



September 21, 2026

KALR STORZ SE & Co. KG
Frank Sugden
Senior Regulatory Intelligence Manager
Dr.-Karl-Storz-Straße 34
Tuttlingen, Baden-Württemberg 78532
Germany

Re: K262547
Trade/Device Name: KARL STORZ TIPCAM1 Rubina
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OWN, GWG
Dated: July 23, 2026
Received: July 23, 2026

Dear Frank Sugden:

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,

MARCO CANNELLA -S

Marco Cannella Ph.D.
Acting Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular 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.

K262547

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Please provide the device trade name(s).

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KARL STORZ TIPCAM1 Rubina

Please provide your Indications for Use below.

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The TIPCAM1 Rubina videoscope is intended to be used together with the camera control unit during diagnostic and/or surgical procedures when endoscopic video assistance is required. For use in all endoscopy and endoscopic surgery within the peritoneal and thoracic cavities, including gynecological and urological anatomy. Indicated for selected thoracoscopically-assisted cardiac surgical procedures, such as:

- Mitral valve repair
- IMA mobilization for cardiac revascularization
- Patent foramen ovale closure
- Atrial septal defect repair
- Left atrial appendage closure/occlusion
- Atrial myxoma excision
- Mitral valve replacement
- Tricuspid valve repair
- Epicardial pacing lead placement

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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Please select the age group(s) for which the device(s) is to be used.

- ☐ Neonates/Newborns (Birth to < 29 days old)
☐ Infants (29 days old to < 2 years old)
☒ Children (2 years old to < 12 years old)
☒ Adolescents (12 years old to < 22 years old)
☒ Adults (22 years old and greater)

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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:	KALR STORZ SE & Co. KG Dr.-Karl-Storz-Straße 34 Tuttlingen, Baden-Württemberg 78532 Germany
Contact:	Frank Sugden Senior Manager Regulatory Intelligence Phone: 805-562-3953 Email: Frank.Sugden@karlstorz.com
Date of Preparation:	September 21, 2026
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: KARL STORZ TIPCAM1 Rubina Classification Name: Endoscope and accessories (21 CFR 876.1500) 510(k) Number: K262547
Regulatory Class:	II
Product Code:	OWN, GWG
Classification Panel:	Gastroenterology/Urology
Predicate Device(s):	KARL STORZ ICG Imaging System (K212695)
Device Description:	The KARL STORZ Imaging System is intended to provide real-time visible (VIS) and near-infrared (NIR) fluorescent imaging and documentation of endoscopic and microscopic procedures in adults and pediatrics. Following the “light in to light out” mental model, the KARL STORZ Imaging System incorporates one of multiple compatible light sources to provide either or both VIS or NIR light into the operating scene within a patient. This light is captured via either a passive telescope or an active videoendoscope (flexible or rigid). In the case of a passive telescope the light is then transferred to a connected camera head or exoscope. All of these active videoendoscopes, camera heads, and exoscopes make of use a connector (multiple options available) to transmit the light to a camera control unit (CCU). Finally, the

	CCU transmits the light to a monitor for the medical professional to see. The TIPCAM1 Rubina videoendoscope is an integrated unit comprised of a camera and a rigid endoscope. A connected light source (TL400 Power LED Rubina for NIR) transmits light (VIS or NIR) through the integrated rigid endoscope via a light guide. Either the IMAGE1 S or IMAGE1 CCU systems process the image transmitted from the TIPCAM1 Rubina via the 4U connector.
Intended Use and Indications for Use:	The TIPCAM1 Rubina videoscope is intended to be used together with the camera control unit during diagnostic and/or surgical procedures when endoscopic video assistance is required. For use in all endoscopy and endoscopic surgery within the peritoneal and thoracic cavities, including gynecological and urological anatomy. Indicated for selected thoracoscopically-assisted cardiac surgical procedures, such as: • Mitral valve repair • IMA mobilization for cardiac revascularization • Patent foramen ovale closure • Atrial septal defect repair • Left atrial appendage closure/occlusion • Atrial myxoma excision • Mitral valve replacement • Tricuspid valve repair • Epicardial pacing lead placement
Technological Characteristics.	TIPCAM1 Rubina remains identical to the cleared KARL STORZ ICG Imaging System in K212695 and reviewed in K233333. There are no changes in technological characteristics.
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 KARL STORZ Imaging System is tested in accordance with the following standards and FDA Guidance: Electrical Safety and EMC • IEC 60601-1 • IEC 60601-1-2 • IEC 60601-2-18 ISO Endoscopic Standards • ISO 8600-1 • ISO 8600-3 • ISO 8600-4 • ISO 8600-5 Software Verification and Validation Testing • Guidance for the Content of Premarket Submissions for Software

	Contained in Medical Device • Level of concern: Moderate Conformance to these standards was not the basis upon which substantial equivalence was determined.
Clinical Performance Data:	Published literature was provided to support the change of the original contraindication in the predicate submission K212695.
Conclusion:	The subject device and predicate device have the same intended use and fundamental endoscopic visualization function. Although the subject device expands the indications to include selected thoroscopically-assisted cardiac procedures, the physical and technological characteristics remain identical to the cleared system. Therefore, the differences in indications do not affect the safety or effectiveness of the device and do not alter its therapeutic, diagnostic, prosthetic, or surgical use. The conclusions drawn from the technological characteristics that the subject device is as safe and effective as the predicate device.