February 12, 2026

Stryker Endoscopy
Irina Glazkova
Staff Regulatory Affairs Specialist
5900 Optical Court
San Jose, California 95138

Re: K260108
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, FCW, GWG, NWB
Dated: January 13, 2026
Received: January 14, 2026

Dear Irina Glazkova:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2026.02.12 14:51:31 -05'00'

Tanisha Hithe
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260108

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 Advanced Imaging Modality 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 Advanced Imaging Modality 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 Advanced Imaging Modality 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 Advanced Imaging Modality 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 Advanced Imaging Modality 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 Advanced Imaging Modality and SafeLight™ Cable are used to perform intraoperative fluorescence imaging of tissues that have taken up the drug.
The L12 LED Light Source with Advanced Imaging Modality 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.

510(k) Summary – K260108

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.

Contact Details:

Applicant Name	Stryker Endoscopy
Applicant Address	5900 Optical Court San Jose, CA 95138
Applicant Contact Telephone	(650) 382-9617
Applicant Contact	Irina Glazkova
Applicant Contact Email	irina.glazkova@stryker.com
Date Prepared	February 11, 2026

Device Name:

Device Trade Name	L12 LED Light Source with AIM
Common Name	Endoscope and accessories
Classification Name	Confocal Optical Imaging
Regulation Number	876.1500
Product Codes	OWN, FCS, FCW, GWG, NWB

Legally Marketed Predicate Device:

Predicate #	Predicate Trade Name	Product Code
K231854	L12 LED Light Source with AIM	OWN, FCS, FCW, GWG, NWB

Device Description Summary:

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 unit designed to illuminate surgical sites in the following applications: visible light, near-infrared fluorescence, and near-infrared transillumination.

Intended Use/Indications for Use:

Upon intravenous administration of SPY AGENT GREEN (indocyanine green for injection, USP), the L12 LED Light Source with Advanced Imaging Modality 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 Advanced Imaging Modality 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 Advanced Imaging Modality 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 Advanced Imaging Modality 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 Advanced Imaging Modality 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 Advanced Imaging Modality and SafeLight™ Cable are used to perform intraoperative fluorescence imaging of tissues that have taken up the drug.

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

Indications of Use Comparison

The subject device, the L12 LED Light Source with AIM, has the same indications for use and intended use as the predicate device.

Technological Comparison

The L12 LED Light Source with AIM (subject device) has the same technological characteristics as the L12 LED Light Source with AIM (predicate device) with the exception of the modified packaging configuration for added support during transport.

Non-Clinical and / or Clinical Tests Summary & Conclusions

Non-clinical testing was designed and developed in accordance with applicable requirements and standards to establish performance and safety of the subject device. These include performance testing to evaluate the updated packaging configuration via FDA-recognized voluntary consensus standard ASTM D4169:2022 (14-576) and LS Light Output (RGBV/NIR) after distribution stress.

The subject device does not require clinical studies to support the determination of substantial equivalence.

The L12 LED Light Source with AIM has the same intended use and indications for use, and fundamental technology as the predicate device. In summary, L12 LED Light Source with AIM is the same or similar with respect to safety and effectiveness to the legally marketed predicate device.