Stryker
Jessie Duong
Manager, Regulatory Affairs
5900 Optical Court
San Jose, California 95138

April 13, 2021

Re: K210088
Trade/Device Name: AIM (Advanced Imaging Modality) System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ, OWN, FCS, FCW
Dated: March 17, 2021
Received: March 18, 2021

Dear Jessie Duong:

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

Digitally signed by Neil R.P. Ogden
Date: 2021.04.13 11:30:32 -04'00'

Neil R.P. Ogden
Assistant Director, THT4A4
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210088

Device Name
AIM (Advanced Imaging Modality) System

Indications for Use *(Describe)*
1688 4K Camera System with Advanced Imaging Modality (AIM):
The 1688 Video Camera is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy and plastic surgery whenever a laparoscope/ endoscope/ arthroscope is indicated for use. The 1688 Video Camera is indicated for use in adults and pediatric patients aged one month or older.

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 and urologists.

L11 LED Light Source with Advanced Imaging Modality (AIM) and SafeLight Cable:
Upon intravenous administration of SPY AGENTTM GREEN (indocyanine green for injection, USP), the L11 LED Light Source with AIM and SafeLightTM Cable is used with SPY AGENT GREEN to provide real-time endoscopic visible and near infrared fluorescence imaging. The L11 LED Light Source with AIM and SafeLight Cable enable surgeons to perform minimally invasive surgery using endoscope visual light as well as visual assessment of vessels, blood flow and related tissue perfusion in adults and pediatric patients aged one month or 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 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. Upon interstitial administration of SPY AGENT GREEN, the 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 L11 LED Light Source is also intended to transilluminate the ureter during open or laparoscopic surgical procedures.

Advanced Imaging Modality (AIM) HD Autoclavable Laparoscope:
The AIM HD Autoclavable Laparoscope is intended to be used for gynecological and general procedures that clinicians deem appropriate for adults and pediatric patients aged one month or older, when the dimensions of the AIM HD Autoclavable Laparoscope are appropriate for the patient size and anatomy.

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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This 510(k) summary is prepared in accordance with the requirements of 21 C.F.R Part 807.92.

Submitter:

Applicant:	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138
Contact Person:	Jessie Duong Manager, Regulatory Affairs Phone: (408) 754-2077 Email: jessie.duong@stryker.com
Date Prepared:	April 8, 2021

Subject Device:

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

Name of Device:	1688 4K Camera System with Advanced Imaging Modality (AIM)
Common or Usual Name	3-chip Video Camera
Classification Name:	Laparoscope, General and Plastic Surgery (21 C.F.R. §876.1500)
Regulatory Class:	II
Product Code:	GCJ
510(k) Review Panel:	General & Plastic Surgery

Name of Device:	L11 LED Light Source with Advanced Imaging Modality (AIM) and SafeLight Cable
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)
Regulatory Class:	II
Product Code:	OWN[1] FCS[2] FCW[3]
510(k) Review Panel:	General & Plastic Surgery[1] Gastroenterology/ Urology[2,3]

[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.

Name of Device	Advanced Imaging Modality (AIM) HD Autoclavable Laparoscope
Common or Usual Name	Laparoscope
Classification Name	Laparoscope, General and Plastic Surgery (21 C.F.R. §876.1500)
Regulatory Class	Class II
Product Code	GCJ
510(k) Review Panel:	General & Plastic Surgery

Predicate Device(s):

Primary Predicate – Advanced Imaging Modality System (1688 4K Camera System with Advanced Imaging Modality, L11 LED Light Source with Advanced Imaging Modality), cleared via K202592.

Reference Predicate – Stryker® IRF Light Source and Safelight Cable, cleared via K142310

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

Device Description:
The AIM (Advanced Imaging Modality) System is an endoscopic real-time 4K visible white light and near-infrared light illumination and imaging system. The AIM (Advanced Imaging Modality) 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) A *Laparoscope* for visible light and near-infrared light illumination and imaging; (4) *SPY AGENT GREEN* (indocyanine green for injection, USP) an optical imaging agent used for fluorescence imaging.

Indications for Use:

Subject Device AIM System (1688, L11) This Submission	Predicate Device AIM System (1688, L11) K202592
Intended Use: Endoscopic white light and near-infrared illumination and imaging during endoscopic procedures.	**Intended Use**: Same as subject device
Indications for Use: **L11 LED Light Source with Advanced Imaging Modality (AIM) and SafeLight Cable** Upon intravenous administration of SPY AGENT™ GREEN (indocyanine green for injection, USP), the L11 LED Light Source with AIM and SafeLight™ Cable is used with SPY AGENT GREEN to provide real-time endoscopic visible and near infrared fluorescence imaging. The L11 LED Light	**Indications for Use:** **L11 LED Light Source with AIM and SafeLight Cable** Upon intravenous administration of SPY AGENT™ GREEN (Indocyanine green for injection, USP), the L11 LED Light Source and SafeLight™ Cable is used with SPY AGENT GREEN to provide real-time endoscopic visible and near infrared fluorescence imaging. The L11 LED Light Source and SafeLight Cable enable surgeons to perform minimally

Subject Device	Predicate Device
AIM System (1688, L11)	AIM System (1688, L11)
This Submission	K202592
Source with AIM and SafeLight Cable enable surgeons to perform minimally invasive surgery using endoscope visual light as well as visual assessment of vessels, blood flow and related tissue perfusion in adults and pediatric patients aged one month or 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 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. Upon interstitial administration of SPY AGENT GREEN, the 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 L11 LED Light Source is also intended to transilluminate the ureter during open or laparoscopic surgical procedures.	invasive surgery using standard endoscope visual light as well as visual 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. Fluorescence imaging of biliary ducts with the L11 LED Light Source 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. Upon interstitial administration of SPY AGENT GREEN, the L11 LED Light Source and SafeLight™ Cable is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes. The L11 LED Light Source is also intended to transilluminate the ureter during open or laparoscopic surgical procedures.
1688 4K Camera System with Advanced Imaging Modality (AIM) The 1688 Video Camera is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy and plastic surgery whenever a laparoscope/ endoscope/ arthroscope is indicated for use. The 1688 Video Camera is indicated for use in adults and pediatric patients aged one month or older. 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 and urologists.	**1688 4K Camera System with Advanced Imaging Modality** The 1688 Video Camera is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy and plastic surgery whenever a laparoscope/ endoscope/ arthroscope is indicated for use. 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 surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.

Subject Device	Predicate Device
AIM System (AIM HD Autoclavable Laparoscope)	**Infrared Fluorescence System (IRF Laparoscope)**
This Submission	**K142310**
Intended Use: Endoscopic white light and near-infrared illumination and imaging during endoscopic procedures.	**Intended Use**: Same as subject device
Indications for Use: The AIM HD Autoclavable Laparoscope is intended to be used for gynecological and general procedures that clinicians deem appropriate for adults and pediatric patients aged one month or older, when the dimensions of the AIM HD Autoclavable Laparoscope are appropriate for the patient size and anatomy.	**Indications for Use:** The Stryker® IRF Laparoscope is intended to be used for gynecological and general procedures that clinicians deem appropriate for the patient.

Comparison of Technological Characteristics with the Predicate Device:

	Subject Device		Predicate Device
Item	**AIM System (1688, L11)**		**AIM System (1688, L11)**
	This Submission		**K202592**
Manufacturer	Stryker		Same as subject device
Imaging Modes	White Light Near-infrared – fluorescence Near-infrared – transillumination		Same as subject device
Device System Components	Camera System Light Source and Light Cable Laparoscopes IRIS Ureteral Kit		Same as subject device
Imaging Agent	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
Safety Standards	IEC 60601-1 IEC 60601-2-18 IEC 60601-1-2 IEC 60825-1		Same as subject device
Camera System	Image Processing/ Video Output	Digital	Same as subject device
	Resolution	4K (up to 3840 x 2160)	Same as subject device
Light Source	Light Source/ Laser	RGB LEDs Infrared Laser	Same as subject device
	Infrared Wavelengths	806nm (used for NIR fluorescence) 830nm (used for NIR transillumination)	Same as subject device
	Laser Safety Classification	Class 1M	Same as subject device

	Subject Device	Predicate Device
Item	**AIM System (AIM HD Autoclavable Laparoscope)**	**Infrared Fluorescence System (IRF Laparoscope)**
	This Submission	**K142310**
Manufacturer	Stryker	Same as subject device
Endoscope Type	Rigid rod lens	Same as subject device
Outer Diameter	5.4mm, 10mm	10mm
Working Length	300 mm for 5.4mm diameter laparoscope 330 mm for 10mm diameter laparoscope	330 mm for 10mm diameter laparoscope
Direction of View	0°, 30°	Same as subject device
Transmission Spectrum	Visible and Near-Infrared	Same as subject device
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-11	Same as subject device
How Provided	Non-Sterile	Same as subject device
Processing	Cleaning, Disinfection (optional), Sterilization	Same as subject device

Non-Clinical Testing

The following non-clinical testing were performed and data/test reports were provided to support substantial equivalence.

- Cytotoxicity (ISO 10993-5, MEM Elution Method)
- Sensitization (ISO 10993-10, Guinea Pig Maximization Test)
- Irritation or Intracutaneous Reactivity (ISO 10993-10, Intracutaneous Injection in Rabbits)
- Acute Systemic Toxicity (ISO 10993-11, Injection in Mice)
- Material Mediated Pyrogenicity (ISO 10993-11, Injection in Rabbits)
- Cleaning, disinfection, and sterilization validations

Clinical Performance Data

Published clinical literature was provided to support the safety and effectiveness of the AIM System when used in the pediatric patient population.

Conclusions:

The modified AIM System is substantially equivalent in design, intended use, principles of operation, technological characteristics and safety features to the predicate device. There are no different questions of safety and/or effectiveness introduced by the modified AIM System when used in the pediatric patient population as instructed during endoscopic imaging using visible white light or near-infrared imaging utilizing SPY AGENT GREEN.