



November 21, 2023

Karl Storz Se & Co. Kg
Emily Rhiel
Specialist, Regulatory Affairs
Dr.-Karl-Storz-Straße 34
Baden-Wurttemberg
Tuttlingen, 78532
Germany

Re: K233333

Trade/Device Name: KARL STORZ ICG Imaging System, KARL STORZ Image1S Camera Control
Unit

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope And Accessories

Regulatory Class: Class II

Product Code: OWN, GWG, FET

Dated: September 28, 2023

Received: September 29, 2023

Dear Emily Rhiel:

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.

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,

Jessica Carr -S

Jessica Carr, 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

Indications for Use

510(k) Number (if known)
K233333

Device Name

KARL STORZ ICG Imaging System
KARL STORZ Image1 S Camera Control Unit

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.

VITOM II ICG System

The KARL STORZ VITOM II 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. The VITOM II ICG System is intended to provide a magnified view of the surgical field in standard white light.

KARL STORZ Image1 S CCU

The Image1 S camera control unit (CCU) in combination with either a compatible camera head or an appropriately indicated video endoscope is intended for real-time visualization, image recording and documentation during general endoscopic and microscopic procedures in adults and pediatrics.

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

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 and the FDA guidance document titled “The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]” issued on July 28, 2014. All data included in this document is accurate and complete to the best of KARL STORZ SE & Co. KG knowledge.

Submitter:	KARL STORZ SE & Co. KG Dr.-Karl-Storz-Straße 34 78532 Tuttlingen, Germany
Contact:	Emily Rhiel Regulatory Affairs Specialist Phone: (774) 318-2820 Email: emily.rhiel@karlstorz.com
Date of Preparation:	November 6, 2023
Type of 510(k) Submission:	Traditional
Device Identification:	KARL STORZ ICG Imaging System KARL STORZ IMAGE1 S Camera Control Unit
Regulatory Class:	II
Product Code:	OWN: Confocal Optical Imaging GWG: Endoscope, Neurological FET: Endoscopic Video Imaging System/Component
Classification Name:	21 CFR 876.1500 (Endoscope and Accessories) 21 CFR 882.1480 (Neurological Endoscopes)
Common Name:	Confocal Optical Imaging
Device Panel:	Gastroenterology/Urology
Predicate Device(s):	KARL STORZ ICG Imaging System (K212695) HOPKINS Telescopes (K221004) Image1 S CCU (TC200US, TC201US, TC300US, TC301US, TC302US, TC304US); Image1 S 4U Camera Head (TH120) (K201135) Predicate devices are manufactured by KARL STORZ SE & Co. KG

Device Description:**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 for general surgical sites including the abdomen, bile ducts, brain/skull base, and the lymph nodes/lymphatic vessels. Components of the system include:

Scopes:

- 3D TIPCAM®1 Rubina videoendoscope
26006ACA/BCA, 26616ACA/BCA
- Rigid Endoscope
26003ACA/ARA/BCA/BRA/FCA/FRA/FCEA/FREA
26046ACA/ARA/BCA/BRA/FCA/FRA
28164AC/BC/FC
- VITOM II ICG/NIR Telescope
20916025AGA

Light Source:

- Power LED Rubina (TL400)
- Foot Switch (UF101)
- Fiber Optic Light Cable (495TIP/NCSC/NAC)

Camera Head:

- Image1 S 4U Rubina (TH121)

Camera Control Unit (CCU):

- Image1 S Connect II (TC201US)
- Image1 S 4U-Link (TC304US)

KARL STORZ Image1 S CCU

The KARL STORZ IMAGE1 S Camera Control Unit (CCU) is a modular CCU that consists of Image1 S Connect and Connect II modules and the link modules. The Connect modules can be connected to minimum of one and a maximum of three links modules. The modularity enables customers to customize their Image1 S system to their specific video needs.

The Image1 S includes, but not limited to, the following features:

- Brightness control
- Enhancement Control
- Automatic Light Source Control
- Shutter Control
- Image/Video Capture

	<ul style="list-style-type: none"> • Seven increments of zoom from 1-2.5x and adaptive zoom <p>Modules of the Image1 S CCU include:</p> <ul style="list-style-type: none"> • Image1 S Connect (TC200US) • Image1 S Connect II (TC201US) • Image1 S H3-Link (TC300US) • Image1 S X-Link (TC301US) • Image1 S D3-Link (TC302US) • Image1 S 4U-Link (TC304US) <p>Accessories to the Image1 S CCU include:</p> <ul style="list-style-type: none"> • Microscope Footswitch (TC019) • Image1 S Pilot (TC014) • LINK Cable (TC011, TC012)
Indications for Use:	<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>VITOM II ICG System</p> <p>The KARL STORZ VITOM II 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. The VITOM II ICG System is intended to provide a magnified view of the surgical field in standard white light.</p> <p>KARL STORZ Image1 S CCU</p> <p>The Image1 S camera control unit (CCU) in combination with either a compatible camera head or an appropriately indicated video endoscope is intended for real-time visualization, image recording and documentation during general endoscopic and microscopic procedures in adults and pediatrics.</p>			
Technological Characteristics:	5mm HOPKINS Rigid Telescope			
	Technological Characteristic	Subject Device: KARL STORZ ICG Imaging System	Primary Predicate: K212695 KARL STORZ ICG Imaging System	Secondary Predicate: K221004 KARL STORZ HOPKINS Telescopes
	Endoscope Type	Rigid, rod lens	Same as subject	Same as subject
	Outer Diameter	5mm	Same as subject	Same as subject
	Direction of View	0° 30° 45°	Same as subject	0° 25° 45°
	Working Length	29cm	Same as subject	Same as subject
	Depth of Field	30 – 80 mm	Same as subject	15.1 – 200mm
	Field of View	68°	Same as subject	Same as subject
	Light Source	External	Same as subject	Same as subject
	Camera Control Unit (CCU)			
	Technological Characteristic	Subject Device: KARL STORZ Image1 S CCU		Primary Predicate: K201135 KARL STORZ Image1 S CCU (TC200US, TC201US, TC300US, TC301US, TC302US, TC304US)
	Brightness Control	Yes		Yes

	Enhancement Control	Yes	Yes
	Light Source Control	Automatic	Same as subject
	Shutter Control	Automatic	Same as subject
	Image/Video Capture	Yes	Yes
	Zoom	1x, 1.2x, 1.5x, 1.75x, 2x, 2.25x, 2.5x	Same as subject
	Adaptive Zoom	Yes	Yes
	Digital Outputs	12G/3G-SDI DisplayPort DVI-D	Same as subject
	Communication Interface	SCB, KS HIVE (Ethernet)	Same as subject
	Control Panel	Microscope Footswitch Pilot	None
	Remote Service	Yes	No
	Software Revision	4.5	4.0
	Light Source		
	Technological Characteristic	Subject Device: KARL STORZ ICG Imaging System	Primary Predicate: K212695 KARL STORZ ICG Imaging System
	Light Source	Dual LEDs	Same as subject
	Light Source Power	100-240 VAC	Same as subject
VIS Light	LED Output: 400-700 nm	Same as subject	
NIR Light	Filtered LED Output: 720-810 nm	Same as subject	
Software Revision	1.11.01	1.08	
Non-Clinical Performance Data:	<p>Electrical Safety and Electromagnetic Compatibility</p> <p>Electrical Safety and Electromagnetic Compatibility testing was conducted in accordance with the following standards:</p> <ul style="list-style-type: none"> IEC 60601-1:2005 + A1:2012 + A2:2021 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance 		

	<ul style="list-style-type: none"> • IEC 60601-1-2 : 2014 + A1:2020, Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Electromagnetic Compatibility <p>Software Verification and Validation</p> <p>Software verification and validation testing was conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Content of Premarket Submissions for Device Software Functions” issued June 14, 2023. The software documentation level conforms to the Basic Level of documentation as there are no risks identified in which a failure or flaw of any device software function(s) could present a hazardous situation with a probable risk of death or serious injury, either to a patient, user of the device, or others in the environment of use.</p>
<p>Clinical Performance Data:</p>	<p>Clinical testing was not required to demonstrate substantial equivalence to the predicate devices.</p>
<p>Conclusion:</p>	<p>The conclusions drawn from the substantial equivalence comparison demonstrate that the subject device is as safe and effective as the predicates.</p>