Stryker
Agatha Szeliga
Regulatory Affairs Manager
5900 Optical Court
San Jose, California 95138

May 10, 2019

Re: K191046
Trade/Device Name: L10 LED Light Source with AIM, L11 LED Light Source with AIM
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: OWN, FCS, FCW
Dated: April 19, 2019
Received: April 19, 2019

Dear Agatha Szeliga:

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,

For Jennifer Stevenson,
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191046

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

Indications for Use *(Describe)*

Upon intravenous administration of SPY AGENT™ GREEN (Indocyanine green for injection, USP), the AIM Light Source and SafeLight Cable are indicated for use 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.

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 submitted in accordance with the requirements of 21 CFR § 807.92.

Submitter:

Applicant	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138
Contact Person	Agatha Szeliga Regulatory Affairs Manager Tel: 604-422-7516 Fax: 604-232-9841 E-mail: agatha.szeliga@stryker.com
Date Prepared	April 19, 2019

Subject Device:

Name of Device	Stryker L10 and L11 LED Light Source with AIM (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. §876.1500)
Regulatory Class	II
Product Code	OWN[1] FCS[2] FCW[3]
510(k) Review Panel	General & Plastic Surgery[1] Gastroenterolgoy/ 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 trans-illuminate 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 AIM Light Source and SafeLight Cable	K173866
L11 LED Light Source with AIM	K182160

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

Device Description:

The Stryker AIM LED Light Source (L10 & L11) is part of the Stryker Infrared Fluorescence (IRF) Imaging System, which is an endoscopic illumination and imaging system for real-time high definition (HD) visible light and near-infrared fluorescence imaging of indocyanine green (ICG) during minimally invasive surgery.

The Stryker Infrared Fluorescence Imaging System consists of the following main components:

- A light source console and a light cable for outputting light within a visible light spectrum as well as near-infrared light spectrum;
- A camera control unit for processing near-infrared and visible light images, and a coupler that is attached to the laparoscope and camera head (cleared separately);
- A laparoscope for visible light and near-infrared light illumination and imaging (cleared separately)
- An imaging agent kit containing ICG

The Stryker AIM LED Light Source uses an illuminator with a laser light source to illuminate the area of surgery. The device is used in conjunction with ICG to achieve its intended use in fluorescence angiography. The ICG is administered intravenously prior to image obtainment. A laser light is illuminated to the site of the surgery using a laparoscope. Absorption of laser light causes excitation of the ICG in the vessels resulting in emission of infrared light at a different wavelength. The camera system captures the infrared emission, processes the image and displays it on a surgical monitor.

Indications for Use:

Upon intravenous administration of SPY AGENT™ GREEN (Indocyanine green for injection, USP), the AIM Light Source and SafeLight Cable are indicated for use 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.

Comparison of Technological Characteristics with the Predicate Device:

Feature	Subject Device	Predicate Device	Predicate Device
	Stryker L10 and L11 LED Light Source with AIM	**Stryker AIM Light Source and SafeLight Cable**	**L11 LED Light Source with Advanced Imaging Modality (AIM)**
Manufacturer	Stryker Endoscopy	Same as subject device	Same as subject device
Submission Reference	Current Submission	K173866	K182160
Intended Use	Endoscopic visible and near-infrared imaging during surgical procedures	Same as subject device	Same as subject device
Indications for Use	See NOTE 1	See NOTE 2	See NOTE 3
Imaging Modes	White Light Near-infrared – Fluorescence Near-infrared – Transillumination	Same as subject device	Same as subject device
Safety Standards	IEC 60601-1 IEC 60601-1-2 IEC 60825-1 IEC 60601-2-18	Same as subject device	Same as subject device
Components	Light Source and SafeLight Cable SPY AGENT™ GREEN Kit	Light Source and SafeLight Cable ICG Imaging Agent Kits	Light Source and SafeLight Cable ICG Imaging Agent Kits
Principle 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
Light Source/ Laser	RGB LEDs Infrared laser	Same as subject device	Same as subject device
Single Use or Reusable	Reusable	Same as subject device	Same as subject device
Contrast Imaging Agent	SPY AGENT™ GREEN (Indocyanine green for injection, USP)	Indocyanine green (ICG)	Indocyanine green (ICG)

NOTE 1: Upon intravenous administration of SPY AGENT™ GREEN (Indocyanine green for injection, USP), the AIM Light Source and SafeLight Cable are indicated for use 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.

NOTE 2: The Stryker® AIM Light Source and SafeLight Cable are indicated for use to provide realtime endoscopic visible and near-infrared fluorescence imaging. The Stryker® AIM Light Source and SafeLight Cable enable 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 and common hepatic duct), using near infrared imaging.

Fluorescence imaging of biliary ducts with the Stryker® AIM Light Source and SafeLight Cable are 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.

NOTE 3: The L11 AIM Light Source 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.

Performance Testing:

The labeling modification proposed within this 510(k) submission for the Stryker L10 and L11 LED Light Source with AIM does not have an impact on the performance characteristics of the devices that were cleared in the previous submissions.

Bench testing was performed to demonstrate compatibility of the Stryker L10 and L11 LED Light Source with AIM with Stryker's SPY AGENT™ GREEN (Indocyanine green for Injection, USP). Results from the imaging studies demonstrated that there was no visible difference observed in fluorescence between Stryker's SPY AGENT™ GREEN and another commercially available ICG imaging agent.

Conclusions:

The information presented within this Special 510(k) premarket notification demonstrates that the Stryker L10 and L11 LED Light Source with AIM is substantially equivalent in design, intended use, principle of operation, technological characteristics and safety features to the predicate devices. There are no new issues of safety and/or effectiveness introduced as a result of the labeling modification proposing the use of the Stryker L10 and L11 Light Source with AIM in conjunction with SPY AGENT™ GREEN imaging agent. It has been demonstrated that the Stryker L10 and L11 LED Light Source with AIM is compatible for use in fluorescence angiography with Stryker's SPY AGENT™ GREEN imaging agent.