May 25, 2022

Stryker
Michelle Hughes
Senior Staff Regulatory Affairs Specialist
5900 Optical Court
San Jose, California 95138

Re: K214046
Trade/Device Name: 780 nm 1688 4K Camera System, 780 nm L11 LED Light Source with AIM and Safelight Cable
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ, OWN, FCS, FCW, GWG
Dated: April 22, 2022
Received: April 25, 2022

Dear Michelle Hughes:

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,

Purva Pandya, D.Eng.
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)*
K214046

Device Name
780nm Advanced Imaging Modality (AIM) System

Indications for Use *(Describe)*

780 nm 1688 4K Camera System :
The 1688 4K Camera System 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 1688 4K Camera System is indicated for 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 1688 Video Camera are general and pediatric surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons, neurosurgeons and urologists.

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 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 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 is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

The 780 nm L11 LED Light Source with AIM is also intended to transilluminate the ureter during open or laparoscopic surgical procedures.

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.

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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(c).

510(k) Number: K214046

Submitter:

Applicant:	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138
Contact Person:	Michelle Hughes Senior Staff Regulatory Affairs Specialist Email: michelle.hughes@stryker.com
Date Prepared:	December 22, 2021

Subject Device:

The subject device is the 780 nm AIM (Advanced Imaging Modality) System, specifically the following system components:

Name of Device:	780 nm 1688 4K Camera System
Common or Usual Name	3-chip Video Camera
Classification Name:	Laparoscope, General and Plastic Surgery (21 C.F.R. §876.1500) Endoscope, Neurological (21 C.F.R. §882.1480)
Regulatory Class:	II
Product Code:	GCJ GWG
510(k) Review Panel:	General & Plastic Surgery Neurology

Name of Device:	780 nm L11 LED Light Source with Advanced Imaging Modality
Common or Usual Name	Light Source, Illuminator
Classification Name:	Confocal Optical Imaging[1] (21 C.F.R. §876.1500) Fiberoptic light ureteral catheter[2] (21 C.F.R. §876.4020) Light Source, Fiberoptic, Routine[3] (21 C.F.R. §876.4020) Endoscope, Neurological[4] (21 C.F.R. §882.1480)
Regulatory Class:	II
Product Code:	OWN[1] FSC[2] FCW[3] GWG[4]
510(k) Review Panel:	General & Plastic Surgery[1] Gastroenterology/ Urology[2,3] Neurology[4]

[1]When used for assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near-infrared imaging
[2]When used to transilluminate the ureter during open or laparoscopic surgical procedures
[3]When used to provide standard endoscopic visible light to support real-time endoscopic visible imaging.

[4]When used to provide standard endoscopic visible light and near-infrared imaging during minimally invasive cranial neurosurgery and endonasal skull base surgery.

Predicate Device(s):

AIM System: 1688 4K Camera System, L11 LED Light Source with AIM and SafeLight Cable	K211202

NOTE: The predicate device has not been subject to a design-related recall.

Device Description:

The 780nm Advanced Imaging Modality (AIM) System is an endoscopic real-time 4K visible white light and near-infrared light illumination and imaging system. Near-infrared illumination is used for both fluorescence imaging using SPY AGENT ™ GREEN (indocyanine green for injection, USP) and transillumination of the ureters during minimally invasive and open surgical procedures, respectively. The 780nm AIM System includes the following components: (1) A *Camera System* for processing near-infrared and visible light images; (2) A *Light Source and SafeLight Cable* for emitting light within the visible light as well as near-infrared light spectrum; (3) An *Endoscope* for visible light and near-infrared light illumination and imaging; (4) The *IRIS Ureteral Kit* for transillumination of the ureters; and, (5) *SPY AGENT ™ GREEN* (indocyanine green for injection, USP) used for fluorescence imaging.

Indications for Use:

780 nm 1688 4K Camera System with Advanced Imaging Modality:

The 1688 4K Camera System 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 1688 4K Camera System is indicated for 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 1688 Video Camera are general and pediatric surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons, neurosurgeons and urologists.

780 nm L11 LED Light Source with Advanced Imaging Modality

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 visual 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 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 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 is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes. The 780 nm L11 LED Light Source with AIM is also intended to transilluminate the ureter during open or laparoscopic surgical procedures.

Comparison of Technological Characteristics with the Predicate Device:

Item	**Subject Device**	**Predicate Device**
	780 nm Advanced Imaging Modality (AIM) System	**Advanced Imaging Modality (AIM) System**
Manufacturer	Stryker	Same as subject device.
Submission Reference	Current Submission	K211202
Intended Use	Endoscopic visible and near-infrared light illumination and imaging during surgical endoscopic procedures	Same as subject device
Indications for Use	NOTE 1	Same as subject device
Imaging Modes	White Light Near-infrared – fluorescence Near-infrared – transillumination	Same as subject device.
System Components	Camera System Light Source and Light Cable Endoscopes IRIS Ureteral Kit SPY AGENT GREEN	Same as subject device.
Principles of Operations	Via an optical endoscope and coupler, light is projected from a light source onto one or more complementary metal oxide semiconductor 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.

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Item		Subject Device	Predicate Device
		780 nm Advanced Imaging Modality (AIM) System	Advanced Imaging Modality (AIM) System
Safety Standards		IEC 60601-1 IEC 60601-2-18 IEC 60601-1-2 IEC 60601-1-6 IEC 60825-1	Same as subject device.
Camera System	Image Processing/Video Output	Digital	Same as subject device.
Light Source	Light Source/ Laser	RGB LEDs Infrared Laser	Same as subject device.
	Laser Safety Classification	Class 1M	Same as subject device.
	Infrared Wavelengths	780nm (used for NIR fluorescence) 830nm (used for NIR transillumination)	806nm (used for NIR fluorescence) 830nm (used for NIR transillumination).

NOTE 1: The 1688 4K Camera System 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 1688 4K Camera System is indicated for 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 1688 Video Camera are general and pediatric surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons, neurosurgeons and urologists.

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 visual 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 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 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 is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes. The 780 nm L11 LED Light Source with AIM is also intended to transilluminate the ureter during open or laparoscopic surgical procedures.

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Performance Data:

Testing was completed in accordance with the following:

Test	Method	Result
Electrical Safety	ANSI IEC 60601-1:2005 + A1:2012 IEC 60601-2-18:2009 IEC 60601-1-6:2013	PASS
EMC Testing	IEC 60601-1-2:2014	PASS
Laser Safety	IEC 60825-1:2014	PASS
Sterilization	AAMI TIR12:2020 ISO 17664-1:2021 AAMI ST58:2013 ISO 14937:2009	PASS
Software Validation & Verification	IEC 62304:2015	PASS
Usability	IEC 62366-1:2020	PASS
Performance - Bench	In accordance with device input specifications	PASS
	Spatial Uniformity	PASS
	Minimum Detectable Fluorescence	PASS
	Fluorescence Detection Depth	PASS
	Clinically Meaningful Limits of Detection	PASS
	Signal to noise	PASS
	Dynamic Range	PASS
	Localization	PASS
Performance - Animal	Testing completed utilizing predicate AIM System, in accordance with device user needs	PASS

Conclusions:

The 780 nm AIM System is substantially equivalent in design, intended use, principles of operation, technological characteristics and safety features to the predicate devices. In summary, the 780 nm Advanced Imaging Modality System is substantially equivalent with respect to safety and effectiveness to the legally marketed predicate device.