



August 13, 2025

Karl Storz SE & Co. KG
Emily Rhiel
Regulatory Affairs Specialist
Dr. Karl-Storz-Straße 34
Tuttlingen, BW 78532
GERMANY

Re: K243653
Trade/Device Name: KARL STORZ HOPKINS Telescopes for Urology
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ
Dated: July 15, 2025
Received: July 15, 2025

Dear Emily Rhiel:

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,

Mark R. Kreitz -S

for Mark J. Antonino, M.S.
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

Indications for Use

Submission Number (if known)

K243653

Device Name

KARL STORZ HOPKINS Telescopes for Urology

Indications for Use (Describe)

Telescopes for adults

KARL STORZ HOPKINS Telescopes for Urology when used with sheaths, obturators, accessories, and instruments are intended to provide visualization and operative access during diagnostic and therapeutic urological procedures in adults.

Telescopes for adults and pediatrics

KARL STORZ HOPKINS Telescopes for Urology when used with sheaths, obturators, accessories, and instruments are intended to provide visualization and operative access during diagnostic and therapeutic urological procedures 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

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 and the FDA guidance document titled *"The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]"* issued on July 28, 2014. All data included in this document is accurate and complete to the best of KARL STORZ SE & Co. KG knowledge.

Submitter:	KARL STORZ SE & Co. KG Dr.-Karl-Storz-Straße 34 78532 Tuttlingen, Germany					
Contact:	Emily Rhiel Regulatory Affairs Specialist Phone: (774) 318-2820 Email: emily.rhiel@karlstorz.com					
Date of Preparation:	August 6, 2025					
Type of 510(k) Submission:	Traditional					
Device Trade name:	KARL STORZ HOPKINS Telescopes for Urology					
Regulatory Class:	II					
Product Code:	FAJ					
Classification Name:	Cystoscope and accessories, Flexible/Rigid (21 CFR Part 876.1500)					
Common Name:	Endoscope and accessories					
Device Panel:	Gastroenterology & Urology					
Predicate Device(s):	K943176 KARL STORZ HOPKINS I&II/OPER/AUTOCLAVABLE TELESCOPES					
Device Description:	The KARL STORZ HOPKINS Telescopes for Urology are rigid cystoscope systems, which provide visualization and operative access during urological procedures in adults and pediatrics. Urological devices consist of sheaths, obturators, accessories, and instruments, which are combined into a cystoscope system for diagnostic or therapeutic procedures in the lower urinary tract such as prostate, bladder, and urethra. The sheath provides a working channel for therapeutic instruments, as well as ports for irrigation and aspiration. The obturator is inserted through the sheath for atraumatic insertion to the surgical site, then removed after placement. The telescope is inserted through the sheath for visualization of the surgical site. All instruments subject to this submission are optical instruments, and compatible with telescopes; the optical instruments are only compatible with adult systems. Compact telescopes are all-in-one cystoscopes with built-in sheaths, obturators, and optics, they do not require device compilation for use. Model numbers are provided in the table below. <table><tr><th>Device Type</th><th>Model Numbers</th></tr><tr><td>HOPKINS Rigid Telescope</td><td>27005AA/BA/BGA/CA/EA/FA,</td></tr></table>		Device Type	Model Numbers	HOPKINS Rigid Telescope	27005AA/BA/BGA/CA/EA/FA,
Device Type	Model Numbers					
HOPKINS Rigid Telescope	27005AA/BA/BGA/CA/EA/FA,					

			27017AA/BA, 27018AA/BA/CA, 27020AA/BA/FA, 27301AA/BA, 27324AA, 27325BA
		Compact Telescope	27035BA/BB
		Sheath	27026A/AA/AB, 27026B/BA/BB, 27026C/CA/CB/CC, 27026DA/DB, 27026U/UA, 27027KL, 27029CN/DN, 27031E/F, 27032K/L/M, 27034A/B
		Obturator	27026AO/BO/CCO/CO/DO/UO, 27027KO, 27028A/B/BU/C/CN/D, 27029OC/OD, 27031EO/FO, 27032LO/MO/OK, 27034AO/BO
		Optical Instruments	27072A/BL/BSA/DU/F/MC/S, 27074B
		Accessories	Telescope Bridge: 27025F/G/GA/GF/GFA, 27027NL, 27032F, 27034G, 27047F Instrument Adaptor: 27074SC/SZ, 27093GN/SC, 27094BY
Indications for Use:		Telescopes for adults KARL STORZ HOPKINS Telescopes for Urology when used with sheaths, obturators, accessories, and instruments are intended to provide visualization and operative access during diagnostic and therapeutic urological procedures in adults. Telescopes for adults and pediatrics KARL STORZ HOPKINS Telescopes for Urology when used with sheaths, obturators, accessories, and instruments are intended to provide visualization and operative access during diagnostic and therapeutic urological procedures in adults and pediatrics.	

Physical and Technological Characteristics:		Subject Device Type: Rigid Endoscope	Telescope Predicate: K943176 KARL STORZ HOPKINS I&II/OPER/AUTOCLAVABLE TELESCOPES
	Endoscope Type	Rigid, rod lens	Same as subject
	Outer Diameter	1.9 – 4mm Compact telescopes: 6.6 & 7.9mm	Same as subject (No compact telescopes)
	Working Length	11.7 – 30.3cm	11.7 – 36.3cm
	Direction of View	0 -120°	-3.7 – 120.5°
	Field of View	37.1 - 100°	36 – 109.3°
	Light Source	External	Same as subject
	Primary Patient Contacting Material	Stainless steel	Chromium Plated Monel 400
	Cleaning & Sterilization	Cleaning: required Sterilization: • Steam • STERRAD modalities • V-PRO modalities	Cleaning: required Sterilization: • Steam • EtO
Non-Clinical Performance Data:	The following non-clinical performance data were provided in support of the substantial equivalence determination. <u>Biocompatibility Evaluation</u> The system complies with the following standards: • ISO 10993-1: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process • ISO 10993-2: Biological evaluation of medical devices – Part 2: Animal welfare requirements • ISO 10993-5: Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity • ISO 10993-10: Biological evaluation of medical devices – Part 10: Tests skin sensitization • ISO 10993-11: Biological evaluation of medical devices – Part 11: Tests for systemic toxicity • ISO 10993-12: Biological evaluation of medical devices – Part 12: Sample preparation and reference materials • ISO 10993-18: Biological evaluation of medical devices – Part 18: Chemical characterization of materials • ISO 10993-23 Biological evaluation of medical devices – Part 23: Tests for irritation 2021 <u>Reprocessing Validation</u> The reprocessing data submitted complies with the following standards: • ISO 11138-1: Sterilization of health care products - Biological indicators - Part 1: General requirements		

- ISO 14937: Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
- ISO 17664-1: Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices
- ISO 17664-2: Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices – Part 2: Non-critical medical devices
- ISO 17665-1: Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 11737-1: Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products
- ISO 11737-2: Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ISO 11737-3: Sterilization of health care products. Microbiological methods – bacterial endotoxin testing”
- ISO 22441: Sterilization of Health Care Products – General Requirements for Characterization of a Sterilization Agent and the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
- AAMI TIR12: Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers
- ASTM F3208-20: Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices.
- ANSI / AAMI ST8: “Hospital Steam Sterilizers
- ANSI / AAMI ST77: Containment Devices for Reusable Medical Device Sterilization
- ANSI / AAMI ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- ANSI / AAMI ST98: Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices

Bench Performance Testing

The bench performance data submitted includes thermal safety and complies with the following standards:

- ISO 8600-1: Endoscopes - Medical endoscopes and endotherapy

	devices -- Part 1: General requirements • ISO 8600-3: Endoscopes - Medical endoscopes and endotherapy devices Part 3: Determination of field of view and direction of view of endoscopes with optics • ISO 8600-5: Optics and photonics — Medical endoscopes and endotherapy devices -Part 5: Determination of optical resolution of endoscopes with optics • IEC 62471: Photobiological safety of lamps and lamp systems • IEC 60601-2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
Clinical Performance Data:	Clinical testing was not required to demonstrate the substantial equivalence to the predicate device. Non-clinical bench testing was sufficient to assess safety and effectiveness and to establish the substantial equivalence of the modifications.
Conclusion:	The conclusions drawn from the non-clinical performance data demonstrates that the subject device is as safe as and as effective as the predicate devices. As such, we conclude that the substantial equivalence of the subject and the predicate devices has been met, and the differences between the subject and the predicate devices do not raise new questions of safety and effectiveness.