



KARL STORZ Endoscopy America  
Mario Trujillo  
Regulatory Affairs Specialist  
2151 E. Grand Avenue  
El Segundo, California 90245

November 15, 2021

Re: K212695  
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: October 28, 2021  
Received: October 29, 2021

Dear Mario Trujillo:

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](mailto: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

## Indications for Use

510(k) Number (if known)

K212695

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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## K212695

### 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:	Mario Trujillo Regulatory Affairs Specialist Tel.: (424) 218-8481 Email: Mario.Trujillo@karlstorz.com
Date of Preparation:	October 21, 2021
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: KARL STORZ ICG Imaging System Classification Name: Confocal Optical Imaging 21 CFR 876.1500 (Endoscope and Accessories) 21 CFR 882.1480 (Neurological Endoscopes)
Regulatory Class:	2
Product Code:	OWN, GWG
Guidance Document:	Not Applicable
Predicate Device:	Primary predicate device KARL STORZ ICG Imaging System (K202925). Secondary predicate device: KARL STORZ ICG Imaging System (K180146). Reference device: TIPCAM1 Rubina Video Endoscope System (K201526)
Device Description:	The modified KARL STORZ ICG Imaging System is identical to the KARL STORZ ICG Imaging System recently cleared under K202925. The modified KARL STORZ ICG Imaging System now includes the following components:  i) TIPCAM®1 Rubina Videoscope (0°, 30°): a 3D image capable videoendoscope with 2D auto-leveling (auto-rotation) and 2D auto-switch display modes.
Intended Use:	The KARL STORZ ICG Imaging System is intended to provide real-time visible and near-infrared fluorescence imaging.

<p>Indications For Use:</p>	<p>The KARL STORZ ICG Imaging System is intended to provide real-time visible (VIS) and near-infrared (NIR) fluorescence imaging.</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, 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 &gt; 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>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>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>
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<p>Technological Characteristics:</p>	<p>The clinical application for the subject KARL STORZ ICG Imaging System is identical to the cleared KARL STORZ ICG Imaging System, K202925.</p> <p>The 4mm, 5mm &amp; 10mm Endoscopes and VITOM ICG telescopes connected to the optical coupler of the Image1 S 4U Rubina camera head, and the TIPCAM®1 Rubina Videoendoscope 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.</p> <p>For the NIR image, the user has three presentations of the ICG imagery to choose from:</p> <ol style="list-style-type: none"> <li>a. Overlay: The white light image is overlaid with the NIR image. The NIR image could either be blue or green</li> <li>b. Intensity Map: The white light image is overlaid with color transformed NIR image.</li> <li>c. Monochromatic: The NIR image is indicated by the color white against a dark background.</li> </ol> <p>The KARL STORZ ICG Imaging System can output a 4K image to the monitor 12G/3G-SDI, DVI-D and DisplayPort digital outputs and also offers 7 increments of zoom ranging from 1x to 2.5x.</p> <p>The reference device, TIPCAM1 Rubina Video Endoscope System, is identical in design and materials of construction to the subject device. The only difference is that the ICG functionality was not included as part of K201526.</p>
<p>Non-Clinical Performance Data:</p>	<p>There are no performance standards or special controls developed under Section 514 of the FD&amp;C Act for endoscopes.</p> <p>However, the KARL STORZ ICG Imaging System, as well as the primary, secondary and reference devices follow the FDA recognized consensus standards and is tested according to the following standards and FDA Guidance:</p> <ul style="list-style-type: none"> <li>• Electrical Safety and EMC             <ul style="list-style-type: none"> <li>o IEC 60601-1</li> <li>o IEC 60601-1-2</li> <li>o IEC 60601-2-18</li> </ul> </li> <li>• ISO Endoscopic Standards             <ul style="list-style-type: none"> <li>o ISO 8600-1</li> <li>o ISO 8600-3</li> <li>o ISO 8600-4</li> <li>o ISO 8600-5</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>o ISO 8600-6</li> <li>• Software Verification and Validation Testing</li> <li>o Guidance for the Content of Premarket Submissions for Software Contained in Medical Device</li> <li>o Level of concern: Moderate</li> </ul> <p>Cleaning and sterilization validations were conducted for the Image1 S 4U Rubina camera head.</p> <p>Additional bench testing was performed to ensure the device met its design specifications. The bench testing performed verified and validated that the KARL STORZ ICG Imaging System has met all its design specification and is substantially equivalent to its predicate device.</p> <p>Conformance to these standards was not the basis upon which substantial equivalence was determined.</p>
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.
Conclusion:	The conclusions drawn from the nonclinical tests demonstrate that the subject device, the KARL STORZ ICG Imaging System performs as well as or better than the predicate devices that are currently marketed for the same intended use.