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

November 19, 2019

Re: K192292
Trade/Device Name: L10 LED Light Source with AIM, L11 LED Light Source with AIM, AIM SafeLight Cable
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: OWN, GCJ
Dated: August 22, 2019
Received: August 23, 2019

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,

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)*
K192292

Device Name
Stryker L10 and L11 LED Light Source with AIM (Advanced Imaging Modality)

Indications for Use *(Describe)*
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.

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:	August 22, 2019

Subject Device:

Name of Device:	AIM Light Source 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] 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), and lymphatic system, including lymphatic vessels and lymph nodes, 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):

PINPOINT Endoscopic Fluorescence Imaging System (primary predicate)	K150956, K161792, K182606
L10 LED Light Source and SafeLight Cable (secondary predicate)	K142310, K151243, K173866, K191046
L11 LED Light Source and SafeLight Cable (secondary predicate)	K182160, K191046

NOTE: The predicate devices have not been subject to a design-related recall.

Device Description:

The AIM Light Source (L10 and L11 LED Light Source) and SafeLight™ Cable are part of the AIM (Advanced Imaging Modality) System. The AIM System is an endoscopic real-time 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 using the IRIS Ureteral Kit during minimally invasive and open surgical procedures, respectively. The AIM Light Source is a light-generating unit designed to illuminate surgical sites in the following applications: visible light, near-infrared fluorescence, and near-infrared transillumination. The SafeLight Cable transmits light from the light source to an endoscope during endoscopic procedures.

Indications for Use:

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.

Comparison of Technological Characteristics with the Predicate Device:

Item	**Subject Device**	**Predicate Devices**	
	AIM Light Source and Safe Light Cable	**PINPONT Endoscopic Fluorescence Imaging System (primary predicate)**	**AIM Light Source and Safe Light Cable (secondary predicate)**
Manufacturer	Stryker	Novadaq Technologies ULC (now a part of Stryker)	Same as subject device
Submission Reference	Current submission	K150956, K161792, K182606	K142310, K151243, K173866, K182160, K191046

Item		Subject Device	Predicate Devices	
		AIM Light Source and Safe Light Cable	**PINPONT Endoscopic Fluorescence Imaging System (primary predicate)**	**AIM Light Source and Safe Light Cable (secondary predicate)**
Intended Use		Endoscopic white light and near-infrared illumination and imaging during endoscopic procedures.	Same as subject device.	Same as subject device
Indications for Use		NOTE 1	Same as subject device. NOTE 2	NOTE 3
Principles of Operation		An electronic driver controls Red/Green/Blue LEDs and 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.	Same as subject device.
Components		Light Source and SafeLight Cable Camera System Laparoscopes IRIS Ureteral Kit Imaging Agent	Video Processor/ Illuminator (VPI) Light Guide Cable Camera Head Laparoscopes Imaging Agent	Same as subject device
Safety Standards		IEC 60601-1 IEC 60601-2-18 IEC 60601-1-2 IEC 60825-1	Same as subject device	Same as subject device
Light Source/ Laser		RGB LEDs Infrared Laser	Same as subject device	Same as subject device
Infrared Wavelengths		806nm (used for NIR fluorescence) 830nm (used for NIR transillumination)	805nm (used for NIR fluorescence)	Same as subject device
L10 Imaging Modes	White Light	Manual	Same as subject device	Same as subject device
	NIR Fluorescence	ENV	Contrast Overlay Color Segmented Fluorescence	Same as subject device
	NIR Trans-illumination	IRIS	None	Same as subject device
L11 Imaging Modes	White Light	Manual Autolight	Manual	Same as subject device
	NIR Fluorescence	ENV Contrast Overlay	Contrast Overlay Color Segmented Fluorescence	Same as subject device

Item		Subject Device	Predicate Devices	
		AIM Light Source and Safe Light Cable	**PINPONT Endoscopic Fluorescence Imaging System (primary predicate)**	**AIM Light Source and Safe Light Cable (secondary predicate)**
	NIR Trans-illumination	IRIS	None	Same as subject device
SafeLight Cable	Single-Use/ Reusable	Reusable	Same as subject device	Same as subject device

NOTE 1: 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 2: Upon intravenous administration of SPY AGENT™ GREEN (Indocyanine green for injection, USP), the PINPOINT Endoscopic Fluorescence Imaging System is used with SPY AGENT GREEN to perform intraoperative fluorescence angiography, and it is also indicated for use in fluorescence imaging of biliary ducts, and when indicated, during intraoperative cholangiography. 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 endoscope 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 in 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. Upon interstitial administration of SPY AGENT GREEN (ICG drug product), the PINPOINT System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

NOTE 3: 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. The AIM Light Source is also intended to transilluminate the ureter during open or laparoscopic surgical procedures.

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	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 input specifications	PASS
Performance - Animal	In accordance with device user needs; Comparative testing to currently legally marketed device in accordance with 21CFR58	PASS; Equivalent

NOTE: The AIM Light Source and SafeLight Cable do not require clinical studies to support the determination of substantial equivalence.

Conclusions:

Based on the information presented, the AIM Light Source and SafeLight Cable is substantially equivalent in design, intended use, principles of operation, technological characteristics and safety features to the predicate devices. The nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legal marketed predicate device, the PINPOINT System. There are no new issues of safety and/or effectiveness introduced by the AIM Light Source and SafeLight Cable for intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes using SPY AGENT™ GREEN the when used as instructed.