August 6, 2021

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

Re: K211202
Trade/Device Name: 1688 4K Camera System, L11 LED Light Source with AIM, AIM SafeLight Cable, Precision S 4K Sinuscopes
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ, GWG, OWN, FCS, FCW, EOB
Dated: July 8, 2021
Received: July 9, 2021

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/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,

for
Adam Pierce
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K211202

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, neurosurgery and plastic surgery whenever a laparoscope/ endoscope/ arthroscope/ sinuscope is indicated for use. The 1688 Video Camera 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.

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 are 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 standard endoscopic visual 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 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 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 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.

Precision S 4K Sinuscope:
The Precision S 4K Sinuscope is intended for use in otolaryngology and head and neck procedures, including rhinology, endoscopic plastic and reconstructive surgery. The Precision S 4K Sinuscope is also intended for use in minimally invasive cranial neurosurgery in adults and pediatric patients and endonasal skull base surgery in adults and pediatric patients > 6 years ofage.

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:	Jessie Duong Manager, Regulatory Affairs Email: jessie.duong@stryker.com
Date Prepared:	July 7, 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
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:	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 (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]

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[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.

Name of Device	Precision S 4K Sinuscope
Common or Usual Name	Sinuscope
Classification Name	Nasopharyngoscope (21 C.F.R. §874.4760) Endoscope, Neurological (21 C.F.R. §882.1480)
Regulatory Class	Class II
Product Code	EOB GWG
510(k) Review Panel:	Ear Nose & Throat Neurology

Predicate Device(s):

Karl Storz ICG Imaging System	K180146 (primary)
AIM System: 1688 4K Camera System, L11 LED Light Source and SafeLight Cable	K210088 (secondary)

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

Reference Device(s):

Precision S 4K Sinuscope	K191102

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) 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* ^{TM} *GREEN* (indocyanine green for injection, USP) an optical imaging agent used for fluorescence imaging.

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Indications for Use:

Subject Device	Predicate Devices	
AIM System ***This Submission***	**Karl Storz ICG Imaging System (K180146, primary)**	**AIM System (K210088, secondary)**
Intended Use: Endoscopic white light and near-infrared illumination and imaging during endoscopic procedures.	**Intended Use:** Same as subject device	**Intended Use:** Same as subject device.
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 with AIM and SafeLight™ Cable are 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 standard endoscopic visual 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 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 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 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.	**Indications for Use:** **Karl Storz ICG Imaging System** The KARL STORZ ICG Imaging System is intended to provide real-time visible (VIS) and near-infrared (NIR) fluorescence imaging. The KARL STORZ Endoscopic ICG 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, or 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 KARL STORZ Endoscopic ICG 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. Additionally, the KARL STORZ Endoscopic ICG System enables surgeon to perform minimally invasive cranial neurosurgery in adults and pediatrics and endonasal skull base surgery in adults and pediatrics > 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. The KARL STORZ VITOM II ICG System is intended for capturing and viewing fluorescent images for the visual assessment of blood flow, as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures. The VITOM II ICG System is intended to provide a	**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 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 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.

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Subject Device	Predicate Devices	
AIM System ***This Submission***	**Karl Storz ICG Imaging System (K180146, primary)**	**AIM System (K210088, secondary)**
The L11 LED Light Source is also intended to transilluminate the ureter during open or laparoscopic surgical procedures.	magnified view of the surgical field in standard white light.	
1688 4K Camera System The 1688 Video Camera 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 Video Camera 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.		**1688 4K Camera System** 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 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.
Precision S 4K Sinuscope The Precision S 4K Sinuscope is intended for use in otolaryngology and head and neck procedures, including rhinology, endoscopic plastic and reconstructive surgery. The Precision S 4K Sinuscope is also intended for use in minimally invasive cranial neurosurgery in adults and pediatric patients and endonasal skull base surgery in adults and pediatric patients > 6 years of age.		N/A

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Comparison of Technological Characteristics with the Predicate Device:

Item		Subject Device	Predicate Device	
		AIM System *(This Submission)*	**Karl Storz ICG Imaging System (K180146, primary)**	**AIM System (K210088 secondary)**
Manufacturer		Stryker	Karl Storz	Stryker
Imaging Modes		White Light Near-infrared – fluorescence Near-infrared – transillumination	White Light Near-infrared – fluorescence	Same as subject device.
System Components		Camera System Light Source and Light Cable Endoscopes IRIS Ureteral Kit SPY AGENT GREEN	Camera System Light Source and Light Cable Endoscopes	
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	IEC 60601-1 IEC 60601-2-18 IEC 60601-1-2	
Camera System	Image Processing/ Video Output	Digital	Same as subject device	
Light Source	Light Source/ Laser	RGB LEDs Infrared Laser	Xenon Lamp	
	Infrared Wavelengths	806nm (used for NIR fluorescence) 830nm (used for NIR transillumination)	690-790nm	
	Laser Safety Classification	Class 1M	Not applicable	
Endoscope	Endoscope Type	Rigid rod lens	Same as subject device	Reference device (K191102) is the same as subject device
	Endoscope Performance Standards	ISO 8600-1	Same as subject device	
	Transmission Spectrum	Visible and near-infrared	Same as subject device	
	Outer Diameter	3.1mm, 4.0mm	4mm 5mm, 10mm	
	Working Length (Outer Diameter)	125mm – 180mm (3.1mm, 4.0mm)	180mm (4mm OD) 290mm (5mm OD) 310mm (10mm OD)	
	Field of View	80° - 105°	80°	
	Depth of Field	7mm – 35mm	8mm – 38mm	
	Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-11	Same as subject device	
	Cleaning	Manual and Automated	Same as subject device	
	Sterilization	Moist Heat Hydrogen Peroxide	Moist Heat	

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Performance Data:

Testing was completed in accordance with the following:

Test	Method	Result
Electrical Safety	ANSI/AAMI ES60601-1:2005 + 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
Biocompatibility	ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-10:2010 ISO 10093-11:2017	Pass
Cleaning	AAMI TIR30:2011 ISO 15883-5:2005	Pass
Sterilization	ISO 14937:2009 AAMI TIR12:2010 AAMI TIR30:2011	Pass
Software Validation & Verification	IEC 62304:2006	Pass
Usability	IEC 62366-1:2015	Pass
Performance – Bench	In accordance with device input specifications	Pass
Performance – Animal	In accordance with device user needs, intended uses Comparative testing to currently legally marketed device in compliance with 21 CFR Part 58, Good Laboratory Practice	Pass

Clinical Data:

Published literature was provided to support a reasonable assurance of safety and effectiveness for the AIM System for use in the neurosurgery indications.

Conclusions:

The AIM 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 AIM System for 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.