June 17, 2022

Stryker
Christie Samsa
Manager, Regulatory Affairs
5900 Optical Court
San Jose, California 95138

Re: K221217
Trade/Device Name: SPY Laparoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ, FCW
Dated: April 25, 2022
Received: April 27, 2022

Dear Christie Samsa:

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 and Part 809); 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,

Long Chen, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K221217

Device Name
SPY Laparoscope

Indications for Use *(Describe)*
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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

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	Christie Samsa Manager, Regulatory Affairs Phone: (978) 500-1303 Email: christie.samsa@stryker.com
Date Prepared	June 9, 2022

Subject Device:

Name of Device	SPY Laparoscope
Common or Usual Name	Laparoscope
Classification Name	Endoscope And Accessories, 21 C.F.R. §876.1500
Regulatory Class	Class II
Product Code	GCJ

Predicate Device:

Name of Device	Stryker AIM (Advanced Imaging Modality) System, K210088

NOTE: The predicate device has not been subject to a design-related recall.

Device Description:

Stryker's SPY Laparoscope is part of Stryker's rigid endoscope product portfolio. Stryker's SPY Laparoscopes are tubular optical instruments 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 and image the anatomy, then forms and relays the image of the surgical site to a camera system for processing and display.

Indications for Use:

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.

Comparison of Technological Characteristics with the Predicate Device:

Feature	Subject Device	Predicate Device
	SPY Laparoscope (Current Submission)	**Stryker AIM (Advanced Imaging Modality) System (K210088)**
Manufacturer	Stryker Endoscopy	Same as subject device
Submission Reference	Current Submission	K210088
Intended Use	Endoscopic white light and near-infrared illumination and imaging during endoscopic procedures.	Same as subject device
Indications for Use Statement	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.	Same as subject device
Image Transmission	Rigid rod lenses	Same as subject device
Outer diameter	5.4mm, 10mm	Same as subject device
Working Length	30cm, 33cm & 45cm	30cm, 33cm
DOV	0°, 30°, 45°	0°, 30°
FOV	75°	Same as subject device
Patient-Contacting Materials	Stainless Steel, Epoxy, Optical Glass (sapphire), Glass Fibers	Same as subject device
Single Use or Reusable	Reusable	Same as subject device
Cleaning	Manual and Automated	Same as subject device
Disinfection	Manual and Automated	Same as subject device
Sterilization Methods	Autoclave, Steris VPRO, Sterrad	Same as subject device
Sterility Assurance Level	10^{-6}	10^{-6}

Performance Testing:

The following performance data were provided in support of the substantial equivalence determination.

Test	Method	Result
Electrical Safety	• IEC 60601-1:2005 + A1:2012 • IEC 60601-2-18:2009	PASS
Packaging	• ASTM D4169:2016	PASS
Biocompatibility	• ISO 10993-1:2018 • ISO 10993-5:2009 • ISO 10993-10:2010 • ISO 10993-11:2017 • FDA Guidance: Use of International Standard ISO 10993-1	PASS
Cleaning & Disinfection	• AAMI TIR 12:2020 • AAMI TIR 30:2011 • ISO 15883-5:2021 • ISO 15883-2:2009 • ISO 15883-1:2009	PASS
Sterilization	• AAMI ST79:2017 • AAMI ST58:2013 • AAMI TIR 12:2020 • ISO 17665-1:2021 • ISO 14937:2009 • FDA Guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling	PASS
Performance - Bench	• Optical and mechanical verification in accordance with device input specifications and comparison to predicate device • ISO 8600-1:2015	PASS
Design Validation	• IEC 62366-1:2020 • In accordance with device user needs	PASS

Conclusions:

The SPY Laparoscope is the same or similar in design, intended use, principles of operation, technological characteristics and safety features to the predicate device. There are no new issues of safety and/or effectiveness introduced by the SPY Laparoscope when used as instructed.