DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 31, 2016

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

Re: K152583
Trade/Device Name: Karl Storz Endoscopic ICG Imaging System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: OWN
Dated: April 13, 2016
Received: April 15, 2016

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 yours,

Herbert P. Lerner -S

for 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)*
K152583

Device Name

KARL STORZ Endoscopic ICG Imaging System

Indications for Use *(Describe)*

The KARL STORZ Endoscopic ICG Imaging System is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The KARL STORZ ICG Imaging 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 Imaging 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.

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 OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information 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.

Applicant:	Karl Storz Endoscopy-America, Inc 2151 E. Grand Avenue EI Segundo, CA 90245
Contact:	Winkie Wong Senior Regulatory Affairs Specialist Phone: (424) 218-8379 Fax: (424) 218-8519
Date of Preparation:	May 18th, 2016
Device Identification:	Trade Name: KARL STORZ Endoscopic ICG Imaging System Common Name: Endoscopic Video Imaging System Classification Name: Endoscope and accessories
Product Code:	OWN
Regulation:	21 CFR part 876.1500 (Endoscope and Accessories)
Predicate Device(s):	The *KARL STORZ Endoscopic ICG Imaging System* is substantially equivalent to the Intuitive Surgical® da Vinci® Fluorescence Imaging Vision System (K124031), marketed by Intuitive Surgical, Inc.
Indications For Use:	The *KARL STORZ Endoscopic ICG Imaging System* is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The KARL STORZ ICG Imaging 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 Imaging 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.

Device Description:

The *KARL STORZ Endoscopic ICG Imaging System* is used to provide real-time high definition (HD) endoscopic video images of visible (VIS) and near-infrared (NIR) indocyanine green (ICG) dye fluorescence during minimally invasive surgery. The system components are rigid ICG Endoscopes for VIS and NIR illumination and imaging, a light source with foot switch for emission of VIS and NIR illumination, a 3 CCD (charge coupled device) color video camera head capable of capturing both VIS and NIR imaging, and KARL STORZ Indocyanine Green (ICG Kit). Additional accessories used with the *KARL STORZ Endoscopic ICG Imaging System* include a standard fiber-optic light cable for transmission of VIS and NIR light and the Image 1 SPIES Camera Control Unit (CCU) cleared in K131953. The *KARL STORZ Endoscopic ICG Imaging System* can be used with any medical grade HD monitor with a DVI-D or 3G-SDI input. The *KARL STORZ Endoscopic ICG Imaging System* is a Class II device under 21 CFR 876.1500.

Technological Comparison Summary:

The *KARL STORZ Endoscopic ICG Imaging System* is substantially equivalent to the Intuitive Surgical® da Vinci® Fluorescence Imaging Vision System (K124031) in terms of its indications for use, design technology and performance specification.

The differences between the subject and predicate device are:

- The subject device uses a Filtered Xenon Light source whereas the Predicate (da Vinci) uses a Laser Diode during NIR Illumination Mode.
- The subject device projects 2D fluorescence image on a dichromatic background whereas the predicate device (da Vinci) projects 3D fluorescence image on a monochromatic background in NIR Illumination Mode.

Bench and comparative testing were used to demonstrate substantial equivalence to the predicate Intuitive Surgical® da Vinci® Fluorescence Imaging Vision System, K124031. 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:

The *KARL STORZ Endoscopic ICG Imaging System* has been successfully tested for its functions and performance, including verification that the spectral characteristics of the ICG system illumination light source, light transmission system and endoscope enable a selective visualization of the ICG fluorescence signal as detected by the camera system. Furthermore, a GLP animal study was successfully performed by the NAMSA testing facility to evaluate the performance of the *KARL STORZ Endoscopic ICG Imaging System* in the

porcine minimally-invasive laparoscopy model.

Safety testing was performed including electrical safety IEC 60601-1 and 60601-2-18, electromagnetic compatibility per IEC 60601-1-2, and biocompatibility of the patient contacting materials per ISO 10993. Additional validations were conducted for system software, the manual cleaning method, and the sterilization process.

Clinical Performance Data:

Clinical testing was not required to demonstrate substantial equivalence to the predicate device.

Conclusion:

The *KARL STORZ Endoscopic ICG Imaging System* is substantially equivalent to the predicate Intuitive Surgical® da Vinci® Fluorescence Imaging Vision System (K124031) with regards to device design, materials, operational principles, and performance characteristics. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as or better than the legally marketed device.