November 6, 2023

Karl Storz SE & Co. Kg
Alita McElroy
Senior Regulatory Affairs Specialist
Dr.-Karl-Storz-Straße 34
Baden-Wurttemberg
Tuttlingen, 78532
Germany

Re: K232857
Trade/Device Name: KARL STORZ ICG Imaging System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OWN, GWG
Dated: September 13, 2023
Received: September 15, 2023

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 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, PhD
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232857

Device Name
KARL STORZ ICG Imaging System

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

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, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near infrared imaging. 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.

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 >1month of age. The VITOM ICG System is intended to provide a magnified view of the surgical field.

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.

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.

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 KARL STORZ SE & Co. KG knowledge.

Submitter:	KARL STORZ SE & Co. KG Dr.-Karl-Storz-Straße 34 78532 Tuttlingen, Germany
Contact:	Alita McElroy Senior Regulatory Affairs Specialist Phone: (424) 218-8376 Fax: (424) 218-8519
Date of Preparation:	October 24, 2023
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: KARL STORZ ICG Imaging System Classification Name: Endoscope and accessories Common Name: Confocal Optical Imaging
Regulatory Class:	II
Product Code:	OWN, GWG
Regulation:	21 CFR 876.1500 (Endoscope and Accessories) 21 CFR 882.1480 (Neurological Endoscopes)
Predicate Device(s):	KARL STORZ ICG Imaging System (K212695) KARL STORZ SE & Co. KG
Device Description:	The subject device KARL STORZ ICG System includes the following components: 1) VITOM EAGLE (TH201): a 3D video exoscope with 4K resolution used during open procedures for the evaluation of tissue perfusion, related tissue-transfer circulation in tissue and free flaps used in plastic, micro and reconstructive surgical procedures. The subject device VITOM EAGLE System is being indicated for use in in adults and pediatrics >1month of age. 2) Fiber Light Cable (495VTE): used to transmit visible and NIR light from the Power LED Rubina light source to the VITOM Eagle. 3) IMAGE1 Pilot (TC014): used to control the optical functions of the VITOM EAGLE. 4) Microscope Footswitch (TC019): alternatively used control the optical functions of the VITOM EAGLE 5) The Power LED Rubina light source (TL400) along with the footswitch (UF101): previously cleared in K201399, K202925 and

	K212695. 6) Image1 S Camera Control Unit (TC201US, TC304US): previously cleared in K201399, K202925 and K212695.
Intended Use	The KARL STORZ ICG Imaging System is intended to provide real- time visible and near-infrared fluorescence imaging.
Indications for Use:	The KARL STORZ ICG Imaging System is intended to provide real- time visible (VIS) and near-infrared (NIR) fluorescence imaging. 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, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near infrared imaging. 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. 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 >1month of age. The VITOM ICG System is intended to provide a magnified view of the surgical field. 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.
Technological Characteristics:	The following comparison table summarizes the technological characteristics between the subject and predicate devices:

Technological Characteristics		KARL STORZ ICG Imaging System	KARL STORZ ICG Imaging System K212695
Imaging System Components		• Exoscope (integrated sensor) • Fiber optic light cable • Light source • Footswitch • Image1 S CCU • IMAGE1 Pilot • Microscope Footswitch	• Exoscope • Fiber optic light cable • Light source • Footswitch • Camera head • Image1 S CCU
Imaging type		White Light and Fluorescent Imaging	White Light and Fluorescent Imaging
Imaging Agent		ICG	ICG
Exoscopes	Focal Distance	WLi/NIR: 16.9cm- 52.9cm	WLi: 25-75cm NIR: 20-30cm
	Direction of View	90°	0°
	Field of View	19°	11°
	Zoom	Optical Zoom: 6x Digital Zoom: 2x	Optical Zoom: 1x Digital Zoom: 2.5x
	Display Type	2D, 3D	2D
Imager	Sensor Type	CMOS	CMOS
	Sensor Resolution	3840 x 2160p	3840 x 2160p
CCU	Brightness Control	Yes	Yes
	Enhancement Control	Yes	Yes

	Automatic Light Source Control	Yes	Yes
	Shutter control	Yes	Yes
	Image/Video Capture	Yes	Yes
	Adaptive Zoom	No	Yes
	Digital Outputs	12G/3G-SDI DisplayPort DVI-D	12G/3G-SDI DisplayPort DVI-D
	Communication Interface	KS HIVE	KS HIVE
	Remote Service	Yes	No
Image Presentation		Displayed image is either the VIS light image or the NIR image. For the NIR image, the user has three presentations of the ICG imagery to choose from: a. Overlay: The white light image is overlaid with the NIR image. The NIR image could either by blue or green b. Intensity Map: The white light image is overlaid with color transformed	Displayed image is either the VIS light image or the NIR image. For the NIR image, the user has three presentations of the ICG imagery to choose from: a. Overlay: The white light image is overlaid with the NIR image. The NIR image could either by blue or green b. Intensity Map: The white light image is overlaid with color transformed NIR image.

		NIR image. c. Monochromatic: The NIR image is indicated by the color white against a dark background.	c. Monochromatic: The NIR image is indicated by the color white against a dark background.
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 ICG Imaging System follows the FDA recognized consensus standards and is tested according to the following standards and FDA Guidance: • Electrical Safety and EMC o IEC 60601-1 o IEC 60601-1-2 • Software Verification and Validation Testing Guidance for the Content of Premarket Submissions for Software Contained in Medical Device The performance of the subject device for NIR imaging has been successfully demonstrated by comparing to the predicate VITOM II ICG/NIR telescope of the KARL STORZ ICG Imaging System cleared under K212695 • Spatial Resolution • Signal to Noise Ratio and Noise • Dynamic Range • Geometric Distortion • Depth of Field • Illumination Detection Uniformity • Latency • Penetration Depth • Simultaneous Color Contrast • Minimum Detectable Concentration of ICG • 3D Zoom and Rotation • 2D and 3D Mode Transition • Image Alignment • Photobiological Safety		
Clinical Performance Data:	Clinical testing was not required to demonstrate the substantial equivalence to the predicate devices. Non-clinical bench testing was sufficient to establish the substantial equivalence of the modifications.		
Substantial Equivalence:	The conclusions drawn from the nonclinical test demonstrate that the subject device is as safe and effective as the predicate device.		