Karl Storz-Endoscopy-America, Inc.
Alita McElroy
Regulatory Affairs Specialist
2151 E. Grand Avenue
El Segundo, California 90245

August 17, 2020

Re: K201399
Trade/Device Name: HOPKINS ICG/NIR 10mm Ridgid Endoscope (modified) 0, 30, 45, HOPKIN ICG/NIR 5mm Ridgid Endoscope (modified) 0, 30, 45, HOPKIN ICG/NIR 4mm Ridgid Endoscope 0, 30, 45, VITOM II ICG/NIR Telescope, Power LED Rubina Light Source, Foot Switch, Fiber Optic Light Cable, Image S CCU, Image S 4U Rubina Camera Head
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: OWN, GWG
Dated: May 27, 2020
Received: May 28, 2020

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Neil R.P. Ogden
Assistant Director, THT4A4
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201399

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.

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 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.

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.

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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 Endoscopy-America, Inc. 2151 E. Grand Avenue EI Segundo, CA 90245
Contact:	Alita McElroy Regulatory Affairs Specialist Phone: (424) 218-8376 Fax: (424) 218-8519
Date of Preparation:	May 27, 2020
Type of 510(k) Submission:	Traditional
510(k) Number:	K201399
Device Identification:	Trade Name: KARL STORZ ICG Imaging System Classification 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 (K180146)
Device Description:	The modified KARL STORZ ICG Imaging System includes the following components: i) Modified 10mm and 5mm HOPKINS ICG/NIR Rigid Endoscopes (0°, 30°, 45°): have an improved optical design with the white light and NIR images in good focus simultaneously. ii) Power LED Rubina Light Source and Footswitch: The light source has two LEDs, white light and NIR. iii) Image1 S 4U Rubina Camera Head: uses a 2 chip 4K camera head that houses 2 CMOS sensors: one for white light and the other for NIR. iv) Camera Control Unit: Image1 S Connect II (TC201US) and Image1 S 4U- Link (TC304US): is used with the

	Image1 S 4U Rubina Camera Head to output a 4K image to the monitor.
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. 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 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.
Technological Characteristics:	The clinical application for the subject KARL STORZ ICG Imaging System is identical to the cleared KARL STORZ ICG Imaging System, K180146. The 4mm, 5mm & 10mm Endoscopes and VITOM ICG telescopes connected to the optical coupler of the Image1 S 4U Rubina camera head, which connects to the Image1 S Camera Control Unit for image processing, as well as to the Power LED Rubina light source light

source via compatible light cable as the source of illumination to allow visualization of internal anatomy. Visualization and navigation is performed initially using VIS imaging. NIR imaging is selected when visual assessment and/or confirmation of vessels, blood flow or tissue perfusion is desired.

The following comparison table summarizes the technological characteristics between the subject and predicate devices:

Technological Characteristics		KARL STORZ ICG Imaging System Subject Device	KARL STORZ ICG System Predicate Device K180146
Endoscopes (5mm and 10mm)	**Direction of View**	0°, 30°, 45°	0°, 30°
	Working Length	29cm (5mm, 0°, 30°, 45°) 31cm (10mm, 0°, 30°, 45°) 42cm (10mm 45°)	29cm (5mm, 0°, 30°) 31cm (10mm, 0°, 30°)
Camera Head	**Imager Type**	2-chip CMOS (one for WLi and one for ICG)	3- chip CCD sensors (one for each red, green and blue)
	Number of Pixels	3840 x 2160p	1920 x 1080p
Camera Control Unit	**Zoom**	1x, 1.2x, 1.5x, 1.75x, 2x, 2.25x, 2.5x	1x, 1.2x, 1.5x, 1.75x, 2x
	Adaptive Zoom	Yes	No
	Digital Outputs	12G/3G-SDI DisplayPort DVI-D	3G-SDI DVI-D
	Communication Interface	KS HIVE	SCB

	Light Source	**Light Source Type**	Dual LEDs	Xenon 300W lamp
		NIR Light	Filtered LED Output: 720-810 nm	Filtered Xenon lamp Output: 690-790 nm
	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 NIR image. c. Monochromatic: The NIR image is indicated by the color white against a dark background.	Displayed image is either the VIS light image or the NIR image. The blue NIR image is overlaid over remnant red-green 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 o IEC 60601-2-18 • ISO Endoscopic Standards o ISO 8600-1 o ISO 8600-3 o ISO 8600-4 o ISO 8600-5 o ISO 8600-6 • Software Verification and Validation Testing o Guidance for the Content of Premarket Submissions for Software Contained in Medical Device o Level of concern: Moderate Cleaning and sterilization validations were conducted for the Image1 S 4U Rubina camera head. Additional bench testing listed below was performed to ensure the device met its design specifications. • Depth of Field • Distortion • Latency • Dynamic Range • Signal to Noise Ratio (SNR) & Sensitivity • Spatial Resolution • Color Reproduction and Color Contrast Enhancement • Illumination Detection Uniformity • Detection Linearity • Direction of View • Field of View • Zoom Characterization • Penetration Depth • ICG Contrast • Concentration Sensitivity • Color Rendering • Coregisteration • Photobiological Safety (UV Exposure and Distal Irradiance)
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 cleaning and sterilization data (Section 17), Software Data (Section 19), Electrical Safety and EMC data (Section 20), as well as the Bench Top Performance Data (Section 21) demonstrated that the subject device is as safe and as effective as the predicate device. As such, we concluded that the substantial equivalence of the subject and the predicate device has been met, and the differences between the subject and predicate do not raise new questions of safety and effectiveness.