November 22, 2025

Karl Storz Se & Co. Kg
% Jordan Verla
Senior Regulatory Affairs Specialist
Karl Storz Endoscopy America
2151 E. Grand Avenue
El Segundo, California 90245

Re: K250927
Trade/Device Name: KARL STORZ Cholangiography Set
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ,
Dated: October 27, 2025
Received: October 27, 2025

Dear Jordan 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 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,

JAMES H. JANG -S
Digitally signed by JAMES H. JANG -S
Date: 2025.11.22 08:07:49 -05'00'

For
Colin Kejing Chen, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250927

Device Name

KARL STORZ Cholangiography Set

Indications for Use *(Describe)*

The Karl Storz Cholangiography Set consists of manually operated reusable surgical devices intended for use by qualified surgeons in minimally invasive intraoperative cholangiography in adults and pediatric patients ≥ 13 years of age.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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 SE & CO. KG Dr.-Karl-Storz-Straße 34 TUTTLINGEN, Baden-Wurttemberg GERMANY, 78532
Contact:	Jordan Lydia Verla Senior Regulatory Affairs Specialist Tel: (424) 218-8100 ext. 8382 Email: Jordan.Verla@karlstorz.com
Date of Preparation:	November 21, 2025
Type of 510(k) Submission:	Traditional
510(k) #:	K250927
Device Identification:	Trade Name: KARL STORZ Cholangiography Set Classification Name: Gastroenterology/Urology (21 CFR 876.1500)
Regulatory Class:	II
Product Code:	GCJ
Classification Panel:	Gastroenterology/Urology
Predicate Device(s):	KARL STORZ Cholangiography Set (K943435)
Device Description:	The KARL STORZ Cholangiography Set are manually operated reusable surgical devices consisting of: Cholangiography Fixation Clamp, Guide Tube for Cholangiocatheter, and BERCI Plastic Stylet. The KARL STORZ Cholangiography Set includes devices which are used to facilitate the execution of cholangiograms (x-ray pictures of the bile ducts) during endoscopic surgery. The KARL STORZ Cholangiography Set was previously cleared under K943435. Modifications have been made to the device since its previous clearance.

<table>
<tr><td></td><td>The Cholangiography Fixation Clamp, Guide Tube for Cholangiocatheter, and BERCI Plastic Stylet work together to ensure accurate and clear cholangiography during minimally invasive procedures.

• The Cholangiography Fixation Clamp secures the catheter in place after insertion, preventing movement and ensuring proper positioning.
• The Guide Tube provides a smooth, controlled pathway for the catheter during insertion.
• The BERCI Plastic Stylet eliminates metal shadows by remaining in place when the metal trocar sheath is removed, preserving clear X-ray imaging of the biliary system.

The devices facilitate precise catheter placement, reduce interference in imaging, and maintain optimal procedure conditions for successful cholangiography.</td></tr>
<tr><td>Indications for Use:</td><td>Indications for Use
The KARL STORZ Cholangiography Set consists of manually operated reusable surgical devices intended for use by qualified surgeons in minimally invasive intraoperative cholangiography in adults and pediatric patients ≥13 years of age.</td></tr>
<tr><td>Technological Characteristics:</td><td>The subject and predicate device have similar technological characteristics and similar operating principles as the subject device.
<table>
<tr><th></th><th>KARL STORZ
KARL STORZ
Cholangiography Set
Subject Device</th><th>KARL STORZ
KARL STORZ
Cholangiography Set and Accessories
Predicate Device (K943435)</th></tr>
<tr><td>Indications for Use</td><td>The KARL STORZ Cholangiography Set consists of manually operated reusable surgical devices intended for use by qualified surgeons in minimally invasive intraoperative cholangiography in adults and pediatric patients ≥ 13 years of age.</td><td>Cholangiography Set and Accessories presented in this notification are intended to be used during endoscopic surgery, including cholangiograms performed during laparoscopic cholecystectomy.</td></tr>
<tr><td>Product Code(s)</td><td>GCJ</td><td>GCJ</td></tr>
<tr><td>Target Population</td><td>Adults & Pediatrics</td><td>Adults</td></tr>
</table></td></tr>
</table>

Anatomical Site	Biliary Anatomy	Biliary Anatomy
	BERCI Plastic Stylet (26020XR)	**BERCI Plastic Stylet (26020XR)**
Outer Diameter	10.5 mm (corresponding marketing size 10 mm	10.5 mm (corresponding marketing size 10 mm
Working Length	500 mm	500 mm
Design Feature	Marking at 25 mm *Laser Marking*	Marking at 25 mm *Marking Notch*
	Guide Tube for Cholangiocatheter (28378GK)	**Guide Tube for Cholangiocatheter (28378GK)**
Outer Diameter	4.8 mm	4.8 mm
Inner Diameter	2.8 mm	2.8 mm
Working Length	307.5 mm	307.5 mm
Connection Technique	The components are welded, and thread glued.	The components are soft soldered and brazed.
	Cholangiography Fixation Clamp (28378CH)	**Cholangiography Fixation Clamp (28378CH)**
Outer Diameter	Not Specified	Not Specified
Inner Diameter	2.1 mm	2.1 mm
Working Length	271.5 mm	271.5 mm
Connection Technique	The components are welded, and thread glued.	The components are soft soldered and brazed.
Design Feature	Luer Lock connection for cleaning	No Luer Lock connection
Cleaning	**BERCI Plastic Stylet (26020XR)** Manual cleaning **Guide Tube for Cholangiocatheter (28378GK)** Manual cleaning **Cholangiography Fixation Clamp (28378CH)** Manual cleaning	**BERCI Plastic Stylet (26020XR)** Manual cleaning **Guide Tube for Cholangiocatheter (28378GK)** Manual cleaning **Cholangiography Fixation Clamp (28378CH)** Manual cleaning

	Sterilization	**BERCI Plastic Stylet (26020XR)** Steam sterilization (Pre-vacuum) **Guide Tube for Cholangiocatheter (28378GK)** Steam sterilization (Pre-vacuum) **Cholangiography Fixation Clamp (28378CH)** Steam sterilization (Pre-vacuum)	**BERCI Plastic Stylet (26020XR)** Steam sterilization (Pre-vacuum) Gravity Flash ETO Aeration HLD **Guide Tube for Cholangiocatheter (28378GK)** Steam sterilization (Pre-vacuum) ETO Aeration **Cholangiography Fixation Clamp (28378CH)** Steam sterilization (Pre-vacuum) ETO Aeration
Non-Clinical Performance Data:	The present submission claims substantial equivalence for product code **GCJ**, which has a device-specific guidance document titled "DRAFT GUIDANCE FOR THE PREPARATION OF A PREMARKET NOTIFICATION FOR EXTENDED LAPAROSCOPY DEVICES (ELD)" issued on August 30,1994; we have followed the recommendations set forth in the guidance for Labeling, Materials, Performance Data – Bench Testing. The KARL STORZ Cholangiography Set follows the FDA recognized consensus standards and is tested according to the following standards and FDA Guidance: **General** • Application of risk management (ISO 14971) • Surgical Instruments – Metallic Materials (ISO 7153-1) **Biocompatibility Summary** • Cytotoxicity (ISO 10993-5) • Acute Systemic Toxicity (ISO 10993-11)		

	• Intracutaneous Irritation (ISO 10993-10) • Maximization Sensitization (ISO 10993-10) • Chemical Characterization (ISO 10993-18) • Tests for Irritation (ISO 10993-23) **Reprocessing (Cleaning and Sterilization)** • ISO 11737-1 • ISO 11737-2 • ISO 17665-1 • ISO 17664-1 • Reprocessing Medical Device in Health Care Settings: Validation Methods and Labeling Bench verification testing was performed to demonstrate the performance of the subject device, KARL STORZ Cholangiography Set in minimally invasive intraoperative cholangiography in adults and pediatric patients ≥ 13 years of age. Functionality tests (interlocking test, load force testing and grasping) have been conducted to demonstrate the safety and effectiveness of the subject device.
Clinical Performance Data:	Published literature was provided to support the safety and effectiveness of the KARL STORZ Cholangiography Set for use in minimally invasive intraoperative cholangiography in adults and pediatric patients ≥ 13 years of age.
Conclusion:	The conclusions drawn from the nonclinical test demonstrate that the subject device is as safe and effective as the predicate device.