



March 16, 2017

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

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

Re: K162880
Trade/Device Name: TIPCAM 1S 3D System
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG
Dated: February 10, 2017
Received: February 14, 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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K162880

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 in the visualization of ventricles and structures within the brain during neurological surgical procedures.

IMAGE 1S is a camera control unit (CCU) for use with camera heads of 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.

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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:	October 12 th , 2016
Device Identification:	Trade Name: TIPCAM® 1S 3D System Common Name: Endoscopic Camera System Classification Name: Endoscopic Camera System
Product Code:	GWG
Regulation:	21 CFR 882.1480
Predicate Device(s):	VS3 Stereoscopic High Definition Vision System (K131434)
Reference Device	SPIES 3D System (K150525)
Device Description:	The TIPCAM® 1S 3D System is intended for use during diagnostic and/or surgical procedures when endoscopic video assistance is required for visualization within ventricles and structures within the brain during neurological surgical procedures. 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 in the

	visualization of ventricles and structures within the brain during neurological surgical 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

	- o Maximization sensitization - o Mucosal Irritation • Software Verification and Validation Testing - o Guidance for the Content of Premarket Submissions for Software Contained in Medical Device - o The software is moderate level of concern • Performance Testing - o White Balance - o Brightness - o Image Enhancement - o Video Output Format - o Zoom - o Image Quality - o Image Capture - o Latency - o Interface Control - o 3D-2D mode • Reprocessing (Cleaning and Steam Sterilization) - o AAMI TIR30:2011 - o AAMI TIR12:2010 - o ANSI/AAMI/ISO 14937:2009 - o ANSI/AAMI ST79:2010/A4:2013 - o 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 also has the same intended use, similar indications, principles of operation and technological characteristics as the cleared Visionsense's VS3 Stereoscopic High Definition Vision System (K131434). Standard Performance Parameters Performance:

		<table> <tr> <th></th><th>TIPCAM®1S 3D System Subject Device</th><th>VS3 Stereoscopic High Definition Vision System <u>K131434</u> Primary Predicate</th></tr> <tr> <td>Depth of Field</td><td>7 – 44 mm</td><td>7 – 30mm and 15 – 60 mm</td></tr> <tr> <td>Direction of View</td><td>0° & 30°</td><td>0 - 70°</td></tr> <tr> <td>Field of View</td><td>80°</td><td>70 - 95°</td></tr> <tr> <td>Working Length</td><td>175 mm</td><td>175 – 300 mm</td></tr> <tr> <td>Diameters</td><td>4mm</td><td>4mm & 5.5mm</td></tr> <tr> <td>Light Source Compatibility</td><td>Xenon & LED</td><td>Xenon</td></tr> <tr> <td>Zoom</td><td>Yes</td><td>Yes</td></tr> <tr> <td>Image Enhancement</td><td>Yes</td><td>Yes</td></tr> <tr> <td>Image Capture</td><td>Yes</td><td>Yes</td></tr> <tr> <td>Video Recording</td><td>Yes</td><td>Yes</td></tr> <tr> <td>Switch Between 2D and 3D Image</td><td>Yes</td><td>Yes</td></tr> <tr> <td>Scope Diameters</td><td>4 mm</td><td>4mm & 5.5mm</td></tr> <tr> <td>Resolution</td><td>HD</td><td>SD</td></tr> </table>		TIPCAM®1S 3D System Subject Device	VS3 Stereoscopic High Definition Vision System <u>K131434</u> Primary Predicate	Depth of Field	7 – 44 mm	7 – 30mm and 15 – 60 mm	Direction of View	0° & 30°	0 - 70°	Field of View	80°	70 - 95°	Working Length	175 mm	175 – 300 mm	Diameters	4mm	4mm & 5.5mm	Light Source Compatibility	Xenon & LED	Xenon	Zoom	Yes	Yes	Image Enhancement	Yes	Yes	Image Capture	Yes	Yes	Video Recording	Yes	Yes	Switch Between 2D and 3D Image	Yes	Yes	Scope Diameters	4 mm	4mm & 5.5mm	Resolution	HD	SD
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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.																																											