November 20, 2018

KARL STORZ Endoscopy-America, Inc.
Winkie Wong
Manager, Regulatory Affairs
2151 E. Grand Avenue
EI Segundo, CA 90245

Re: K182696
Trade/Device Name: Telepack X LED
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FET
Dated: September 25, 2018
Received: September 27, 2018

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Jeffrey W. Cooper -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)*
K182696

Device Name
Telepack X LED

Indications for Use *(Describe)*
The TELE PACK X LED is an all-in-one Imaging System, which comprises a light source for illumination, Camera Control Unit (CCU) for use with compatible camera heads or video endoscopes for image processing, as well as a monitor for image display, intended for the visualization of endoscopic and microscopic procedures.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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 Regulatory Affairs Manager 424-218-8379 (phone)
Date of Preparation:	September 24th, 2018
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: Telepack X LED Classification Name: Endoscopic Video Imaging System/Component
Product Code:	FET
Regulation:	21 CFR 876.1500 (Endoscope and Accessories)
Predicate Device(s):	Image 1 Video Imaging System (K070716) – Primary KARL STORZ ICG Imaging System (K180146) – Reference ***The above predicate and reference device have not been subject to any recall***
Device Description:	The Telepack X LED is a portable and compact all-in-one imaging system that includes a 15 inch screen display, a camera control unit and internal LED light source, that is intended to be connected to a compatible device (camera head or videonendoscope) for the purpose of visualization and documentation of endoscopic and microscopic procedures as well as stroboscopy.

	The Telepack X LED includes a LED illumination light source to illuminate the intended area and a 15 inch monitor for display. It also allows the users to redefine the functions that take place when a button is pressed. The Telepack X LED is a non-patient contacting and require only wipe down as needed.
Intended Use and Indications for use:	The TELE PACK X LED is an all-in-one Imaging System, which comprises a light source for illumination, Camera Control Unit (CCU) for use with compatible camera heads or video endoscopes for image processing, as well as a monitor for image display, intended for the visualization of endoscopic and microscopic procedures.
Technological Characteristics:	The Telepack X LED is a portable and compact all-in-one imaging system that includes a 15 inch screen display, a camera control unit and internal LED light source, that is intended to be connected to a compatible device (camera head or videonendoscope) for the purpose of visualization and documentation of endoscopic and microscopic procedures as well as stroboscopy. The Telepack X LED includes, but not limited to, the following features: • Image capture • Flip or mirror image • Zoom • Brightness control • Light source control • White Balance The dimension of the subject device is 450 x 350 x 150 mm and weighs 7kg. It is not intended to be soiled and is non-patient contacting. It includes moderate level of concern software. The device has been tested and passed the electrical safety and EMC testing, which is certified to be Class I protection against electrical shock, Type BF protection against electrical shock from stroboscopy and camera applied parts, Type CF protection against electrical shock from light and lastly drip-water protection against moisture per IPX1.

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
	  o IEC 52471
	• Software Verification and Validation Testing
	  o Guidance for the Content of Premarket Submissions for Software Contained in Medical Device
	  o Level of concern: Moderate
	• Performance Testing
	  o Minimum Illumination
	  o Spatial Resolution
	  o Color Performance
	  o Latency
	  o White Balance
	  o AE Step Response
	  o Head Button Functionality
	
	Additional bench testing was performed to ensure the device met its design specifications. The bench testing performed verified and validated that the Telepack X LED 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 intended use, operating principles, technological characteristics and features are similar, if not identical, between that subject device and the Image 1 Video Imaging System (K070716). The minor difference between the subject and predicate devices that does not raise new or different questions or safety and effectiveness are:

	• The subject device seeks clearance on the CCU, internal light source and internal display to be used with compatible camera heads and videoendoscopes, whereas the predicate device sought clearance on the CCU and camera heads with use of an external standard light source and external display as part of the submission. • The subject device allows image, video and audio files to be stored via an external SD memory card or the hospital's/office's network server, whereas the predicate allows image, video and audio files to be stored via an external device. *(Function not under review as this function is 510k exempt per product code, LMD, and does not have impact on the performance of the device)* • The subject device does not offer interoperability (the ability to control external devices), whereas the predicate does. • The subject device does not offer split screen enhancement, whereas the predicate does. • The subject device is slightly larger and heavier than the predicate device • Due to the internal light source the subject device offer, the subject device is compliant to IEC 62471, whereas for the predicate, the compliance to IEC 62471 is achieved by the external light source. As proven by the comparisons, the above differences do not raise different questions of safety and effectiveness because the intended use, operating principles, technological characteristics, and features are similar, if not identical. Both systems also comply with identical standards and safety testing, where applicable. Substantial equivalence on the effectiveness of the subject device is supported by the comparison of the images and standard image quality characteristics including, but not limited to, resolution, latency, white balance and AE step response between subject and predicate devices.
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 Telepack X LED is substantially equivalent to its predicate device. The non-clinical bench and comparative testing demonstrate that the device is as safe and effective as the legally marketed devices.