KARL STORZ Endoscopy America, Inc.
Alita McElroy
Regulatory Affairs Specialist
2151 E. Grand Avenue
El Segundo, California 90245

December 17, 2020

Re: K202925
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 28, 2020
Received: September 29, 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
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)*
K202925

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 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.

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.

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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
510(k) Number:	K202925
Date of Preparation:	December 16, 2020
Type of 510(k) Submission:	Traditional
Trade Name:	KARL STORZ ICG Imaging System
Common Name:	Confocal Optical Imaging
Regulatory Class:	II
Product Code:	OWN, GWG
Classification Number and Name:	21 CFR 876.1500 (Endoscope and Accessories) 21 CFR 882.1480 (Neurological Endoscopes)
Predicate Device(s):	PINPOINT Endoscopic Fluorescence Imaging System (K182606)- Primary KARL STORZ ICG Imaging System (K201399)- Secondary
Device Description:	The subject device, KARL STORZ ICG Imaging System includes the following components : • 4mm, 5mm & 10mm HOPKINS ICG/NIR Endoscopes • VITOM II ICG Telescope • Image1 S Rubina Camera head • Power LED Rubina light source, footswitch • Fiber Light Cables • Image1 S CCU

	The expanded indication for visualization of the lymphatic vessel is only to the Endoscopic ICG system that includes the 4mm, 5mm & 10mm HOPKINS ICG/NIR Endoscopes. The addition of the reprocessing modalities is to the 4mm, 5mm & 10mm HOPKINS ICG/NIR Endoscopes and the VITOM II ICG/NIR telescope. The endoscopes/telescope are intended to be connected to the optical coupler of the camera head, which connects to the CCU for image processing, as well as to the light source via compatible light cable as the source of illumination to allow visualization of internal anatomy. The users can switch between WLi (standard white light) mode, for visualization of the endoscopic and microscopic procedures and NIR (Near Infrared) mode to detect ICG presence. The KARL STORZ ICG Imaging System can be used with any medical grade monitor with a DVI-D or 12G/3G-SDI input.
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 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. 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.
Comparison of Indication for Use:	The subject device includes the endoscopic system (4mm, 5mm & 10mm HOPKINS ICG/NIR Endoscopes) for fluorescence imaging and visualization of the lymphatic system in addition to the already cleared minimally invasive procedures, neurosurgery, endonasal skull base surgery. The primary predicate device only includes the endoscopic system for fluorescence imaging and visualization of the lymphatic system and for minimally invasive procedures. The difference in the indication does not raise new issues of safety and effectiveness because the primary predicate device is chosen to only support the expanded indication of the subject device i.e imaging and visualization of the lymphatic system as the other indications of the subject device have been previously cleared. The subject device includes imaging and visualization of the lymphatic system in addition to the already cleared minimally invasive procedures, neurosurgery, endonasal skull base surgery, whereas the secondary predicate device is only indicated for minimally invasive surgery, neurosurgery and endonasal skull base surgery. The difference in indication does not raise new issues of safety and effectiveness because the secondary predicate is chosen due to its identical intended use, operating principles and technological characteristics.

Technological Characteristics:	The KARL STORZ ICG Imaging System is substantially equivalent to the legally marketed primary predicate device, PINPOINT Endoscopic Fluorescence Imaging System cleared under K182606 and the secondary predicate device, KARL STORZ ICG Imaging System cleared under K201399. The primary predicate was chosen to support the expanded indication for imaging and visualization of the lymphatic system. The subject and primary predicate device are identical in terms of intended use and mode of imaging to provide real time visible (VIS) and near-infrared fluorescence (NIR) imaging. The subject and primary predicate devices have the same integral components – a light source and light cable for outputting light, a camera control unit for processing NIR and VIS light images, a camera head and rigid endoscopes for VIS and NIR light illumination and imaging. The main differences between the subject primary predicate devices include the following: • The subject device can output a 4K image to the monitor while the primary predicate device outputs a high definition image. • The subject device uses a LED light source for NIR imaging whereas the predicate device provides NIR light using laser diode. • In NIR mode, the subject device displays either one of the three ICG presentations whereas the primary predicate device generates a parallel display showing four simultaneous images on the monitor. The subject and secondary devices have identical intended use, operating principles, technological characteristics. The differences between the subject device and the cleared KARL STORZ ICG Imaging System are the expanded indication for use of the ICG Endoscopic System (4mm, 5mm & 10mm HOPKINS ICG/NIR endoscopes) for imaging and visualization of the lymphatic system and the addition of sterilization modalities to the ICG scopes (4mm, 5mm, 10mm HOPKINS ICG/NIR Endoscopes and VITOM II ICG/NIR telescope).
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 The expansion of the indication of the subject device does not change the biocompatibility, electrical safety, electromagnetic compatibility, or software validations and remain identical since last clearance (K201399). Sterilization validations of the additional modalities were conducted for the HOPKINS ICG/NIR Endoscopes and the VITOM II ICG/NIR telescopes. The performance of the subject device, KARL STORZ ICG Imaging System for VIS imaging has been verified and previously cleared in K201399 as the expanded indication for fluorescence imaging and visualization of the lymphatic system does not affect its performance in white light mode. The photobiological safety of the subject device per the FDA recognized standard IEC 62471 has been verified and previously cleared in K201399. The performance of the subject device for NIR imaging has been demonstrated by comparing to the primary predicate device, PINPOINT Endoscopic Fluorescence Imaging System to support the expanded indication for fluorescent imaging and visualization of the lymphatic system
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 substantial equivalence of the expanded indications.
Conclusion:	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 primary and secondary predicate devices. As such, we concluded that the substantial equivalence of the subject and the predicate devices has been met, and the differences between the subject and predicate do not raise new questions of safety and effectiveness.