February 2, 2018

KARL STORZ Endoscopy-America, Inc.
AnnaLisa Smullin
Regulatory Engineer
2151 E. Grand Avenue
El Segundo, CA 90245

Re: K171402
Trade/Device Name: KARL STORZ Slim Nasopharyngolaryngoscope
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: January 2, 2018
Received: January 3, 2018

Dear AnnaLisa Smullin:

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 yours,

Eric A. Mann -S

for Malvina B. 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)*
K171402

Device Name
KARL STORZ Slim Nasopharyngolaryngoscope System

Indications for Use *(Describe)*
The KARL STORZ Slim Nasopharyngolaryngoscope System is indicated to provide visualization and access of the nasal lumens and airway anatomy (including nasopharyngeal and trachea) during diagnostic and therapeutic procedures in adult and pediatric patients.

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 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:	AnnaLisa Smullin Regulatory Engineer Phone: (424) 218-8376 Fax: (424) 218-8519
Date of Preparation:	January 30, 2018
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: KARL STORZ Slim Nasopharyngolaryngoscope System Classification Name: Nasopharyngoscope (21 CFR Part 874.4760)
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(s):	Primary Predicate Device: KARL STORZ Endoscopy-America's Karl Storz Rhino-Laryngo-Broncho-Fiberscope (K981458) Secondary Predicate Device: MAHE INTL., INC's MAHE Pediatric Naso Pharyngoscope (K030857) Reference: KARL STORZ Endoscopy-America's KARL STORZ Flexible Video-Neuro-Endoscope System (K161112)
Device Description:	The KARL STORZ Slim Nasopharyngolaryngoscope (Model Number: 11161V) is a reusable, flexible videoscope used for examination of the nasal lumens and airway anatomy. The KARL STORZ Slim Nasopharyngolaryngoscope System is identical to the

	KARL STORZ Flexible Video-Neuro-Endoscope System, which is currently distributed under K161112.
Intended Use:	The KARL STORZ Slim Nasopharyngolaryngoscope System is intended for visualization purposes during ENT diagnostic and therapeutic procedures.
Indications For Use:	The KARL STORZ Slim Nasopharyngolaryngoscope System is indicated to provide visualization and access of the nasal lumens and airway anatomy (including nasopharyngeal and trachea) during diagnostic and therapeutic procedures in adult and pediatric patients.
Technological Characteristics:	**Comparison Table: Subject vs. Primary, Secondary Predicate Devices**

	Subject Device **KARL STORZ Slim Nasopharyngo-laryngoscope System**	**Primary Predicate Device, K981458** **KARL STORZ Rhino-Laryngo-Broncho-Fiberscope**	**Secondary Predicate Device, K030857** **MAHE Pediatric Nasopharyngo-scope**	**Reference Device, K161112** **KARL STORZ Flexible Video-Neuro-Endoscope System**
Physical Characteristics				
Type of Scope	Flexible	Flexible	Flexible	Flexible
Distal Tip Diameter	8.5 Fr, 2.83 mm (elliptical: 3.2 mm x 2.4 mm)	3.5 mm	2.8 mm	8.5 Fr, 2.83 mm (elliptical: 3.2 mm x 2.4 mm)
Working Shaft Length	350 mm	340 mm	300 mm	350 mm
Working Channel Diameter	1.2 mm	1.2 mm	No working channel	1.2 mm
Deflection (°)	Up: 270^0 Down: 270^0	Up: 180^0 Down: 100^0	Up: 120^0 Down: 100^0	Up: 270^0 Down: 270^0
Optical Characteristics				
Type of Imager	CMOS chip	Fiberscope	Fiberscope	CMOS chip
Field of View	90^0	85^0	95^0	90^0
Direction of View	0^0	0^0	0^0	0^0
Light Source	Internal LED	External Xenon	External LED	Internal LED
Cleaning and Sterilization Methods				
Cleaning	Manual	Manual	Manual	Manual
Sterilization	- STERRAD NX - STERRAD 100NX - STERIS SYSTEM 1E - V-PRO maX - V-PRO 60 - EtO	- EtO	Unknown	- STERRAD NX - STERRAD 100NX - STERIS SYSTEM 1E - V-PRO maX - V-PRO 60 - EtO
HLD	- CIDEX	- CIDEX	Unknown	No HLD

Non-Clinical Performance Data:	**Electrical Safety and Electromagnetic Compatibility Summary** The device design, including the electrical safety and electromagnetic compatibility (EMC), has not changed since clearance of the reference device, the KARL STORZ Flexible Video-Neuro-Endoscope System in K161112. The electrical safety and EMC data submitted in K161112 was in compliance with the following FDA recognized standards: • ANSI/AAMI ES 60601-1:2005 (Recognition Number: 19-4) • IEC 60601-1-2:2007 (Recognition Number: 19-8) As the subject device remains identical to the reference device, no additional electrical safety or EMC data is needed for the KARL STORZ Slim Nasopharyngolaryngoscope System. **Bench Testing Summary** The device design, including the performance has not changed since clearance of the reference device, the KARL STORZ Flexible Video-Neuro-Endoscope System in K161112. The performance data submitted in K161112 was in compliance with the following FDA recognized standards: • ISO 8600-1: Fourth edition: 2015-10-15 (Recognition Number: 9-110) • ISO 8600-3: First edition: 1997-07-01 (Recognition Number: 9-84) • ISO 8600-4: Second edition: 2014-03-15 (Recognition Number: 9-94) As the subject device remains identical to the reference device, no additional performance data is needed for the KARL STORZ Slim Nasopharyngolaryngoscope System. **Biocompatibility Summary** The device design, including the materials, has not changed since clearance of the reference device, the KARL STORZ Flexible Video-Neuro-Endoscope System in K161112.The Biological Evaluation data submitted in K161112 was in compliance with the following FDA recognized standards: • ISO 10993-1:2009/(R) 2013 (Recognition Number: 2-156) • ISO 10993-5:2009/ (R) 2014 (Recognition Number: 2-153) • ISO 10993-10:2010 (Recognition Number: 2-173) • ISO 10993-11:2006/ (R) 2010 (Recognition Number: 2-118) As the subject device remains identical to the reference device, no additional biological evaluation data is needed for the KARL STORZ Slim Nasopharyngolaryngoscope System.

	High Level Disinfection (HLD) Summary The reference device, the KARL STORZ Flexible Video-Neuro-Endoscope System (K161112), is a critical device per Spaulding Classification, whereas the subject device is a semi-critical device, requiring a thorough cleaning followed by sterilization or high level disinfection (HLD). In order to support an additional HLD method (CIDEX), a new HLD validation study was performed using a representative device. The HLD data submitted was in compliance with the following FDA standards. Where applicable, FDA standard recognition numbers are noted: • AAMI TIR12: 2010 • ISO 15883-5:2005 • AAMI TIR30:2011 • AAMI/ANSI/ISO 11737-1:2006/ (R)2011 (Recognition Number: 14-227) ASTM E1837-96:2014
Clinical Performance Data:	Clinical testing was not required to demonstrate substantial equivalence to the predicate devices. Non-clinical bench testing was sufficient to establish the substantial equivalence of the modifications.
Conclusion:	The conclusions drawn from the nonclinical tests demonstrate that the subject device, KARL STORZ Slim Nasopharyngolaryngoscope System performs as well as or better than the legally marketed predicate devices.