November 5, 2018

Stryker
April Malmborg
Director, Regulatory Affairs
5900 Optical Court
San Jose, California 95138

Re: K182160
Trade/Device Name: 1688 Camera Control Unit ; 1688 AIM 4K Camera Head, C-Mount ; 1688 AIM 4K Camera Head with Integrated Coupler ; AIM 4K Coupler, 20mm, C-Mount ; L11 LED Light Source with AIM
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ, OWN, FCS, FCW
Dated: August 7, 2018
Received: August 9, 2018

Dear April Malmborg:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K182160

Device Name
1688 Camera Control Unit ; 1688 AIM 4K Camera Head, C-Mount ; 1688 AIM 4K Camera Head with Integrated Coupler ; AIM 4K Coupler, 20mm, C-Mount ; L11 LED Light Source with AIM

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:
The L11 AIM Light Source and SafeLightTM Cable are indicated for use to provide real-time endoscopic visible and near-infrared fluorescence imaging. The L11 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 L11 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.

The L11 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.

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).

Submitter:

Applicant:	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138
Contact Person:	April Malmborg, RAC Director, Regulatory Affairs Phone: (408) 754-2473 Facsimile: (408) 754-2598 Email: april.malmborg@stryker.com
Date Prepared:	October 29, 2018

Subject Device:

The subject device is the AIM (Advanced Imaging Modality) System, 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] FSC[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):

Stryker® Infrared Fluorescence Imaging (IRF) System	K173866, K151243, K142310, K132785
PINPOINT Endoscopic Fluorescence Imaging System	K150956, K161792

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 light as well as near-infrared light 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) *Imaging Agent Kits* containing ICG used for fluorescence imaging.

Indications for Use:

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:
The L11 AIM Light Source and SafeLight™ Cable are indicated for use to provide real-time endoscopic visible and near-infrared fluorescence imaging. The L11 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 L11 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.

The L11 AIM Light Source 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 Devices**	
		AIM (Advanced Imaging Modality) System	**Stryker Infrared Fluorescence (IRF) Imaging System**	**PINPOINT Endoscopic Fluorescence Imaging System**
Manufacturer		Stryker	Same as subject device	Novadaq Technologies (now a part of Stryker)
Submission Reference		Current Submission	K173866, K151243, K142310, K132785	K150956
Intended Use		Endoscopic visible and near-infrared light illumination and imaging during surgical endoscopic procedures	Same as subject device	Same as subject device
Indications for Use		NOTE 1	Same as subject device	NOTE 2 (same as L11 LED Light Source)
Imaging Modes		White Light Near-infrared – fluorescence Near-infrared – transillumination	Same as subject device	White Light Near -infrared – fluorescence
Safety Standards		IEC 60601-1 IEC 60601-2-18 IEC 60601-1-2 IEC 60825-1	Same as subject device	Same as subject device
System Components		Camera System Light Source and SafeLight Cable Laparoscopes IRIS Ureteral Kits Imaging Agent Kits	Same as subject device	Video Processor/ Illuminator Camera Head Light Guide Cable Laparoscopes Imaging Agent Kits
Camera System	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	Same as subject device
	Image Sensor	CMOS image sensor	Same as subject device	Same as subject device
	Image Processing/ Video Output	Digital	Same as subject device	Same as subject device
	Resolution	4K (up to3840 x 2160)	Up to 1920 x 1080	Up to 1920 x 1080
Light Source	Principles of Operation	An electronic driver controls Red/Green/Blue LEDs & a near-infrared laser diode which are combined through	Same as subject device	Same as subject device

Item		Subject Device	Predicate Devices	
		AIM (Advanced Imaging Modality) System	**Stryker Infrared Fluorescence (IRF) Imaging System**	**PINPOINT Endoscopic Fluorescence Imaging System**
		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.		
	Light Source/ Laser	RGB LEDs Infrared Laser	Same as subject device	Same as subject device

NOTE 1: 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.

The L11 AIM Light Source and SafeLight™ Cable are indicated for use to provide real-time endoscopic visible and near-infrared fluorescence imaging. The L11 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 L11 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. The L11 AIM Light Source is also intended to transilluminate the ureter during open or laparoscopic surgical procedures.

NOTE 2: The PINPOINT Endoscopic Fluorescence Imaging System is indicated for use to provide real time endoscopic visible and near-infrared fluorescence imaging. The PINPOINT System enables surgeons to perform minimally invasive surgery using standard endoscopic visible 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 or common hepatic duct), using near-infrared imaging. Fluorescence imaging of biliary ducts with the PINPOINT 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.

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 60601-1-2:2010	PASS
Laser Safety	IEC 60825-1:2014	PASS
Sterilization	ISO 14937:2009	PASS

Test	Method	Result
Software Validation & Verification	IEC 62304:2006	PASS
Usability	IEC 62366-1:2015	PASS
Performance - Bench	In accordance with device performance specifications	PASS
Performance - Animal	In accordance with user needs; Comparative testing to currently legally marketed device in compliance	PASS

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

Conclusions:

The AIM (Advanced Imaging Modality) System is substantially equivalent in design, intended use, principles of operation, technological characteristics and safety features to the predicate devices. There are no new issues of safety and/or effectiveness introduced by the 1688 4K Camera System or L11 LED Light Source when used as instructed.