**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 25, 2017

KARL STORZ Endoscopy- America, Inc.
Winkie Wong
Senior Regulatory Affairs Specialist
2151 E. Grand Avenue
El Segundo, CA 90245

Re: K171238
Trade/Device Name: KARL STORZ ICG Imaging System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: OWN
Dated: April 26, 2017
Received: April 27, 2017

Dear Winkie Wong:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K171238

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.

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.

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| Submitter: | KARL STORZ Endoscopy-America, Inc.<br>2151 E. Grand Avenue<br>EI Segundo, CA 90245 |
| Contact: | Winkie Wong<br>Senior Regulatory Affairs Specialist<br>Phone: (424) 218-8379<br>Fax: (424) 218-8519 |
| Date of Preparation: | April 26, 2017 |
| Type of 510(k) Submission: | Special |
| Device Identification: | Trade Name: KARL STORZ ICG Imaging System<br><br>Classification Name: Confocal Optical Imaging |
| Regulatory Class: | II |
| Product Code: | OWN |
| Regulation: | 21 CFR part 876.1500 (Endoscope and Accessories) |
| Predicate Device(s): | Primary Predicate Device: KARL STORZ Endoscopic ICG System (K62882)<br><br>These predicate devices have not been subject to a design-related recall. |
| Device Description: | The KARL STORZ ICG Imaging System is used to provide real-time high definition (HD) endoscopic or telescope images of visible (VIS) and near-infrared (NIR) indocyanine green (ICG) dye fluorescence during minimally invasive surgery as well as plastic, micro- and reconstructive surgical procedures.<br><br>The overall system includes a 5mm &10mm HOPKINS ICG/NIR Endoscope for use in minimally invasive procedures and a VITOM II ICG/NIR Telescope for use in plastic, micro- and reconstructive surgical procedures for VIS and NIR illumination and imaging, a light source with foot switch for emission of VIS and NIR illumination, a color video camera head capable of capturing both |

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| | VIS and NIR imaging, and KARL STORZ ICG Kit. Additional accessories used with the KARL STORZ ICG Imaging System include two standard fiber-optic light cables for transmission of VIS and NIR light and the Image1S Camera Control Unit (CCU).<br><br>The KARL STORZ ICG Imaging System can be used with any medical grade HD monitor with a DVI-D or 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.<br><br>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.<br><br>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 KARL STORZ ICG Imaging System is modification of and substantially equivalent to the KARL STORZ ICG Imaging System (K162882) in terms of its indications for use, design technology, and performance specifications.<br><br>The main difference between the subject and the primary predicate device is the addition of a 5mm ICG Endoscope to the KARL STORZ Endoscopic ICG System to be used in minimal invasive surgery.<br><br>Bench and comparative testing were used to demonstrate |

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| | substantial equivalence to the primary predicate device.<br><br>Therefore, the differences between the subject device and the predicate device do not raise any new issues of safety and effectiveness. |
| 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 standard:<br><br>• IEC 60601-1<br>• IEC 60601-1-2<br>• IEC 60601-2-18<br>• ISO 8600-1<br>• ISO 8600-3<br>• ISO 8600-4<br>• ISO 8600-5<br>• ISO 8600-6<br>• ISO 14971<br>• ISO 10993<br><br>Additional bench testing was performed to ensure the device met its design specifications.<br><br>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 devices. |
| Clinical Performance Data: | Clinical testing was not required to demonstrate the substantial equivalence to the predicate devices. Non-clinical bench testing was sufficient to assess safety and effectiveness and to establish the substantial equivalence of the modifications. |
| Conclusion: | The conclusions drawn from the non-clinical tests such as the cleaning and sterilization summary, the risk evaluation on the modification of the system and biological evaluation summary demonstrated that the subject device is as safe as and as effective as the predicate device. 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 the predicate devices do not raise new or different questions of safety and effectiveness. |