December 20, 2022

KARL STORZ Endoscopy America, Inc.
Alita McElroy
Senior Regulatory Affairs Specialist
2151 E. Grand Ave
El Segundo, California 90245

Re: K221004
Trade/Device Name: HOPKINS Telescopes
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: November 19, 2022
Received: November 21, 2022

Dear Alita McElroy:

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,

Jessica Carr -S

for Long Chen, PhD
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)*

K221004

Device Name
HOPKINS Telescopes

Indications for Use *(Describe)*

The HOPKINS Telescopes are intended to provide visualization during laparoscopy, thoracoscopy and general surgery in adults and pediatrics.

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
K221004

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 EI Segundo, CA 90245
Contact:	Alita McElroy Senior Regulatory Affairs Specialist Phone: (424) 218-8376 Email: Alita.McElroy@karlstorz.com
Date of Preparation:	December 19, 2022
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: HOPKINS Telescopes Classification Name: Laparoscope, General and Plastic Surgery (21 CFR 876.1500)
Regulatory Class:	II
Product Code:	GCJ
Classification Panel:	General and Plastic Surgery
Predicate Device(s):	KARL STORZ HOPKINS I and II Rigid Autoclavable Telescopes (K935279)
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 0º, 25º and 45º direction of view, 5mm diameter and 29cm working lengths.
Intended Use and Indications for Use:	The HOPKINS Telescopes are intended to provide visualization during laparoscopy, thoracoscopy and general surgery in adults and pediatrics.

Technological Characteristics.

Technological Characteristics	HOPKINS Telescopes Subject Device K221004	KARL STORZ HOPKINS I and II Rigid Autoclavable Telescopes Predicate Device K935279	Comparison
Physical Characteristics			
Endoscope Type	Rigid, rod lens	Rigid, rod lens	same
Outer Diameter	5mm	4mm-10mm	similar
Working Length	29cm	29cm-35cm	similar
Optical Characteristics			
Direction of View	0°, 25°, 45°	0°, 30°	different
Field of View	68°	65°- 70°	similar
Depth of Field	15.1mm-200mm	11.4mm- 200mm	different
Light source	External	External	same
Reprocessing Methods			
Cleaning	Manual, Automatic	Manual	different
Sterilization modalities	Steam (pre-vacuum), STERRAD 100S, STERRAD NX, STERRAD 100NX, STERIS V-PRO 1, V-PRO 1 Plus	Steam (pre-vaccum), EO, Chemical Disinfection	different

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:

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) **Thermal Safety** • IEC 60601-2-18:2009 (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:	Published literature was provided to support the safety and effectiveness of the HOPKINS Telescopes for use in pediatrics during laparoscopy, thoracoscopy and general surgery.
Conclusion:	The conclusions drawn from the nonclinical test demonstrate that the subject device is as safe and effective as the predicate device.