February 12, 2024

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

Re: K233635
Trade/Device Name: SPY Cystoscope/Hysteroscope
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH, FAJ, NWB
Received: January 29, 2024

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.

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,

Jason Roberts -S

Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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)*
K233635

Device Name
SPY Cystoscope/Hysteroscope

Indications for Use *(Describe)*
The SPY Cystoscopes/Hysteroscopes are intended to provide visualization in general urological and gynecological surgery through the minimally invasive approach, by utilizing natural orifices to access the surgical site.

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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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	Michelle Ross Staff Regulatory Affairs Specialist Phone: (408) 677-6491 Email: michelle.ross1@stryker.com
Date Prepared	February 7, 2024

Subject Device:

Name of Device	SPY Cystoscopes/Hysteroscopes
Common or Usual Name	Hysteroscope and Cystoscope
Classification Name	Hysteroscope (and accessories) (21 C.F.R. 884.1690)
Regulatory Class	Class II
Product Code	HIH
Subsequent Product Code:	FAJ NWB

Predicate Device:

Predicate Device	Ideal Eyes Autoclavable Cystoscopes and Hysteroscopes	K040390
Reference Device	Stryker AIM HD Autoclavable Laparoscope	K210088

NOTE: The predicate and reference devices have not been subject to a design-related recall.

Device Description:

The SPY Cystoscope/Hysteroscope is part of Stryker's rigid endoscope product portfolio. The SPY Cystoscope/Hysteroscope 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 Cystoscope/Hysteroscope transmits light in the visible spectrum to illuminate the anatomy, then forms and relays the image of the surgical site to a camera system for image processing and display.

Indications for Use:

The SPY Cystoscopes/Hysteroscopes are intended to provide visualization in general urological and gynecological surgery through the minimally invasive approach, by utilizing natural orifices to access the surgical site.

Comparison of Technological Characteristics with the Predicate Device:

Feature	Subject Device	Predicate Device
	SPY Cystoscopes/ Hysteroscopes (Current Submission)	**Ideal Eyes Autoclavable Cystoscopes and Hysteroscopes (K040390)**
Manufacturer	Stryker Endoscopy	Same as subject device
Intended Use	Endoscopic illumination and imaging during endoscopic procedures.	Same as subject device
Indications for Use Statement	The SPY Cystoscopes/Hysteroscopes are intended to provide visualization in general urological and gynecological surgery through the minimally invasive approach, by utilizing natural orifices to access the surgical site.	The Stryker Urology and Gynecology Hardware System is intended to provide the user with the means for endoscopic diagnostic and therapeutic surgical procedures. Examples of use of the product include the visualization and manipulation of anatomy, ablation, biopsy, incision, and resection of tissue, and/or as the surgeon deems appropriate. The system is intended for use in general urological and gynecological surgery through the minimally invasive approach, by utilizing natural orifices to access the surgical site. They are intended for use in, but not limited to, the following types of procedures: • Dilation of the urethra, and cold-slitting of urethral strictures. • Trans-urethral incision and resection of the prostate • Trans-urethral removal of bladder tumors • Trans-cervical resection and ablation of the endometrium • Trans-cervical resection of fibroids
Image Transmission	Rigid rod lenses	Same as subject device
Outer diameter	4.0mm	2.7-4.0mm
Working Length	290-300mm	240-300mm
DOV	0°, 12°, 30°, 70°	0°-120°
FOV	65°-75°	60°-90°
Working Channel	No	Same as subject device
Locking Mechanism	Speed-Lock (with optional O-Adapter), Karl Storz (KS)-compatible	Speed-Lock
Patient-Contacting Materials	Stainless Steel, Epoxy, Optical Glass, Glass Fibers	Stainless Steel, Epoxy, glass fiber, optical glass, German Silver
Single Use or Reusable	Reusable	Same as subject device
Cleaning	Manual and Automated	Same as subject device
Disinfection	Automated	Same as subject device

Feature	Subject Device	Predicate Device
	SPY Cystoscopes/ Hysteroscopes (Current Submission)	**Ideal Eyes Autoclavable Cystoscopes and Hysteroscopes (K040390)**
Sterilization Methods	Autoclave, Hydrogen Peroxide (Steris, Sterrad)	Autoclave, Hydrogen Peroxide (Steris, Sterrad), Ethylene Oxide (EO)
Sterility Assurance Level	10^{-6}	10^{-6}

The subject and predicate devices have the same intended use to provide visualization during gynecological and urological surgery. The predicate device included urology and gynecology hardware in addition to cystoscopes and hysteroscopes; therefore, only a subset of the predicate device indications for use are applicable to the subject device. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety or effectiveness and can be evaluated through performance testing.

Performance Testing:

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

Test	Method	Result
Electrical Safety	In accordance with FDA-recognized voluntary consensus standard IEC 60601-1:2020 (19-49)	Pass
	In accordance with FDA-recognized voluntary consensus standard IEC 60601-2-18:2009 (9-114)	Pass
Packaging	In accordance with FDA-recognized voluntary consensus standard ASTM D4169:2022 (14-576)	Pass
Biocompatibility	In accordance with FDA-recognized voluntary consensus standard ISO 10993-1:2018 (2-258)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 10993-5:2009 (2-245)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 10993-10:2021 (2-296)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 10993-23:2021 (2-291)	Pass
Cleaning, Disinfection & Sterilization (Reprocessing)	In accordance with AAMI TIR12:2020	Pass
	In accordance with FDA-recognized voluntary consensus standard ANSI AAMI ST98:2022 (14-583)	Pass
	In accordance with ISO 15883-1:2009	Pass
	In accordance with FDA-recognized voluntary consensus standard ANSI AAMI ST79:2017 + A1:2020, A2:2020, A3:2020, A4:2020 (14-562)	Pass
	In accordance with FDA-recognized voluntary consensus standard ANSI AAMI ST58:2013/(R)2018 (14-432)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 17664-1:2021 (14-578)	Pass

Test	Method	Result
	In accordance with FDA-recognized voluntary consensus standard ISO 17664-2:2021 (14-579)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 17665-1:2006 (14-333)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 14937:2009 (14-337)	Pass
Performance – Bench	Comparative testing to currently legally marketed predicate device: - Optical verification - Contrast	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 8600-1:2015 (9-110)	Pass
	Hardware compatibility testing	Pass

Conclusions:

The SPY Cystoscope/Hysteroscope is similar in design, intended use, principles of operation, technological characteristics and safety features to the predicate device. The results of non-clinical performance testing demonstrate that the SPY Cystoscope/Hysteroscope is as safe and effective as the legally marketed predicate device to support a substantial equivalence determination.