



February 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: K254242

Trade/Device Name: KARL STORZ ICG Imaging System with RUBINA Lens
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OWN, GWG, FET
Dated: December 29, 2025
Received: December 29, 2025

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

TANISHA Digitally signed by
TANISHA L. HITHE -S
L. HITHE -S Date: 2026.02.26
15:39:12 -05'00'

Tanisha Hithe
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

Indications for Use

510(k) Number (if known)
K254242

Device Name
KARL STORZ ICG Imaging System with RUBINA® Lens System

Indications for Use (Describe)

KARL STORZ ICG Imaging System

The KARL STORZ ICG Imaging System is intended to provide real-time visible (VIS) and near-infrared (NIR) fluorescence imaging.

Endoscopic ICG System

Upon intravenous administration and use of ICG consistent with its approved label, the KARL STORZ Endoscopic ICG System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion in adults and pediatric patients ≥ 1 month of age, and at least one of the major extrahepatic bile ducts (cystic duct, common bile duct and common hepatic duct) in adults and pediatric patients ≥ 12 years of age, using near infrared imaging in accordance with the appropriately indicated endoscope. Fluorescence imaging of biliary ducts with the KARL STORZ Endoscopic ICG System is intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.

Additionally, the KARL STORZ Endoscopic ICG System enables surgeon to perform minimally invasive cranial neurosurgery in adults and pediatrics and endonasal skull base surgery in adults and pediatrics > 6 years of age using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion using near infrared imaging.

Upon interstitial administration and use of ICG consistent with its approved label, the KARL STORZ Endoscopic ICG System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

Exoscopic ICG System

VITOM ICG SYSTEM

The KARL STORZ VITOM ICG System is intended for capturing and viewing fluorescent images for the visual assessment of blood flow, as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures in adults and pediatrics ≥ 1 month of age.

The VITOM ICG System is intended to provide a magnified view of the surgical field.

RUBINA Lens System

The RUBINA Lens System is intended for capturing and viewing fluorescent images for the visual assessment of blood flow, as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures in adults and pediatrics ≥ 1 month of age.

Upon interstitial administration and use of the ICG consistent with its approved label, the RUBINA Lens System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

Upon intradermal administration and use of the ICG consistent with its approved label, the RUBINA Lens System is indicated for fluorescence imaging of lymph nodes and delineation of lymphatic vessels during lymphatic mapping in

adults undergoing breast surgical procedures for which fluorescence imaging is a component of intraoperative management.

The RUBINA Lens System is intended to provide a wide-angle view of the surgical field.

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 # K254242

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-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:	February 11, 2026
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: KARL STORZ ICG Imaging System with RUBINA® Lens System Classification Name: 21 CFR 876.1500 (Endoscope and accessories) 21 CFR 882.1480 (Nuerological endoscope)
Regulatory Class:	II
Product Code:	OWN, GWG, FET
Classification Panel:	Gastroenterology/Urology
Predicate Device(s):	KARL STORZ ICG Imaging System, KARL STORZ Image 1S, Camera Control Unit (K233333) SPY Portable Handheld Imaging (SPY-PHI) System (K230727)
Device Description:	The RUBINA® Lens supports anatomical visualization under white light and NIR/ICG fluorescence. Its native 16:9 full-screen image eliminates the need for digital zoom, enabling shorter working distances that help maintain fluorescence signal capture during procedures requiring continuous visualization of lymphatic or perfusion-related structures. The device incorporates a wide-angle optical design and expanded focus range, supporting consistent imaging across variable working distances for applications such as:

- Fluorescence-guided assessment of tissue perfusion
- Visualization of lymphatic pathways and sentinel lymph nodes

The RUBINA® Lens features a 90° direction of view and may be used handheld or mounted to a compatible holding arm. Rotation of the attached camera head allows horizon adjustment to maintain anatomical orientation.

The system provides continuous white-light and NIR/ICG visualization for display on standard operating room monitors. The device achieves optimal illumination at approximately 18 cm and maintains fluorescence visualization across a broad working distance range, supporting use in applications such as perfusion assessment and lymphatic mapping.

The subject device RUBINA® Lens is compatible with the following components within the *KARL STORZ ICG Imaging System*:

- IMAGE1 S™ Rubina® camera head (TH121) previously cleared on K201399 and K202925.
- IMAGE1 S™ Camera Control Unit (CCU) (TC201US, TC304US) previously cleared on K212695, K201135, K233333, K232857.
- Fiber Light Cables (495NCSC, 495TIP): used to transmit visible and NIR light from the Power LED Rubina Light Source (TL400) to the RUBINA® Lens. The 495NCSC was previously cleared K201399, and K202925. The 495TIP Fiber Light Cable was most recently cleared in K233333.
- The Power LED Rubina® Light Source (TL400) previously cleared in K201399, K202925, K212695, K232857, and K233333. The TL400 is included as a subject device, as the *KARL STORZ ICG Imaging System* Indications for Use reflected in the TL400 labeling require revision within this 510(k). No modifications have been made to the TL400 with respect to materials, technological characteristics, performance, reprocessing, or any other essential design features.
- Footswitch (UF101): [Optional] Previously cleared in K201399, K202925, K212695, and K232857.

<p>Indications for Use:</p>	<p><i>Indications for Use:</i></p> <p>KARL STORZ ICG Imaging System</p> <p>The KARL STORZ ICG Imaging System is intended to provide real-time visible (VIS) and near-infrared (NIR) fluorescence imaging.</p> <p>Endoscopic ICG System</p> <p>Upon intravenous administration and use of ICG consistent with its approved label, the KARL STORZ Endoscopic ICG System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion in adults and pediatric patients ≥ 1 month of age, and at least one of the major extrahepatic bile ducts (cystic duct, common bile duct and common hepatic duct) in adults and pediatric patients ≥ 12 years of age, using near infrared imaging in accordance with the appropriately indicated endoscope. Fluorescence imaging of biliary ducts with the KARL STORZ Endoscopic ICG System is intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.</p> <p>Additionally, the KARL STORZ Endoscopic ICG System enables surgeon to perform minimally invasive cranial neurosurgery in adults and pediatrics and endonasal skull base surgery in adults and pediatrics > 6 years of age using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion using near infrared imaging.</p> <p>Upon interstitial administration and use of ICG consistent with its approved label, the KARL STORZ Endoscopic ICG System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.</p> <p>Exoscopic ICG System</p> <p><i>VITOM ICG SYSTEM</i></p> <p>The KARL STORZ VITOM ICG System is intended for capturing and viewing fluorescent images for the visual assessment of blood flow, as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures in adults and pediatrics ≥ 1 month of age.</p> <p>The VITOM ICG System is intended to provide a magnified view of the surgical field.</p>
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<p>Technological Characteristics:</p>	<p>The subject and predicate devices have similar technological characteristics and similar operating principles as the subject device.</p> <table border="1" data-bbox="431 1293 1429 1879"> <tr> <td data-bbox="431 1293 675 1556"></td> <td data-bbox="675 1293 922 1556"> <p>KARL STORZ ICG Imaging System with RUBINA® Lens System Subject Device K254242</p> </td> <td data-bbox="922 1293 1170 1556"> <p>KARL STORZ ICG Imaging System, KARL STORZ Image 1S, Camera Control Unit Primary Predicate Device (K233333)</p> </td> <td data-bbox="1170 1293 1429 1556"> <p>SPY Portable Handheld Imaging (SPY-PHI) System Secondary Predicate Device (K230727)</p> </td> </tr> <tr> <td data-bbox="431 1556 675 1879"> <p>Imaging System Components</p> </td> <td data-bbox="675 1556 922 1879"> <p>Video Endoscopes Rigid Endoscopes Camera Head Camera Control Unit Light Source Light Cable VITOM II NIR/ICG Telescope RUBINA Lens</p> </td> <td data-bbox="922 1556 1170 1879"> <p>Rigid Endoscopes Camera Head Camera Control Unit Light Source Light Cable VITOM II NIR/ICG Telescope</p> </td> <td data-bbox="1170 1556 1429 1879"> <p>SPY-PHI Imager Video Processor/ Illuminator SPY-QP Fluorescence Assessment Software</p> </td> </tr> </table>		<p>KARL STORZ ICG Imaging System with RUBINA® Lens System Subject Device K254242</p>	<p>KARL STORZ ICG Imaging System, KARL STORZ Image 1S, Camera Control Unit Primary Predicate Device (K233333)</p>	<p>SPY Portable Handheld Imaging (SPY-PHI) System Secondary Predicate Device (K230727)</p>	<p>Imaging System Components</p>	<p>Video Endoscopes Rigid Endoscopes Camera Head Camera Control Unit Light Source Light Cable VITOM II NIR/ICG Telescope RUBINA Lens</p>	<p>Rigid Endoscopes Camera Head Camera Control Unit Light Source Light Cable VITOM II NIR/ICG Telescope</p>	<p>SPY-PHI Imager Video Processor/ Illuminator SPY-QP Fluorescence Assessment Software</p>
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		Footswitch			
	Imaging Type	White Light and Fluorescent Imaging	White Light and Fluorescent Imaging	White Light and Fluorescent Imaging	
	Imaging Agent	ICG	ICG	ICG	
	Exoscope	Depth of Field	(10-30cm) 18 cm	VIS: 25-75 cm NIR: 20-30 cm	10-40cm
		Field of View	32,4° ± 3°	VITOM II NIR/ICG 11.68°	Unknown
		Direction of View	90° ± 3°	0°	Unknown
		Display Type	2D	2D	2D
	Imager	Sensor Type	2-chip CMOS (one for White Light and one for NIR)	2-chip CMOS (one for White Light and one for NIR)	CMOS image sensor
		Sensor Resolution	3840 x 2160p*	3840 x 2160p	1080p (1920x1080)
	Image Presentation	<p>Displayed image is either the VIS light image or the NIR image.</p> <p>For the NIR image, the user has three presentations of the ICG imagery to choose from:</p> <p>a. Overlay: The white light image is overlaid with the NIR image. The NIR image could either be blue or green</p> <p>b. Intensity Map: The white light image is overlaid with color transformed NIR image.</p> <p>c. Monochromatic: The NIR image is indicated by the color white against a dark background.</p>	<p>Displayed image is either the VIS light image or the NIR image.</p> <p>For the NIR image, the user has three presentations of the ICG imagery to choose from:</p> <p>a. Overlay: The white light image is overlaid with the NIR image. The NIR image could either be blue or green</p> <p>b. Intensity Map: The white light image is overlaid with color transformed NIR image.</p> <p>c. Monochromatic: The NIR image is indicated by the color white against a dark background.</p>	<p>Displayed image is either the VIS light image or the NIR image.</p> <p>For the NIR image, the user has three presentations of the ICG imagery to choose from:</p> <p>a. Overlay: The white light image is overlaid with the NIR image. The NIR image could either be blue or green</p> <p>b. Intensity Map: The white light image is overlaid with color transformed NIR image.</p> <p>c. Monochromatic: The NIR image is indicated by the color white against a dark background.</p>	<p>White Light Near-Infrared: -Overlay Mode* -SPY Mode (Contrast)* -SPY Color Segmented Fluorescence (CSF)</p> <p><i>*SPY Mode (Contrast) and Overlay Mode are recommended for use in breast lymphatic mapping</i></p>
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				

	<p>follows the FDA recognized consensus standards and is tested according to the following standards and FDA Guidance:</p> <p>Risk</p> <ul style="list-style-type: none"> • ISO 14971:2019 <p>Usability</p> <ul style="list-style-type: none"> • IEC 62366-1:2015 + Amd.1:2020 <p>Photobiological Safety</p> <ul style="list-style-type: none"> • IEC 62471:2006 <p>Electrical Safety and EMC</p> <ul style="list-style-type: none"> • IEC 60601-1 • IEC 60601-2-18 (3rd Edition) <p>Reprocessing (Cleaning and Sterilization)</p> <ul style="list-style-type: none"> • AAMI TIR12:2020 • ANSI/AAMI/ST8:2013/(R)2018 • ANSI/AAMI ST77:2013 • 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 11138-3:2017 • ISO 11737-1:2021 • ISO 11737-2:2019 • ISO 17664-1:2021 • ISO 17665-1:2006-11 • Reprocessing Medical Device in Health Care Settings: Validation Methods and Labeling <p>Comparative bench testing between the subject and predicate devices demonstrated that the RUBINA® Lens System has met all design specifications and is substantially equivalent to the predicate devices.</p>
<p>Clinical Performance Data</p>	<p>Clinical testing was not required to support this submission because substantial equivalence was established through comparative bench testing and performance evaluation against predicate devices. The subject device has the same intended use and similar technological characteristics, and the</p>

	differences in technology do not raise new questions of safety or effectiveness. Comprehensive bench testing, including optical performance, NIR/ICG imaging performance, and safety evaluations, adequately demonstrates that the subject device performs as intended under clinically relevant conditions.
Conclusion:	The conclusions drawn from the non-clinical tests demonstrate that the subject device, the <i>KARL STORZ ICG Imaging System with RUBINA® Lens System</i> is as safe and effective as the predicate devices and supports substantial equivalence to the predicate devices.