January 24, 2020

Karl Storz SE & Co. KG
Alexey Davidov
Manager Regulatory Affairs, US Submissions
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen, Germany

Re: K192523
Trade/Device Name: CMOS Video Esophagoscope SSU
Regulation Number: 21 CFR 874.4710
Regulation Name: Esophagoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOX
Dated: December 24, 2019
Received: December 27, 2019

Dear Alexey Davidov:

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,

for Michael Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental 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)*
K192523

Device Name
CMOS Video Esophagoscope SSU

Indications for Use *(Describe)*
The CMOS Video Esophagoscope SSU is intended to provide visualization of nasal sinuses, larynx, esophagus and gastroesophageal junction during diagnostic procedures.

The E-Box serves as an adaptor for operating the flexible single-use videoscope on the compatible CCU.

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 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 and the FDA guidance document titled "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" issued on July 28, 2014. All data included in this document is accurate and complete to the best of KARL STORZ SE & Co. KG knowledge.

Submitter:	KARL STORZ SE & Co. KG Dr.-Karl-Storz-Straße 34 78532 Tuttlingen, Germany
Contact:	Alexey Davidov Manager Regulatory Affairs, US Submissions Phone: +49 (0)7461 708-7909 Fax: +49 (0)7461 708-75095 Email: Alexey.Davidov@karlstorz.com
Date of Preparation:	September 9, 2019
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: CMOS Video Esophagoscope SSU Classification Name: Esophagoscope (Flexible Or Rigid) (21 CFR Part 874.4710)
Regulatory Class:	II
Product Code:	EOX
Guidance Document:	Not Applicable for EOX product codes
Recognized Consensus Standards:	Not Applicable for EOX product codes
Predicate Device:	Predicate device: KARL STORZ Endoscopy-America's Trans-Nasal Esophagoscope Model 11302BD1 (K051972). The predicate device has not been subjects to a design-related recalls. No reference devices were used in this submission.
Device Description:	The CMOS Video Esophagoscope SSU System includes three main components: (1) the CMOS Video Esophagoscope SSU (091370-01), (2) E-Box adaptor (TP010) and (3) the CCU. CMOS Video Esophagoscope SSU is compatible with two KARL STORZ CCUs: C-HUB and C-MAC. CMOS Video Esophagoscope SSU is provided sterile (EtO), for single use only.

<table>
<tr><td>Intended Use:</td><td>CMOS Video Esophagoscope SSU is intended for visualization purposes during ENT procedures.</td></tr>
<tr><td>Indications for Use:</td><td>The CMOS Video Esophagoscope SSU is intended to provide visualization of nasal sinuses, larynx, esophagus and gastro-esophageal junction during diagnostic procedures.

The E-Box serves as an adaptor for operating the flexible single-use videoscope on the compatible CCU.</td></tr>
<tr><td>Technological Characteristics:</td><td>Comparison Table: Subject vs. Predicate Device
<table>
<tr><th></th><th>Subject Device
CMOS Video Esophagoscope SSU</th><th>Predicate device K051972
Trans-Nasal Esophagoscope 11302BD1</th></tr>
<tr><td colspan="3">Physical Characteristics</td></tr>
<tr><td>Type of Scope</td><td>Flexible video endoscope</td><td>Same as the subject device</td></tr>
<tr><td>Insertion Shaft Diameter</td><td>3.5 mm</td><td>3.7 mm</td></tr>
<tr><td>Insertion Shaft Length</td><td>750 mm</td><td>650 mm</td></tr>
<tr><td>Deflection</td><td>210° Up, 140° Down</td><td>140° Up, 140° Down</td></tr>
<tr><td colspan="3">Optical and System Characteristics</td></tr>
<tr><td>Type of Imager</td><td>CMOS</td><td>None</td></tr>
<tr><td>Direction of View</td><td>0°</td><td>Same as the subject device</td></tr>
<tr><td>Field of view</td><td>110°</td><td>87°</td></tr>
<tr><td>Light Source</td><td>Internal LED</td><td>External light source</td></tr>
<tr><td colspan="3">Reprocessing Methods</td></tr>
<tr><td>How device is provided</td><td>Sterile single-use</td><td>Unsterile, reusable</td></tr>
<tr><td>EO Sterilization Cycle</td><td>„6.Storz / 1.75 bar / 50° C / 80 min / 17.5h“</td><td>N/A</td></tr>
<tr><td>Sterilizing agent</td><td>Mixture of EO in CO2; resulting concentration: 8,5 ± 0,5 % EO; CO2 added up to 100 %</td><td>N/A</td></tr>
</table></td></tr>
<tr><td>Non-Clinical Performance Data:</td><td>Electrical Safety and Electromagnetic Compatibility Summary
The electrical safety and EMC data for the subject device and compatible CCUs was provided to FDA and was in compliance with the following FDA recognized standards:
✓ ANSI/AAMI ES:60601-1:2005
✓ IEC 60601-1-2:2007

Bench Testing Summary
The performance data submitted in the submission is in compliance with the following FDA recognized standards:
✓ ISO 8600-1:2015
✓ ISO 8600-3:1997
✓ ISO 8600-4:2014
✓ ISO 8600-5:2005
✓ IEC 62471:2006
✓ IEC 60601-2-18:2009

Animal Study
Animal study was not required to demonstrate the substantial equivalence to the predicate devices.</td></tr>
</table>

	Biocompatibility Summary The biocompatibility evaluation for the patient contacting components of the CMOS Video Esophagoscope SSU was performed according to ISO 10993-1 and FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"". Tests in accordance with following standards were conducted based on contact type and duration: ✓ ISO 10993-1:2009/(R)2013 ✓ ISO 10993-5:2009/(R)2014 ✓ ISO 10993-10:2010/(R)2014 ✓ ISO 10993-11:2006/(R) 2010 ✓ ISO 10993-12:2012 *Sterilization Validation Summary* The CMOS Video Esophagoscope SSU is provided sterile and does not require user reprocessing. The subject device is validated to be sterilized with EO in accordance with validated sterilization cycle "6.Storz". Sterilization validation is in compliance with the following standard: ✓ ANSI AAMI ISO 11135:2014 *Software Verification and Validation Summary* Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", issued on May 11, 2005. The software for this device was considered as a "minor" level of concern, since a failure or latent flaw in the software is unlikely to cause any injury to the patient or operator.
Clinical Performance Data:	Clinical testing was not required to demonstrate the substantial equivalence to the predicate device. Non-clinical bench testing and labeling were sufficient to establish the substantial equivalence of the modifications.
Conclusion:	The conclusions drawn from the nonclinical tests demonstrate that the subject device, the CMOS Video Esophagoscope SSU is substantially equivalent to the predicate device, that is currently marketed for the same intended use.