June 23, 2020

Karl Storz Endoscopy America, Inc.
Winkie Wong
Manager, Regulatory Affairs
2151 E. Grand Ave
El Segundo, CA 90245

Re: K201096
Trade/Device Name: CO2mbiLED
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FCX, FEQ, NTN
Dated: April 20, 2020
Received: April 24, 2020

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/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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*

K201096

Device Name
CO2mbi LED SCB

Indications for Use *(Describe)*

The CO2mbi LED SCB is a combination of an LED light source, intended to provide illumination, and an insufflation/ irrigation pump, intended to insufflate CO2 or air as a distention media in the gastrointestional tract or water irrigation for lens cleaning when used in conjunction with flexible endoscopes for GI endoscopic 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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:	June 22nd, 2020
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: CO_2mbiLED Classification Name: Insufflator, Automatic Carbon-Dioxide for Endoscope (FCX) Pump, air, Non-Manual, For Endoscope (FEQ) LED Light Source
Product Code:	FCX, FEQ, NTN
Regulation:	21 CFR 876.1500 (Endoscope and Accessories)
Device Class:	II
Classification Panel:	Gastroenterology/ Urology
Predicate Device(s):	CO_2MPACT (K111648) – Primary Xenon 100 SCB (K082925) – Secondary ***The above predicate and reference device have not been subject to any recall***
Device Description:	CO_2mbi LED SCB is a portable and compact all-in-one LED Light source and insufflation unit that includes a touchscreen control

	display, an insufflation pump and internal LED light source, intended to be connected to a compatible GI Videoendoscope and CCU for illumination and insufflation purposes. It is also equipped with a water bottle and lid with tube to provide irrigation for lens cleaning.
Intended Use and Indications for use:	The CO2mbi LED SCB is a combination of an LED light source, intended to provide illumination, and an insufflation/irrigation pump, intended to insufflate CO2 or air as a distention media in the gastrointestional tract or water irrigation for lens cleaning when used in conjunction with flexible endoscopes for GI endoscopic procedures.
Substantial Equivalence:	The intended use, operating principles, technological characteristics and features are similar, if not identical, between that subject device and predicates, primary – CO_2MPACT (K111648) and secondary – Xenon 100 SCB (K082925). The minor differences between the subject and predicate devices that do not raise new or different questions or safety and effectiveness are: • The subject device offers additional options (CO_2, air or combination of both) for distension media when compared to either of the predicates (CO_2 or air only). • The subject device and predicate devices have slightly different flow rates and flow rate settings. • The subject device has slightly different operating pressures and pressure to activate pressure relief valve (CO_2) As proven by the comparisons and rationale in this section, the above differences do not raise different questions of safety and effectiveness because the intended use, operating principles, technological characteristics, and features are significantly 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 flow rate, flow rate settings, operating pressure and pressure to activate pressure relief valve (Table F) and bench testing to show that the subject device function as intended (*Section 21 – Performance Testing*).

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 CO_2mbiLED 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 60601-2-2
	  o IEC 60601-2-18
	  o IEC 62471
	• Software Verification and Validation Testing
	  o Guidance for the Content of Premarket Submissions for Software Contained in Medical Device
	  o Level of concern: Moderate
	
	Additional bench testing was performed to ensure the device met its design specifications. The bench testing performed verified and validated that the CO_2mbiLED has met all its design specification and is substantially equivalent to its 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 CO_2mbiLED 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.