



September 25, 2026

Karl Storz SE & CO.KG
Alita McElroy
Regulatory Affairs Manager
Dr.-Karl-Storz-Straße 34
Baden-Württemberg
Tuttlingen, 78532
Germany

Re: K254252

Trade/Device Name: UNIDRIVE SIII System; HOPKINS Telescope 0° (26205AMA) Operating Sheath (26205CD) Obturator (26205OC) Shaver Blade (26205SA) Shaver Blade (26205SB) Shaver Blade (091133-01/-10) Shaver Blade (091134-01/-10)

Regulation Number: 21 CFR§ 884.1690

Regulation Name: Hysteroscope and Accessories

Regulatory Class: II

Product Code: HIH

Dated: August 7, 2026

Received: August 10, 2026

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 (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,

Reginald K. Avery -S

for

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K254252

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Please provide the device trade name(s).

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UNIDRIVE SIII System:
HOPKINS Telescope 0° (26205AMA)
Operating Sheath (26205CD)
Obturator (26205OC)
Shaver Blade (26205SA)
Shaver Blade (26205SB)
Shaver Blade (091133-01/-10)
Shaver Blade (091134-01/-10)

Please provide your Indications for Use below.

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The UNIDRIVE S III system is intended for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue.

The HOPKINS Telescope when used with the obturator and sheath is intended to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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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. 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 Regulatory Affairs Manager Phone: (424) 218-8376 Email: Alita.McElroy@karlstorz.com
Date of Preparation:	September 23, 2026
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: UNIDRIVE SIII System HOPKINS Telescope 0° (26205AMA) Operating Sheath (26205CD) Obturator (26205OC) Shaver Blade (26205SA) Shaver Blade (26205SB) Shaver Blade (091133-01/-10) Shaver Blade (091134-01/-10) Common Name: Hysteroscope and accessories Classification Name: Hysteroscope and accessories (21 CFR 884.1690)
Regulatory Class:	II
Product Code:	HIH
Classification Panel:	Obstetrics/Gynecology
Predicate Device(s):	Predicate: UNIDRIVE SIII System (K223520) <i>The predicate has not been subject to a design related recall</i>

Device Description:	The UNIDRIVE® S III system is a motorized surgical device intended for intrauterine use to hysteroscopically resect and remove tissue. This submission adds the following new system components to the UNIDRIVE SIII System previously cleared in K223520: • HOPKINS Telescope 0° (26205AMA) • Obturator (26205OC) • Operating Sheath (26205CD) • Shaver Blades (26205SA, 26205SB) • Shaver Blades (091133-01/-10, 091134-01/-10) The UNIDRIVE S III system has a motor control unit and can be used with the DrillCut-X II Shaver handpiece GYN which houses the subject shaver blades. The DrillCut-X II Shaver handpiece GYN is connected to the motor connection socket of the control unit. The UNIDRIVE S III system control unit detects the handpiece automatically and loads the standard parameters. The control unit displays the available speed range on the screen, and the maximum speed can be preset using the +/- buttons. The shaver blade upon being connected to the DrillCut-X II Shaver handpiece GYN is inserted into the working channel of the compatible HOPKINS Telescope. The shaver blades are activated via a one-pedal footswitch that is connected to the UNIDRIVE SIII control unit. The shaver blades consist of two sheaths that fit into each other. The inner sheath oscillates within the outer sheath to enable tissue resection. The obturator is used to create access and facilitate insertion of the HOPKINS Telescope. The sheath is used optionally to provide an outflow channel if instruments other than the shaver blades are used to facilitate exchange of fluids. There are no changes to the system components of the UNIDRIVE SIII System cleared in K223520 with the exception of the DrillCut-X II Shaver handpiece GYN (26702050) that has updated manual cleaning instructions and sterilization dry time has been reduced from 60 minutes to 20 minutes.
Indications for Use:	The UNIDRIVE S III system is intended for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue. The HOPKINS Telescope when used with the obturator and sheath is intended to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures.

Technological Characteristics.	The subject and predicate devices are identical in their intended use and operating principle. The main differences between the subject and predicate devices include the following: - The subject device includes an operating sheath in addition to other components (control unit, footswitch shaver handpiece, shaver blade, endoscope, obturator) while the predicate does not include an operating sheath but includes other common components as the subject device. - The subject device includes shaver blades with outer diameter of 3mm and 4mm while the predicate includes shaver blades with outer diameter of 4mm.
	- The subject device includes sterile single use shaver blades as well as non-sterile reusable shaver blades while the predicate device includes only non-sterile reusable shaver blades. - The subject device includes an endoscope with 0° direction of view, outer diameter of 5.3mm and working channel diameter of 3.1mm while the predicate includes an endoscope with 6° direction of view, outer diameter of 7.3mm and working channel of 4.3mm.
Non-Clinical Performance Data:	There are no performance standards or special controls developed under Section 514 of the FD&C Act for the UNIDRIVE SIII System. However, the UNIDRIVE SIII System follows the FDA recognized consensus standards and is tested according to the following standards and FDA Guidance: Hysteroscopes and Gynecologic Laparoscopes Guidance - Hysteroscopes and Gynecologic Laparoscopes - Submission Guidance for a 510(k) ISO Endoscopic Standards - ISO 8600-1:2015 - ISO 8600-3:2019 - ISO 8600-5:2020 Biocompatibility Summary - Cytotoxicity (ISO 10993-5) - Sensitization (ISO 10993-10) - Irritation (ISO 10993-23) - Acute Systemic Toxicity (ISO 10993-11) - Material Mediated Pyrogenicity (Rabbit Pyrogen Study per USP) Thermal Safety - IEC 60601-2-18:2009 (3RD Edition)

	Reprocessing and Sterilization • AAMI TIR12: 2020 • AAMI TIR30: 2011 • AAMI TIR39: 2009 • ANSI/AAMI ST79:2017 • ANSI/AAMI/ISO 17655-1:2006/2013 • ANSI/AAMI/ISO 17655-2:2009 • ISO17664-1:2021 • ISO 17664-2:2021
	• Reprocessing Medical Device in Health Care Settings: Validation Methods and Labeling • ISO 11137-1:2025 • ISO 11137-2:2013 • ISO 11137-3:2017 The cutting performance of the subject device, UNIDRIVE SIII system has been successfully demonstrated by comparing to the predicate device UNIDRIVE SIII System cleared in K223520. Additional comparative bench testing between the subject and predicate devices was conducted to demonstrate the optical performance of the subject hysteroscope that is part of the subject UNIDRIVE SIII system to meet its intended use.
Clinical Performance Data:	Clinical Testing was not required to demonstrate substantial equivalence to the predicate device. Non-clinical testing was adequate to establish substantial equivalence.
Conclusion:	The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe and effective as the predicate device to support a substantial equivalence determination.