph nodes and delineation of lymphatic vessels during lymphatic mapping in adults with breast cancer for which this procedure is a component of intraoperative management.

NOTE 3:
1788 4K Camera System:
The 1788 4K Camera System with Advanced Imaging Modality is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, neurosurgery and plastic surgery whenever a laparoscope/ endoscope/arthroscope/ sinuscope is indicated for use. The 1788 4K Camera System with Advanced Imaging Modality is indicated for use in adults and pediatric patients.

A few examples of the more common endoscope surgeries are Laparoscopic cholecystectomy, Laparoscopic hernia repair, Laparoscopic appendectomy, Laparoscopic pelvic lymph node detection, Laparoscopically assisted hysterectomy, Laparoscopic and thorascopic anterior spinal fusion, Anterior cruciate ligament reconstruction, Knee arthroscopy, Small joint arthroscopy, Decompression fixation, Wedge resection, Lung biopsy, Pleural biopsy, Dorsal sympathectomy, Pleurodesis, Internal mammary artery dissection for coronary artery bypass, Coronary artery bypass grafting where endoscopic visualization is indicated and Examination of the evacuated cardiac chamber during performance of valve replacement.

The users of the 1788 4K Camera System with Advanced Imaging Modality are general and pediatric surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT/neurosurgeons and urologists.

L12 LED Light Source:
Upon intravenous administration of SPY AGENT GREEN (indocyanine green for injection, USP), the L12 LED Light Source with Advanced Imaging Modality and SafeLight Cable are used with SPY AGENT GREEN to provide real-time endoscopic visible and near-infrared fluorescence imaging. The L12 LED Light Source with Advanced Imaging Modality 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 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 L12 LED Light Source with Advanced Imaging Modality 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 L12 LED Light Source with Advanced Imaging Modality 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 tissue perfusion using near infrared imaging.

Upon interstitial administration of SPY AGENT GREEN, the L12 LED Light Source with Advanced Imaging Modality 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 L12 LED Light Source with Advanced Imaging Modality and SafeLight™ Cable are used to perform intraoperative fluorescence imaging of tissues that have taken up the drug.

The L12 LED Light Source with Advanced Imaging Modality is also intended to transilluminate the ureter during open or laparoscopic surgical procedures.

Performance Testing:

The following performance data were provided in support of the substantial equivalence determination.

Summary of Testing		
Test	**Method**	**Result**
Disinfection and Cleaning	In accordance with FDA-recognized voluntary consensus standard AAMI ST98:2022 (14-583)	Pass
	In accordance with FDA-recognized voluntary consensus standard AAMI TIR12: 2020/(R)2023 (14-602)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 17664-2:2021 (14-579)	Pass
Software Verification and Validation	In accordance with FDA-recognized voluntary consensus standard IEC 62304:2006/ AMDI: 2015 (13-79)	Pass
Cybersecurity	In accordance with FDA Guidance for Industry and Staff - *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (February 2026)*	Pass
Electrical Safety and EMC	In accordance with FDA-recognized voluntary consensus standard IEC 60601-1:2020 (19-49)	Pass
	In accordance with FDA-recognized voluntary consensus standard IEC 60601-1-6: 2020 (5-132)	Pass
	In accordance with FDA-recognized voluntary consensus standard IEC 60601-1-2:2014+A1:2020 (19-36)	Pass
	In accordance with FDA-recognized voluntary consensus standard IEC TS 60601-4-2:2024 (19-50)	Pass
Laser Safety	In accordance with FDA-recognized voluntary consensus standard IEC 60825-1: 2014 (12-273)	Pass
Photobiological Safety	In accordance with FDA-recognized voluntary consensus standard IEC 62471:2006 (12-249)	Pass
Packaging	In accordance with FDA-recognized voluntary consensus standard ASTM D4332-22 (5-136)	Pass
	In accordance with FDA-recognized voluntary consensus standard ASTM D4169-22 (14-576)	Pass
Performance Testing–Bench	In accordance with device input specifications	Pass
	Head-to-head comparative testing to currently legally marketed predicate (SPY-PHI System and 1788 4K AIM Platform) and reference (VS3-IR) devices:	Pass

Summary of Testing		
Test	**Method**	**Result**
	- Spatial uniformity - Minimum detectable fluorescence - Fluorescence detection depth - Clinically meaningful limits of detection - Signal to noise - Dynamic Range - Localization - Distortion and Resolution	
Performance Testing – Animal	In accordance with user needs and intended uses	Pass
	Side-by-side comparison to legally marketed (SPY-PHI System and 1788 4K AIM Platform) and reference (VS3-IR) devices	Pass
	In accordance with FDA-recognized voluntary consensus standard IEC 62366-1:2020 (5-129)	Pass
	In accordance with 21 CFR Part 58 Good Laboratory Practice for Nonclinical Laboratory Studies	Pass

Conclusions:

The 780 nm SPY-PHI System is the same or similar in design, intended use, principles of operation, technological characteristics and safety features to the predicate devices. In summary, the 780 nm SPY-PHI System is the same or similar with respect to safety and effectiveness to the legally marketed predicate devices.