March 22, 2019

KARL STORZ Endoscopy-America, Inc.
Nozomi Yagi
Sr. Regulatory Affairs Specialist
2151 E. Grand Avenue
El Segundo, California 90245

Re: K182186
Trade/Device Name: CMOS Video-Rhino-Laryngoscope System
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: August 9, 2018
Received: August 13, 2018

Dear Nozomi Yagi:

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,

Srinivas Nandkumar -S

for Malvina Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat 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)*
K182186

Device Name
CMOS Video-Rhino-Laryngoscope System

Indications for Use *(Describe)*
The CMOS Video-Rhino-Laryngoscope System is indicated to provide visualization of the nasal lumens and airway anatomy (including nasopharyngeal and trachea) during diagnostic 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 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. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Submitter:	KARL STORZ Endoscopy-America, Inc. 2151 E. Grand Avenue EI Segundo, CA 90245
Contact:	Nozomi Yagi Sr. Regulatory Affairs Specialist Phone: (424) 218-8351 Fax: (424) 218-8519
Date of Preparation:	March 22, 2019
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: CMOS Video-Rhino-Laryngoscope System Classification Name: Endoscope, Neurological (21 CFR Part 882.1480)
Regulatory Class:	II
Product Code:	EOB
Guidance Document:	Not Applicable for EOB product code
Recognized Consensus Standards:	Not Applicable for EOB product code
Predicate Device:	Primary Predicate Device: KARL STORZ Endoscopy-America's CMOS Video Rhino-Laryngoscope System Model 11101CM (K103467)
Device Description:	The CMOS Video-Rhino-Laryngoscope System includes two main components: (1) the CMOS Video-Rhino-Laryngoscope (11102CM) and (2) the CCU. The CMOS Video-Rhino-Laryngoscope is compatible with two KARL STORZ CCUs: C-HUB and C-MAC.
Intended Use:	The CMOS Video-Rhino-Laryngoscope System is intended for visualization purposes during ENT procedures.
Indications For Use:	The CMOS Video-Rhino-Laryngoscope System is indicated to provide visualization of the nasal lumens and airway anatomy (including

<table>
<tr><td></td><td>nasopharyngeal and trachea) during diagnostic procedures.</td></tr>
<tr><td>Technological Characteristics:</td><td>
Comparison Table: Subject vs. Primary Predicate Devices
<table>
<tr><th></th><th>Subject Device

CMOS Video-Rhino-Laryngoscope System</th><th>Primary Predicate, K103467
CMOS V-R-L 11101CM</th></tr>
<tr><td colspan="3">Physical Characteristics</td></tr>
<tr><td>Type of Scope</td><td>Flexible</td><td>Same as the subject device</td></tr>
<tr><td>Insertion Shaft Diameter</td><td>2.9 mm</td><td>3.7 mm</td></tr>
<tr><td>Insertion Shaft Length</td><td>300 mm</td><td>Same as the subject device</td></tr>
<tr><td>Deflection</td><td>140° Up, 140° Down</td><td>Same as the subject device</td></tr>
<tr><td colspan="3">Optical and System Characteristics</td></tr>
<tr><td>Type of Imager</td><td>CMOS</td><td>Same as the subject device</td></tr>
<tr><td>Direction of View</td><td>0°</td><td>Same as the subject device</td></tr>
<tr><td>Light Source</td><td>Internal LED</td><td>Same as the subject device</td></tr>
<tr><td>Field of View</td><td>100</td><td>85</td></tr>
<tr><td>Depth of Field</td><td>5-50mm</td><td>8-50mm</td></tr>
<tr><td>On-axis Resolution (minimal)</td><td>16 Lp/mm at 5mm
1.8Lp/mm at 50mm</td><td>8.0 Lp/mm at 8mm
1.4 Lp/mm at 50 mm</td></tr>
<tr><td colspan="3">Reprocessing Methods</td></tr>
<tr><td>Cleaning</td><td>Manual</td><td>Same as the subject device</td></tr>
<tr><td>Sterilization</td><td>Yes</td><td>Same as the subject device</td></tr>
<tr><td>HLD</td><td>Yes</td><td>Same as the subject device</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 included in the submission is 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

Biocompatibility Summary
The biocompatibility evaluation for the patient contacting components of the neuroscope was performed according to ISO 10993-1 and FDA Guidance. The following tests were conducted based contact type and duration:

ISO 10993-5:2009/(R) 2014
ISO 10993-10:2010
ISO 10993-11:2006/(R) 2010

Reprocessing Validation Summary
The CMOS Video-Rhino-Laryngoscope (Part Number: 11102CM) is provided non-sterile and is reusable. The users are required to reprocess it for initial and after each use. The subject device contacts intact mucosal membranes so it is a semi-critical device per Spaulding Classification, requiring thorough cleaning followed by sterilization or high level disinfection (HLD) after each use. For this reason, we performed validation activities for cleaning, sterilization, and HLD according to the
</td></tr>
</table>

	FDA Guidance. The reprocessing data submitted is in compliance with the following standards: • AAMI TIR 12:2010 • ISO 15883-5:2005 • AAMI TIR 30:2011 • AAMI/ANSI/ISO 11737-1:2006/ (R)2011 • ASTM E1837-96:2014
Clinical Performance Data:	Clinical testing was not required to demonstrate the substantial equivalence to the predicate devices. Non-clinical bench testing was sufficient to establish the substantial equivalence of the modifications.
Substantial Equivalence	As proven by the comparisons, the minor difference between the subject and predicate devices shown in *Technological Characteristics* section of this summary do not raise new or 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 performance data between the subject and predicate devices.
Conclusion:	The conclusions drawn from the nonclinical tests demonstrate that the subject device, the CMOS Video-Rhino-Laryngoscope System is substantially equivalent to the legally marketed predicate device.