April 11, 2023

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

Re: K230754
Trade/Device Name: L12 LED Light Source with AIM
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OWN, FCS, GWG, FCW
Dated: March 17, 2023
Received: March 17, 2023

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,

Jessica Carr -S

Jessica Carr, Ph.D.
Acting Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230754

Device Name
L12 LED Light Source with AIM

Indications for Use *(Describe)*

Upon intravenous administration of SPY AGENT GREEN (indocyanine green for injection, USP), the L12 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 L12 LED Light Source with AIM and SafeLight Cable enable surgeons to perform minimally invasive surgery using standard endoscopic visible 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 L12 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 L12 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 L12 LED Light Source with AIM and SafeLight Cable are used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

Upon administration and use of pafolacianine consistent with its approved label, the L12 LED Light Source with AIM and SafeLight™ Cable are used to perform intraoperative fluorescence imaging of tissues that have taken up the drug.

The L12 LED Light Source with AIM 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).

510(k) Number : K230754

Submitter:

Applicant:	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138
Contact Person:	April Malmborg Senior Director Regulatory Affairs Email: april.malmborg@stryker.com
Date Prepared:	April 3, 2023

Subject Device:

Name of Device:	L12 LED Light Source with AIM
Common or Usual Name	Light Source, Illuminator
Classification Name:	Endoscope and Accessories[1,3] (21 C.F.R. §876.1500) Fiberoptic light ureteral catheter[2] (21 C.F.R. §876.4020) Endoscope, Neurological[4] (21 C.F.R. §882.1480)
Regulatory Class:	II
Product Code:	OWN[1] FCS[2] FCW[3] GWG[4]
510(k) Review Panel:	General & Plastic Surgery[1] Gastroenterology/ Urology[2,3] Neurology[4]

[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.

Predicate Device(s):

780 nm L11 LED Light Source with AIM (Stryker Endoscopy)	K221611*, K214046

*primary predicate

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Device Description:

The L12 LED Light Source with AIM is part of the Advanced Imaging Modality (AIM) System. The system is an endoscopic real-time 4K visible white light and near-infrared illumination and transillumination imaging system. Near-infrared illumination is used for fluorescence imaging using indocyanine green and pafolacianine injection. Near-infrared illumination is also intended for use during transillumination of the ureters using the IRIS Ureteral Kit during minimally invasive and open surgical procedures. The L12 LED Light Source is a light-generating until designed to illuminate surgical sites in the following applications: visible light, near-infrared fluorescence, and near-infrared transillumination.

Indications for Use:

Upon intravenous administration of SPY AGENT^{TM}GREEN (indocyanine green for injection, USP), the L12 LED Light Source with AIM and SafeLight^{TM} Cable are used with SPY AGENT GREEN to provide real-time endoscopic visible and near infrared fluorescence imaging. The L12 LED Light Source with AIM and SafeLight Cable enable surgeons to perform minimally invasive surgery using standard endoscopic visible 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 L12 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 L12 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 L12 LED Light Source with AIM and SafeLight Cable are used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

Upon administration and use of pafolacianine consistent with its approved label, the L12 LED Light Source with AIM and SafeLight™ Cable are used to perform intraoperative fluorescence imaging of tissues that have taken up the drug.

The L12 LED Light Source with AIM is also intended to transilluminate the ureter during open or laparoscopic surgical procedures.

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Comparison of Technological Characteristics with the Predicate Device:

Item		Subject Device	Predicate Device
		L12 LED Light Source with AIM	**780 nm L11 LED Light Source with AIM**
Manufacturer		Stryker	Same as subject device.
Submission Reference		Current submission	K221611, K214046
Intended Use		Endoscopic white light and near-infrared illumination and imaging during endoscopic procedures.	Same as subject device
Indications for Use		NOTE 1	Same as subject device
Imaging Modes	White Light	Manual Autolight	Same as subject device
	Near-infrared Fluorescence	ENV Contrast Overlay - Without IRIS - With IRIS	ENV Contrast Overlay - Without IRIS
	Near-infrared transillumination	IRIS	Same as subject device
Imaging Agents		SPY AGENT™ GREEN (indocyanine green for injection, USP) pafolacianine	Same as subject device
Principles of Operation		Via an optical light guide, endoscope and coupler, light is projected from a light source and either reflected or absorbed and fluoresced 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.
System Components		Light Source (subject of this submission) SafeLight Cable Camera System Laparoscopes IRIS Ureteral Kit *NOTE: This represents the components of the AIM System.*	Same as subject device.
Safety Standards		IEC 60601-1 IEC 60601-2-18 IEC 60601-1-2 IEC 60601-1-6 IEC 60825-1	Same as subject device.
Laser Safety Classification		Class 1M	Same as subject device.
Light Source/ Laser		RGB LEDs/ Infrared Laser	Same as subject device.
Excitation Wavelength(s)		Near-infrared fluorescence: 780 nm Near-infrared transillumination: 830 nm	Same as subject device.

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NOTE 1: Upon intravenous administration of SPY AGENT™ GREEN (indocyanine green for injection, USP), the L12 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 L12 LED Light Source with AIM and SafeLight Cable enable surgeons to perform minimally invasive surgery using standard endoscopic visible 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 L12 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 L12 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 L12 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. Upon administration and use of pafolacianine consistent with its approved label, the L12 LED Light Source and SafeLight™ Cable is used to perform intraoperative fluorescence imaging of tissues that have taken up the drug. The L12 LED Light Source with AIM is also intended to transilluminate the ureter during open or laparoscopic surgical procedures.

Performance Data:

Test	Method	Result
Software	Light Source Software Functional Test	PASS
	Light Source Communication	PASS
Performance Testing - Bench	Light Source Light Output	PASS
	Light Source Power Draw	PASS
	Light Source Cable Compatibility	PASS
	Light Source Timing	PASS

NOTE: The L12 LED Light Source with AIM is not patient contacting; therefore, biocompatibility testing was not required to support the determination of substantial equivalence.

NOTE: The L12 LED Light Source does not require clinical studies to support the determination of substantial equivalence.

Conclusions:

The L12 LED Light Source with AIM is the same or similar in design, intended use, principles of operation, technological characteristics and safety features to the predicate devices. In summary, the L12 LED Light Source with AIM is the same or similar with respect to safety and effectiveness to the legally marketed predicate devices.