August 26, 2026

Karl Storz SE & CO. KG
Jordan Lydia Verla
Senior Regulatory Affairs Specialist
Dr.-Karl-Storz-Straße 34
Baden-Wurttemberg
Tuttlingen, 78532
Germany

Re: K254103
Trade/Device Name: KARL STORZ HOPKINS Telescopes, HOPKINS Forward-Oblique Telescope, KARL STORZ ENDOCAMELEON ARTHRO HOPKINS Telescope
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: July 24, 2026
Received: July 24, 2026

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 (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2026.08.26 15:26:47 -04'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic 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)*
K254103

Device Name
KARL STORZ HOPKINS Telescopes, HOPKINS Forward-Oblique Telescope, KARL STORZ ENDOCAMELEON ARTHRO HOPKINS Telescope

Indications for Use *(Describe)*
For 28208BA, 28300BA, 28305BA, 28719BA, 28731AWA, 28731BWA, 28731CWA:
The KARL STORZ HOPKINS Telescopes and HOPKINS Forward-Oblique Telescope are intended for use in visualization during arthroscopic surgical procedures in the hip, knee, shoulder, elbow, wrist, and ankle.

For 28731AE:
The KARL STORZ ENDOCAMELEON ARTHRO HOPKINS Telescope is intended for use in visualization during arthroscopic surgical procedures in the hip, knee, shoulder, elbow, wrist, and ankle.

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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510(k) Summary

Submitter:	KARL STORZ SE & CO. KG Dr.-Karl-Storz-Straße 34 TUTTLINGEN, Baden-Württemberg GERMANY, 78532
Contact:	Jordan Lydia Verla Senior Regulatory Affairs Specialist Tel: (424) 218-8100 ext. 8382 Email: Jordan.Verla@karlstorz.com
Date of Preparation:	August 26, 2026
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: KARL STORZ HOPKINS Telescopes, HOPKINS Forward-Oblique Telescope, KARL STORZ ENDOCAMELEON ARTHRO HOPKINS Telescope Classification Name: Arthroscope (21 CFR 888.1100)
Regulatory Class:	II
Product Code:	HRX
Classification Panel:	Orthopedic
Predicate Device(s):	STRYKER Arthroscopes (K202659) KS Arthroscopic Telescopes (K943052)
Device Description:	The KARL STORZ HOPKINS Telescopes for Arthroscopy product family includes HOPKINS Forward-Oblique Telescope, HOPKINS Telescope, and ENDOCAMELEON ARTHRO HOPKINS Telescope models. The KARL STORZ HOPKINS Telescopes for Arthroscopy are rigid endoscopic visualization devices intended to provide real-time imaging of intra-articular anatomical structures during arthroscopic surgical procedures. The devices are used to support minimally invasive visualization of joint anatomy during standard arthroscopic procedures. The KARL STORZ HOPKINS product line includes arthroscopes available in multiple diameters, viewing angles, and configurations, including the

	ENDOCAMELEON HOPKINS Arthroscope. The ENDOCAMELEON variant incorporates an adjustable direction-of-view mechanism that allows the viewing angle to be varied intraoperatively within the joint using an integrated control wheel. The arthroscopes are for use in joint-specific use dependent on the arthroscope model. They support visualization of intra-articular structures such as cartilage, ligaments, menisci, labral structures, and synovial tissue. Selection of the appropriate arthroscope configuration is based on the surgeon's clinical judgment and procedural requirements.
Indications for Use:	*Indications for Use:* For 28208BA, 28300BA, 28305BA, 28719BA, 28731AWA, 28731BWA, 28731CWA: The KARL STORZ HOPKINS Telescopes and HOPKINS Forward-Oblique Telescope are intended for use in visualization during arthroscopic surgical procedures in the hip, knee, shoulder, elbow, wrist, and ankle. For 28731AE: The KARL STORZ ENDOCAMELEON ARTHRO HOPKINS Telescope is intended for use in visualization during arthroscopic surgical procedures in the hip, knee, shoulder, elbow, wrist, and ankle.
Technological Characteristics:	The subject and predicate devices have similar technological characteristics and similar operating principles as the subject device.

	KARL STORZ HOPKINS Telescopes, HOPKINS Forward-Oblique Telescope, KARL STORZ ENDOCAMELEON ARTHRO HOPKINS Telescope Subject Device	**STRYKER ARTHROSCOPES (K202659)**	**KS ARTHROSCOPIC TELESCOPES (K943052)**
Endoscope Type	Rigid, rod lens	Same as subject	Same as subject
Direction of View	0°, 30°, 70° 15°–90° (Endocameleon)	0°, 30°, 45°, 70°, and 30° reverse cant	0°, 30°, 70°, 90°, 120°
Diameter	1.9mm, 2.4mm, 2.7mm, 4mm	1.9mm, 2.4mm, 2.7mm, 2.9mm, 4mm	Same as subject

	Working Length	66mm, 98mm, 111mm, 173mm, 175mm, 180mm, 188mm	58mm, 72mm, 75mm, 120mm, 140mm, 165mm, 200mm	40mm, 100mm, 125mm, 170mm, 175mm, 185mm
	Field of View	32.3°; 48.26°; 57.2°; 69.3°; 69.6°; 99.8°; 100°	65°; 80°; 105°	Same as subject
	Light Source	External	Same as subject	Same as subject

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 subject device follows the FDA recognized consensus standards and is tested according to the following standards and FDA Guidance:

Risk

- ISO 14971:2019

Usability

- IEC 62366-1:2015 + Amd.1:2020

ISO Endoscopic Standards

- ISO 8600-1
- ISO 8600-3
- ISO 8600-5
- ISO 8600-6

Photobiological Safety

- IEC 62471:2006

Biocompatibility Summary

- Biological Evaluation (ISO 10993-1)
- Cytotoxicity (ISO 10993-5)
- Intracutaneous Irritation (ISO 10993-10)
- Maximization Sensitization (ISO 10993-10)
- Acute Systemic Toxicity (ISO 10993-11)
- Material-Mediated Pyrogenicity (ISO 10993-11)
- Sample Preparation (ISO 10993-12)
- Chemical Characterization (ISO 10993-18)
- Tests for Irritation (ISO 10993-23)

Electrical Safety and EMC

	• IEC 60601-1 • IEC 60601-2-18 (3rd Edition) **Reprocessing (Cleaning and Sterilization)** • AAMI TIR12:2020 • ANSI/AAMI/ST8:2013/(R)2018 • ANSI/AAMI ST77:2013 • ANSI/AAMI ST79:2017 • ANSI/AAMI ST98:2022 • ANSI/AAMI/ISO 14937:2009/(R)2013 • ANSI/AAMI/ISO 17665-1:2006/(R)2013 • ASTM F3208-20 • DIN EN 285:2021 • DIN EN ISO 11138-1:2017 • DIN EN ISO 11138-3:2017 • EN 556-1:2002 • ISO 11737-1:2021 • ISO 11737-2:2019 • ISO 17664-1:2021 • ISO 17664-2:2021 • ISO 17665-2:2009 • ISO 22441:2022 • Reprocessing Medical Device in Health Care Settings: Validation Methods and Labeling Comparative bench testing between the subject and predicate devices demonstrated that the KARL STORZ HOPKINS Telescopes, HOPKINS Forward-Oblique Telescope, KARL STORZ ENDOCAMELEON ARTHRO HOPKINS Telescope have met all design specifications and are substantially equivalent to the predicate devices.
Clinical Performance Data	Published literature was provided to support the safety and effectiveness of the KARL STORZ HOPKINS Telescopes, HOPKINS Forward-Oblique Telescope, KARL STORZ ENDOCAMELEON ARTHRO HOPKINS Telescope for visualization during arthroscopic surgical procedures.
Conclusion:	The conclusions drawn from the non-clinical tests demonstrate that the subject device, the KARL STORZ HOPKINS Telescopes, HOPKINS Forward-Oblique Telescope, KARL STORZ ENDOCAMELEON ARTHRO HOPKINS Telescope are as safe and effective as the predicate devices and supports substantial equivalence to the predicate devices.