April 17, 2018

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

Re: K180146
Trade/Device Name: KARL STORZ ICG Imaging System
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG, OWN
Dated: January 16, 2018
Received: January 18, 2018

Dear Ms. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180146

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, or 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 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 424-218-8379 424-218-8519
Date of Preparation:	January 15, 2018
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: KARL STORZ ICG Imaging System Classification Name: Neurological Endoscope
Product Code:	GWG, OWN
Regulation:	21 CFR 876.1480 (Neurological Endoscope)
Predicate Device(s):	KARL STORZ ICG Imaging System (K171238) – Primary KSEA Neuroendoscopes and Accessories (K021050) – Secondary ***The above predicate has not been subject to any recall***
Device Description:	The KARL STORZ ICG Imaging System is used to provide real-time high-definition (HD) endoscopic or telescopic images of visible (VIS) and near-infrared (NIR) indocyanine green (ICG) dye fluorescence during minimally invasive, neuro- and endonasal skull base surgery as well as plastic, micro- and reconstructive surgical procedures in general and pediatric populations.

	The overall system includes a 4mm HOPKINS ICG/NIR Endoscope (0°, 30° or 45°) for use in neuro- and endonasal skull base surgery, a 5mm & 10mm HOPKINS ICG/NIR Endoscope (0° or 30°) 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 VIS and NIR imaging, and a KARL STORZ ICG Kit. Additional accessories used with the KARL STORZ ICG Imaging System include two standards fiber-optic light cables for transmission of VIS and NIR light and the Image1 S Camera Control Unit (CCU). 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 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, or 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 KARL STORZ ICG Imaging System includes the following components and accessories: • 4mm, 5mm & 10mm HOPKINS ICG/NIR Endoscopes • VITOM II ICG Telescope • Camera Head (H3Z-FI) • Fiber optic Light Cables • Light Source • Image1 S CCU 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. 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.

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
	  ○ IEC 60601-1
	  ○ IEC 60601-1-2
	  ○ IEC 60601-2-18
	• ISO Endoscopic Standards
	  ○ ISO 8600-1
	  ○ ISO 8600-3
	  ○ ISO 8600-4
	  ○ ISO 8600-5
	  ○ ISO 8600-6
	• Biocompatibility (ISO 10993)
	  ○ Cytotoxicity

	○ Systemic toxicity ○ Intracutaneous irritation ○ Maximization sensitization ○ Mucosal Irritation • Software Verification and Validation Testing ○ Guidance for the Content of Premarket Submissions for Software Contained in Medical Device ○ Level of concern: Moderate • Performance Testing ○ Color Performance ○ Detection Linearity ○ Distortion ○ Dynamic Range ○ Illumination ○ Resolution ○ SNR & Sensitivity ○ Depth of Field ○ UV Exposure ○ Irradiance ○ Color Reproduction • Reprocessing (Cleaning and Steam Sterilization) ○ AAMI TIR30:2011 ○ AAMI TIR 12:2010 ○ ANSI/AAMI/ISO 14937:2009 ○ ANSI/AAMI ST9:2010/A4:2013 ○ ISO TS 15883:2005 ○ Processing/Reprocessing Medical Device in Health Care Settings: Validation Methods and Labeling 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 devices.
Clinical Performance Data:	Clinical published literatures were provided to support the effectiveness of NIR imaging in the neuro- and endonasal skull

	base surgeries as well as the use of the KARL STORZ ICG Imaging System in pediatrics.
Substantial Equivalence:	The KARL STORZ ICG Imaging System is a modification of and substantially equivalent to the primary predicate, KARL STORZ Imaging System (K171238), in regards to its intended use, design, technology, and performance specifications. The main difference between the subject and primary predicate device is the addition of the 4mm HOPKINS ICG/NIR Endoscopes to the KARL STORZ Endoscopic ICG System to be used in neuro- and endonasal skull base surgery in adults and pediatrics. The KARL STORZ ICG Imaging System is also substantial equivalent to the secondary predicate, KSEA Neuroendoscope & Accessories, in regards to its intended use (VIS imaging), design, technology, and performance specifications. The main difference between the subject and secondary predicate device is the addition of filter located at the eyepiece of the endoscope for the purpose of NIR imaging. Bench and comparative testing were used to demonstrate substantial equivalence to the predicate devices. Clinical published literatures were used to support the expanded indications for NIR imaging in neuro- and endonasal skull base surgeries as well as the use of the KARL STORZ ICG Imaging system in pediatrics. Therefore, the differences between the subject device and the predicate device do not raise any new issues of safety and effectiveness.

Standard Performance Parameters Comparison:

	KARL STORZ ICG Imaging System Subject Device	KARL STORZ ICG System Primary Predicate Device K162882	KS Neuro-endoscopes and Accessories Secondary Predicate Device K021050
(D1) Endoscope Type	Rigid, rod lens	Rigid, rod lens	Rigid, rod lens
(D2) Endoscope Diameters	4mm, 5mm & 10mm	5mm & 10mm	2.7mm, 4mm & 4.8mm
(D3) Direction of View	0°, 30°, 45°	0°, 30°	0°, 30°, 45°
(D4) Working Length	18cm (4mm) 29cm (5mm) 31cm (10mm)	29cm (5mm) 31cm (10mm)	18 or 20 cm
Depth of Field	8mm – 38mm	30mm – 80mm (5mm) 30mm – 110mm (10mm)	8mm – 38mm
Field of View	80°	74°	80°
Imaging Type	Visible and near-infrared imaging	Visible and near-infrared imaging	Visible Imaging
Imaging Agent	ICG	ICG	N/A

	Light Source Compatibility	Xenon	Xenon	Xenon
Bibliography	Published literatures were used to support the expanded indications for NIR imaging in neuro- and endonasal skull base surgeries as well as the use of the KARL STORZ ICG Imaging system in pediatrics. NIR Imaging in Neuro and Endonasal Skull Base Surgery: • Geltzeiler M, Nakassa ACI, Setty P, Zenonos G, Hebert A, Wang E, Fernandez-Miranda J, Snyderman C, Gardner P. (2017). Evaluation of Intranasal Flap Perfusion by Intraoperative ICG Fluorescence Angiography. Journal of Neurological Surgery Part B: Skull Base. 78. S1-S156. 10.1055/s-0037-1600668. • Nakassa ACI, Wang E, Fernandez-Miranda J, Snyderman C, Gardner P. (2017). Usefulness of Indocyanine Green Fluorescence Endoscopy for Intraoperative Differentiation of Intracranial Tumors and Adjacent Structures. Journal of Neurological Surgery Part B: Skull Base. 78. S1-S156. 10.1055/s-0037-1600677. • Hide T, Yano S, Kuratsu J. (2014) Indocyanine Green Fluorescence Endoscopy at Endonasal Transsphenoidal Surgery for an Intracavernous Sinus Dermoid Cyst: Case Report. Neurologia Medico-Chirurgica. .54(12):999-1003. doi:10.2176/nmc.cr.2014-0087. • Hide T, Yano S, Shinojima N, Kuratsu J. (2015) Usefulness of the Indocyanine Green Fluorescence Endoscope in Endonasal Transsphenoidal Surgery. Journal of Neurological Surgery. Published online February 27, 2015; DOI: 10.3171/2014.9.JNS14599 Pediatric Use of subject device: • Patrick C. Walz, Charles A. Elmaraghy and Kris R. Jatana (2015). Endoscopic Skull Base Surgery in the Pediatric Patient, Endoscopy - Innovative Uses and Emerging Technologies, Associate Prof. Somchai Amornyotin (Ed.), InTech, DOI: 10.5772/60555. Available from: https://www.intechopen.com/books/endoscopy-innovative-uses-and-emerging-technologies/endoscopic-skull-base-surgery-in-the-pediatric-patient • Alessandro Fiorindi, Alessandro Boaro, Giulia Del Moro, Pierluigi Longatti; Fluorescein-Guided Neuroendoscopy for Intraventricular Lesions: A Case Series, *Operative Neurosurgery*, Volume 13, Issue 2, 1 April 2017, Pages 173–181, https://doi.org/10.1093/ons/opw008. • Yamamichi T, Oue T, Yonekura T, Owari M, Nakahata K, Umeda S, Nara K, Ueno T, Uehara S, Usui N. Clinical application of indocyanine green (ICG) fluorescent imaging of hepatoblastoma. J Pediatr Surg. 2015 May;50(5):833-6. doi: 10.1016/j.jpedsurg.2015.01.014. Epub 2015 Feb 3, https://www.ncbi.nlm.nih.gov/pubmed/25783395 • Kitagawa N. (2016) Application of Indocyanine Green Fluorescence Imaging to Pediatric Hepatoblastoma Surgery. In: Kusano M., Kokudo N.,			

	Toi M., Kaibori M. (eds) (2016) ICG Fluorescence Imaging and Navigation Surgery. Springer, Tokyo, ICG Fluorescence Imaging and Navigation Surgery pp343-350., https://doi.org/10.1007/978-4-431-55528-5_31
Clinical Performance Data:	Clinical performance is not required to demonstrate substantial equivalence to the predicate devices. Non-clinical bench testing was sufficient to establish substantial equivalence.
Conclusion:	The KARL STORZ ICG Imaging System is substantially equivalent to its predicate devices. The non-clinical testing and supporting clinical literatures demonstrate that the device is as safe and effective as the legally marketed devices.