September 14, 2023

Karl Storz Endoscopy America, Inc.
Jordan Lydia Verla
Senior Regulatory Affairs Specialist
2151 E. Grand Avenue
El Segundo, CA 90245

Re: K223885
Trade/Device Name: HOPKINS Telescopes
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and Accessories
Regulatory Class: II
Product Code: HIH
Dated: August 28, 2023
Received: August 29, 2023

Dear Jordan Lydia Verla:

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/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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223885

Device Name
HOPKINS Telescopes

Indications for Use *(Describe)*
The HOPKINS Telescopes when used with sheaths are intended to be used to permit viewing of the cervical and uterine cavity for the purpose of performing diagnostic and 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.

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7. 510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Submitter:	KARL STORZ Endoscopy-America, Inc. 2151 E. Grand Avenue El Segundo, CA 90245
Contact:	Jordan Lydia Verla Senior Regulatory Affairs Specialist Tel: (424) 218-8100 ext. 8382 Email: Jordan.Verla@karlstorz.com
Date of Preparation:	September 11, 2023
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: HOPKINS Telescopes Classification Name: Hysteroscope and accessories (21 CFR 884.1690)
Regulatory Class:	II
Product Code:	HIH
Classification Panel:	Obstetrics/Gynecology
Predicate Device(s):	KARL STORZ Magnifying Hysteroscopes (K935716) The predicate device has not been subject to a design-related recall.
Device Description:	The HOPKINS Telescopes are rigid telescopes that utilize the rod lens technology. At the distal end of the telescope's shaft is the lens and the other end of the shaft is attached to the eyepiece. Throughout the central lumen of the HOPKINS Telescopes, optical glass rods are used to transmit and magnify the image received from the lens. The HOPKINS Telescopes are available with 0°, 12° and 30° direction of view, 2mm, 2.9mm, 4mm diameter and 26cm, 30cm, 36cm working lengths.
Intended Use and Indications for Use:	*Intended Use:* The HOPKINS Telescopes in conjunction with the sheath are intended to be used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures.

	Indications for Use: The HOPKINS Telescopes when used with sheaths are intended to be used to permit viewing of the cervical and uterine cavity for the purpose of performing diagnostic and surgical procedures.
Technological Characteristics:	The subject and predicate devices have similar indications for use, operating principle, and similar technological characteristics.

	HOPKINS Telescopes Subject Device	**Magnifying Hysteroscopes Predicate Device K935716**
Indications for Use	The HOPKINS Telescopes when used with sheaths are intended to be used to permit viewing of the cervical and uterine cavity for the purpose of performing diagnostic and surgical procedures.	I. Diagnostic Hysteroscopy A. Indications for Use • Abnormal uterine bleeding • Infertility and pregnancy wastage • Evaluation of abnormal hysterosalpingogram • Intrauterine foreign body • Pelvic pain B. Absolute Contraindications for Use • Acute Pelvic Inflammatory Disease (PID) C. Relative Contraindications for Use • Inability to distend uterus • Cervical/vaginal infection • Uterine bleeding or menses • Known pregnancy • Invasive carcinoma of the cervix • Recent uterine perforation • Medical contraindication • Intolerance to anesthesia D. Warnings • Suspicion of pregnancy should suggest a pregnancy test prior to

			performance of diagnostic hysteroscopy. E. Precautions • Vaginal ultrasonography prior to hysteroscopy may identify clinical conditions that will alter patient management. F. Operative Hysteroscopy A. Indications for Use • Directed biopsy • Removal of submucuous fibroids and large polyps • Submucosous myomectomy • Transection of intrauterine adhesions • Transection of intrauterine septa • Endometrial ablation B. Absolute Contraindications for Use • Acute PID C. Relative Contraindications for Use • Inability to distend uterus • Cervical/vaginal infection • Uterine bleeding or menses • Known pregnancy • Invasive carcinoma of the cervix • Recent uterine perforation • Medical contraindication • Intolerance to anesthesia D. Relative Contraindications to Endometrial Ablation • Hysteroscopic endometrial ablation, whether by laser or electrosurgery, should not be undertaken before

			adequate training, preceptorship and clinical experience. Additionally, tissue sampling is required prior to destruction of the endometrium. The following are clinical conditions that can significantly complicate hysteroscopic endometrial ablation: • Adenomatous endometrial hyperplasia • Severe adenomyosis • Pelvic pain (subtle PID) • Uterine anomalies E. Relative Contraindications to Hysteroscopic Myomectomy • Hysteroscopic myomectomy, whether by laser or electrosurgery, should not be undertaken before adequate training, preceptorship and clinical experience. The following are clinical conditions that can significantly complicate hysteroscopic myomectomy: Severe anemia Inability to circumnavigate the myoma F. Warnings

		• If a liquid distention medium is used (continuous flow hysteroscopy), strict fluid intake and output surveillance should be maintained. Intrauterine instillation exceeding 2 liters should be followed with great care to avoid the possibility of fluid overload. G. Complications • Hyponatremia • Hypothermia • Uterine perforation, resulting in possible injury to bowel, bladder, major blood vessels and ureter • Pulmonary edema • Cerebral edema
Product Code(s)	HIH	HIH
Target Population	Adults	Adults
Anatomical site	Cervical canal, uterine cavity	Cervical canal, uterine cavity
Where used	Hospital	Hospital
Endoscope Type	Rigid, rod lens	Rigid, rod lens
Distal Tip Diameter	Scope: 2mm, 2.9mm, 4mm Sheaths: 2.3mm-8mm	Scope: 2.7mm, 2.9mm, 4mm
Working Length	Scope: 26cm, 30cm, 36cm	Scope: 18cm, 30cm
Direction of View	0°, 12°, 30°	30°
Field of View	79°, 59°, 88°, 82°, 86°, 62° (laboratory measurement)	82°, 60°, 68°, 68°, 51°, 81°
Depth of Field	0mm-362mm	5mm-302mm
Light Source	External	External

	Patient-Contacting Material	Scopes: Surgical Stainless Steel Sheaths: Surgical Stainless Steel Bridges: Surgical Stainless Steel	Chromium Plated Monel 400
	Cleaning	Manual, Automatic	Manual
	Sterilization	Scopes: Steam (pre-vacuum), STERRAD 100NX, STERRAD NX, STERRAD 100S, STERIS V-PRO Trophyscope: Steam (pre-vacuum), STERRAD 100NX, STERIS V-PRO Bridges: Steam (pre-vacuum) Sheaths: Steam (pre-vacuum)	EO Sterilization
Non-Clinical Performance Data:	There are no performance standards or special controls developed under Section 514 of the FD&C Act for endoscopes. However, the HOPKINS Telescopes follows the FDA recognized consensus standards and is tested according to the following standards and FDA Guidance: **FDA Guidance** • Hysteroscopes and Gynecology Laparoscopes - Submission Guidance for a 510(k) **ISO Endoscopic Standards** • ISO 8600-1 • ISO 8600-3 • ISO 8600-5 • ISO 8600-6 **Biocompatibility Summary** • Cytotoxicity (ISO 10993-5) • Acute Systemic Toxicity (ISO 10993-11) • Intracutaneous Irritation (ISO 10993-10) • Maximization Sensitization (ISO 10993-10) **Electrical Safety and EMC**		

	• IEC 60601-2-18 (3RD Edition) **Reprocessing (Cleaning and Sterilization)** • AAMI TIR12: 2010 • AAMI TIR30: 2011 • ANSI/AAMI ST8: 2013 • ANSI/AAMI ST77:2013 • ANSI/AAMI ST79:2017 • ANSI/AAMI ST81:2004/(R)2010 • AAMI/ISO 14937:2009 • ANSI/AAMI/ISO 17655-1:2006/2013 • Reprocessing Medical Device in Health Care Settings: Validation Methods and Labeling Comparative bench testing between the subject and predicate device demonstrated that the HOPKINS Telescopes has met all its design specification and is substantially equivalent to its predicate device.
Clinical Performance Data:	Clinical studies were not required to demonstrate substantial equivalence to the predicate device.
Conclusion:	The conclusions drawn from the nonclinical test demonstrate that the subject device is as safe and effective as the predicate device to support a substantial equivalence determination.