July 24, 2025

Stryker Endoscopy
Michelle Ross
Staff Specialist, Regulatory Affairs
5900 Optical Court
San Jose, California 95138

Re: K252010
Trade/Device Name: SPY Laparoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 27, 2025
Received: June 27, 2025

Dear Michelle Ross:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

JAMES H. JANG -S

Digitally signed by JAMES H. JANG -S
Date: 2025.07.24 07:23:06 -04'00'

James Jang, 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252010

Please provide the device trade name(s).

SPY Laparoscope

Please provide your Indications for Use below.

The SPY Laparoscope is intended to be used for gynecological and general procedures that clinicians deem appropriate for the adult or pediatric patient aged one month or older, when the dimensions of the SPY Laparoscope are appropriate for the patient size and anatomy.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K252010

510(k) Summary

Prepared on: 2025-07-23

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Stryker Endoscopy
Applicant Address	5900 Optical Court San Jose CA 95138 United States
Applicant Contact Telephone	408-677-6491
Applicant Contact	Ms. Michelle Ross
Applicant Contact Email	michelle.ross1@stryker.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	SPY Laparoscope
Common Name	Endoscope and accessories
Classification Name	Laparoscope, General & Plastic Surgery
Regulation Number	876.1500
Product Code(s)	GCJ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221217	SPY Laparoscope	GCJ
K910132	Stryker Laparoscope	GCJ

Device Description Summary

21 CFR 807.92(a)(4)

The SPY Laparoscope is part of Stryker's rigid endoscope product portfolio. The SPY Laparoscope is an optical instrument used to visualize or image a patient's anatomy during minimally invasive, endoscopic procedures for examination, diagnosis or therapy. The SPY Laparoscope transmits light in both the visible and near-infrared spectrum to illuminate the anatomy, then forms and relays the image of the surgical site to a camera system for image processing and display.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The SPY Laparoscope is intended to be used for gynecological and general procedures that clinicians deem appropriate for the adult or pediatric patient aged one month or older, when the dimensions of the SPY Laparoscope are appropriate for the patient size and anatomy.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device has the same indications for use and intended use as the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

Differences in technological characteristics, specifically a) smaller outer diameter (3.3mm vs. 5.4mm and 10mm), b) shorter working length (25cm vs. 30cm, 33cm and 45cm), and c) larger field of view (80°±5° vs. 75°±5°), do not raise different questions of safety or

effectiveness. Testing summarized within this submission demonstrates the device conforms with design input requirements, user needs and intended uses. Comparative bench top testing demonstrates the subject and reference device's optical performance are equivalent. Risk management activities concluded that the benefits associated with the use of the device outweigh the residual risk; the overall residual risk is acceptable. The combination of this data demonstrates that the subject device is substantially equivalent with respect to safety and effectiveness to the legally marketed predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical testing was designed and developed in accordance with applicable requirements and standards to establish performance and safety of the subject device (SPY Laparoscope). The following performance data were provided in support of the substantial equivalence determination:

1. Packaging
- In accordance with FDA-recognized voluntary consensus standard ASTM D4169:2022 (14-576)

2. Performance – Bench

Comparative testing to currently legally marketed reference device:
- Optical verification: Fiber Transmission, Illumination, Optical Transmission, Vignetting, Modulated Transfer Function (MTF), Distortion, Chromatic Aberration, NIR Transmission, Field of View (FOV), Apparent Field of View (AFOV), and Image Runout etc.
- In accordance with FDA-recognized voluntary consensus standard ISO 8600-1:2015 (9-110)
- In accordance with FDA-recognized voluntary consensus standard ISO 8600-3:2019 (9-123)
- In accordance with FDA-recognized voluntary consensus standard ISO 8600-4:2023 (9-146)
- In accordance with FDA-recognized voluntary consensus standard ISO 8600-5:2020 (9-131)

3. Electrical Safety
- In accordance with FDA-recognized voluntary consensus standard IEC 60601-1:2020 (19-49)
- In accordance with FDA-recognized voluntary consensus standard IEC 60601-2-18:2009 (9-114)

4. Biocompatibility
- In accordance with FDA-recognized voluntary consensus standard ISO 10993-1:2018 (2-258)
- In accordance with FDA-recognized voluntary consensus standard ISO 10993-5:2009 (2-245)
- In accordance with FDA-recognized voluntary consensus standard ISO 10993-10:2021 (2-296)
- In accordance with FDA-recognized voluntary consensus standard ISO 10993-11:2017 (2-255)
- In accordance with FDA-recognized voluntary consensus standard ISO 10993-23:2021 (2-291)

5. Cleaning, Disinfection & Sterilization (Reprocessing)
- In accordance with FDA-recognized voluntary consensus standard AAMI TIR12:2020/(R)2023 (14-602)
- In accordance with FDA-recognized voluntary consensus standard ANSI AAMI ST98:2022 (14-583)
- In accordance with FDA-recognized voluntary consensus standard ANSI AAMI ST79:2017 + A1:2020, A2:2020, A3:2020, A4:2020 (14-562)
- In accordance with FDA-recognized voluntary consensus standard ANSI AAMI ST58:2024 (14-607)
- In accordance with FDA-recognized voluntary consensus standard ISO 17664-1:2021 (14-578)
- In accordance with FDA-recognized voluntary consensus standard ISO 17665:2024 (14-601)
- In accordance with FDA-recognized voluntary consensus standard ISO 14937:2009 (14-337)
- In accordance with FDA-recognized voluntary consensus standard ISO 22441:2022 (14-586)
- In accordance with ISO 15883-1:2006 + A1:2014
- In accordance with ISO 15883-2:2006
- In accordance with ISO 15883-5:2021

6. Miscellaneous
- In accordance with FDA-recognized voluntary consensus standard ISO 14971 (5-125)

Verification and validation testing successfully completed demonstrated that the device conform with recognized safety standards, design input specifications, user needs and intended uses.

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

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