DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 2, 2017

Karl Storz Endoscopy America, Inc.
Ms. Winkie Wong
Senior Regulatory Affairs Specialist
2151 E. Grand Avenue
El Segundo, CA 90245

Re: K162410
Trade/Device Name: TIPCAM 1S 3D System
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: January 27, 2017
Received: January 31, 2017

Dear Ms. 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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162410

Device Name
TIPCAM 1S 3D System

Indications for Use *(Describe)*

TIPCAM 1S 3D: The Rigid Videoendoscope is intended to be used together with the camera control unit for use to visualize the nasal cavity and nasal pharynx during diagnostic and therapeutic procedures.

IMAGE1 S is a camera control unit (CCU) for use with camera heads or videoendoscopes for the visualization and documentation 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.

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 Senior Regulatory Affairs Specialist 424-218-8379 424-218-8519
Date of Preparation:	January 24, 2017
Device Identification:	Trade Name: TIPCAM®1S 3D System Common Name: Endoscopic Camera System Classification Name: Endoscopic Camera System
Product Code:	EOB
Regulation:	21 CFR 874.4760
Predicate Device(s):	VSII Visionsense Stereoscopic Vision System (K082667) ***The above predicate has not been subject to any recall***
Reference Device	SPIES 3D System (K150525) KARL STORZ Rigid Telescopes (K945788) ***The above reference device has not been subject to any recall***
Device Description:	The TIPCAM®1S 3D System is intended for use during diagnostic and/or surgical procedures when endoscopic video assistance is required within nasal cavity and nasal pharynx. The TIPCAM®1S 3D System is a medical device system which consists of a 4mm Tipcam®1S and a previously 510k cleared camera control unit (CCU), K150525.

Indications For Use:	TIPCAM®1S 3D: The Rigid Videoendoscope is intended to be used together with the camera control unit for use to visualize the nasal cavity and nasal pharynx during diagnostic and therapeutic procedures. IMAGE1 S is a camera control unit (CCU) for use with camera heads or videoendoscopes for the visualization and documentation of endoscopic and microscopic procedures.
Technological Characteristics:	The TIPCAM®1S 3D System includes the following components: • 4mm 3D TIPCAM®1S Videoendoscope, 0° or 30° • Image1S CCU (Image1S Connect + D3-Link) The 4mm TIPCAM®1S 3D Videoendoscope is intended to be connected to a compatible light source via a light cable as the source of illumination to allow visualization of inside the patient's anatomy and the Image1S CCU for image processing. The live image will be captured by the videoendoscope, processed by the CCU and finally projected to any connected medical grade monitors.

Non-Clinical
 	
Performance Data:
	There are no performance standards or special controls developed under Section 514 of the FD&C Act for endoscopes. However, SPIES 3D System follows the FDA recognized consensus standards and is tested according to the following standard and FDA Guidance:
	
	• Electrical Safety and EMC
	  o IEC 60601-1
	  o IEC 60601-1-2
	  o IEC 60601-2-18
	• ISO Endoscopes Standards
	  o ISO 8600-1
	  o ISO 8600-3
	  o ISO 8600-4
	  o ISO 8600-5
	  o ISO 8600-6
	• Biocompatibility testing (ISO 10993-1)
	  o Cytotoxicity
	  o Systemic toxicity
	  o Intracutaneous irritation

	○ Maximization sensitization ○ Mucosal Irritation • Software Verification and Validation Testing ○ Guidance for the Content of Premarket Submissions for Software Contained in Medical Device ○ The software is moderate level of concern • Performance Testing ○ White Balance ○ Brightness ○ Image Enhancement ○ Video Output Format ○ Zoom ○ Image Quality ○ Image Capture ○ Latency ○ Interface Control ○ 3D-2D mode • Reprocessing (Cleaning and Steam Sterilization) ○ AAMI TIR30:2011 ○ AAMI TIR12:2010 ○ ANSI/AAMI/ISO 14937:2009 ○ ANSI/AAMI ST79:2010/A4:2013 ○ ISO TS 15883-5:2005 ○ Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.
Clinical Performance Data:	No clinical information is required for this submission
Substantial Equivalence:	The TIPCAM®1S 3D System has the same intended use and indication or use, similar principles of operation and technological characteristics as the cleared Visionsense's VSII Visionsense Stereoscopic Vision System (K082667). Below is a list of similarities between the TIPCAM®1S 3D System and its predicate devices: • All systems use a 4mm diameter rigid endoscope with a length of 175mm and direction of view of 0° or 30°.

	• All systems include a CCU for image processing. • All systems include the same basic functional feature, such as zoom, image enhancement, image capture, video recording and switch between 2D and 3D images. The following technological differences exist between the subject and predicate devices: • The subject device system includes a 4mm rigid videoendoscope while the predicate device system includes a 4mm and 5.5mm rigid endoscope to be attached to a camera head. • Different resolution (HD vs. SD) • LED light source compatibility
Conclusion:	The TIPCAM®1S 3D System is substantially equivalent to its predicate devices. The non-clinical testing demonstrates that the device is as safe and effective as the legally marketed devices.