Stryker
Divya Sekar
Staff Regulatory Affairs Specialist
5900 Optical Ct.
San Jose, California 95138

October 8, 2020

Re: K202592
Trade/Device Name: Advanced Imaging Modality System (1688 4K Camera System with Advanced Imaging Modality, L11 LED Light Source with Advanced Imaging Modality)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ, OWN, FCS, FCW
Dated: September 4, 2020
Received: September 8, 2020

Dear Divya Sekar:

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, MS
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)*
K202592

Device Name
Advanced Imaging Modality System (1688 4K Camera System with Advance Imaging Modality; L11 LED Light Source with Advanced Imaging Modality)

Indications for Use *(Describe)*

1688 4K Camera System with Advance 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.

L11 LED Light Source with Advanced Imaging Modality:
Upon intravenous administration of SPY AGENTTM GREEN (Indocyanine green for injection, USP), the AIM Light Source and SafeLightTM Cable is used with SPY AGENT GREEN to provide real-time endoscopic visible and near infrared fluorescence imaging. The AIM Light Source and SafeLight Cable enable surgeons to perform minimally 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 AIM 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 (ICG drug product), the AIM Light Source and SafeLightTM Cable is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.
The AIM Light Source 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.

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This 510(k) summary is submitted 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:	Divya Sekar Staff Regulatory Affairs Specialist Phone: (669) 204-4851 Email: divya.sekar@stryker.com
Date Prepared:	September 8, 2020

Subject Device:

The subject device is the Advanced Imaging Modality System (1688 4K Camera System with Advance Imaging Modality; L11 LED Light Source with Advanced Imaging Modality), and specifically the following system components:

Name of Device:	1688 4K Camera System with Advance Imaging Modality
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
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.

Predicate Device(s):

Primary Predicate Device	Advanced Imaging Modality System (1688 4K Camera System with Advance Imaging Modality; L11 LED Light Source with Advanced Imaging Modality)	K182160
Reference Predicate Devices	1688 4K Camera System with Advance Imaging Modality	K200310
	L11 LED Light Source with Advanced Imaging Modality	K192292, K191046

NOTE: The predicate devices have 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. Near-infrared illumination is used for both fluorescence imaging using indocyanine green (ICG) and transillumination of the ureters during minimally invasive and open surgical procedures, respectively. 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 as well as near-infrared spectrum; (3) A *Laparoscope* for visible light and near-infrared light illumination and imaging; (4) The *IRIS Ureteral Kit* for transillumination of the ureters; and, (5) SPY AGENT^{TM} GREEN (indocyanine green for injection, USP) used for fluorescence imaging.

The modified AIM System (subject device) and predicate device are the same, with the exception of the 1688 4K Pendulum Camera Head and the optional *Defog* feature. The 1688 4K Pendulum Camera Head was cleared under K200310 and works as intended with the L11 LED Light Source that was cleared under K182160, K191046 and K192292. The optional *Defog* feature reduces the likelihood of fogged images common to irrigated surgical procedures.

Indications for Use:

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.

L11 LED Light Source with Advanced Imaging Modality:

Upon intravenous administration of SPY AGENT™ GREEN (Indocyanine green for injection, USP), the AIM Light Source and SafeLight™ Cable is used with SPY AGENT GREEN to provide real-time endoscopic visible and near-infrared fluorescence imaging. The AIM Light Source and SafeLight Cable enable surgeons to perform minimally 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 AIM 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 (ICG drug product), the AIM 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 AIM Light Source is also intended to transilluminate the ureter during open or laparoscopic surgical procedures.

NOTE: The 1688 4K Camera System with Advance Imaging Modality indications for use is identical to the predicate device cleared under K182160.
The L11 LED Light Source with Advanced Imaging Modality indications for use is similar to the predicate device cleared under K182160. The differences in the L11 LED Light Source with Advanced Imaging Modality indications for use were cleared under K191046 and K192292 (when used with 1688 4K Camera System cleared via K182160).

Comparison of Technological Characteristics with the Predicate Device:

Item	**Subject Device**	**Predicate Device**
	AIM (Advanced Imaging Modality) System	**AIM (Advanced Imaging Modality) System**
Manufacturer	Stryker	Same as subject device
Submission Reference	Current Submission	K182160
Intended Use	Endoscopic visible and near-infrared light illumination and imaging during surgical endoscopic procedures	Same as subject device
Imaging Modes	White Light (Manual & Autolight[1]) Near-infrared – fluorescence Near-infrared – transillumination	White Light (Manual & Autolight) Near-infrared – fluorescence Near-infrared – transillumination

Item		Subject Device	Predicate Device
		AIM (Advanced Imaging Modality) System	**AIM (Advanced Imaging Modality) System**
Safety Standards		IEC 60601-1 IEC 60601-2-18 IEC 60601-1-2 IEC 60825-1	Same as subject device
Camera System	System Components	Camera Control Unit Camera Head(s): Standard, Integrated, and Pendulum[2] Coupler	Camera Control Unit Camera Head(s): Standard & Integrated Coupler
	Principles of Operation	Via an optical scope and coupler, light is projected 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
	Image Sensor	CMOS image sensor	Same as subject device
	Image Processing/ Video Output	Digital	Same as subject device
	Resolution	4K (up to 3840 x 2160)	Same as subject device
	Frame Rate	60 frames per second	Same as subject device
Light Source	Principles of Operation	An electronic driver controls Red/Green/Blue LEDs & a near-infrared laser diode which are combined through dichroic mirrors and projected onto an output light collimator. A fiber output bundle can be inserted into the light source to couple light to the distal end and into an endoscope.	Same as subject device
	Light Source/Laser	RGB LEDs Infrared Laser	Same as subject device

[1] The optional *Defog* feature is available in Autolight imaging mode for the subject device. It reduces the likelihood of fogged images common to irrigated surgical procedures.
[2] The 1688 4K Pendulum Camera Head was cleared under K200310.

Performance Data:

The following performance data, including image quality assessments, were provided to demonstrate the optional *Defog* feature works as intended under clinically relevant ambient conditions (i.e. temperature and relative humidity) to support the substantial equivalence determination:

Test	Method	Results
Performance Testing	Laser Output System Temperature Verification Image Quality Assessments	Pass
Software Verification	IEC 62304:2015	Pass

NOTE: The AIM (Advanced Imaging Modality) System does not require clinical studies to support the determination of substantial equivalence.

Conclusions:

The comparison of the indications for use, technological characteristics and performance data demonstrates the subject device is substantially equivalent to the predicate device.