November 20, 2020

Karl Storz Endoscopy-America, Inc.
Mario Trujillo
Associate Regulatory Affairs Specialist
2151 E. Grand Avenue
El Segundo, CA 90245

Re: K201526
Trade/Device Name: TIPCAM®1 Rubina Video Endoscope System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: GCJ, FGB, HET
Dated: October 21, 2020
Received: October 23, 2020

Dear Mario Trujillo:

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,

Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201526

Device Name
TIPCAM®1 Rubina Video Endoscope System

Indications for Use *(Describe)*
The TIPCAM®1 Rubina Video Endoscope System is intended to be used together with the camera control unit during diagnostic and/or surgical procedures when endoscopic video assistance is required. For use in all endoscopy and endoscopic surgery within the peritoneal and thoracic cavity, including gynecological and urological anatomy.

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 KARL STORZ Endoscopy-America's knowledge.

Applicant:	KARL STORZ Endoscopy-America, Inc. 2151 E. Grand Avenue El Segundo, CA 90245
Contact:	Mario Trujillo Associate Regulatory Affairs Specialist Tel.: (424) 218-8481 Email: Mario.Trujillo@karlstorz.com
Date of Preparation:	November 19, 2020
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: TIPCAM®1 Rubina Video Endoscope System Regulation Name: Endoscope and Accessories
Regulatory Class:	2
Product Code:	GCJ, FGB, HET
Regulation Number:	21 CFR 876.1500
Predicate Device(s):	SPIES 3D System (K150525) This predicate device has not been subject to a design-related recall.
Device Description:	The TIPCAM®1 Rubina video endoscope is an integrated unit that includes a camera and an endoscope. The endoscope receives the illumination light from the light source by the light guide connector connected to the light source device. The illumination light is transferred to the distal end through the optical fiber bundle inside of the endoscope and illuminates the inside of the patient body through the illumination lens at the distal end. The endoscope receives the reflected light from the inner lumen of a patient by the objective lens at the distal end. The built-in dual CMOS sensors convert the light to an electrical signal, and the signal is sent to the camera control unit (Image1 S Connect II + 4U-Link) via the attached cable for processing and display.
Intended Use:	TIPCAM®1 Rubina videoscopes and corresponding accessories (camera control unit, light sources, monitor) are used for endoscopic imaging of the surgical field during diagnostic and/or surgical procedures in the abdominal and thoracic cavity. TIPCAM®1 Rubina videoscopes are designed for short-term use in surgically invasive procedures

Indications For Use:	The TIPCAM®1 Rubina Video Endoscope System is intended to be used together with the camera control unit during diagnostic and/or surgical procedures when endoscopic video assistance is required. For use in all endoscopy and endoscopic surgery within the peritoneal and thoracic cavity, including gynecological and urological anatomy.
Technological Characteristics:	The predicate and subject devices are both camera systems that are used for observation purposes in general endoscopic surgery within the thoracic and peritoneal cavity, including gynecological and urological anatomy. There are some minor differences in the technological characteristics. These differences are: • The subject device has two image viewing features: A 2D auto-leveling (autorotation) mode which allows the user to maintain fixed horizon while rotating the endoscope and a 2D Auto-switch mode that automatically switches the image from 3D mode to 2D Auto-leveling mode when the scope is rotated outside the 3D viewing range to prevent the user from losing the perspective of the image. • The subject device is also available in a 30° direction of view model in addition to the 0° model. • The total length of the subject endoscope is 5mm longer than the predicate These differences do not raise different questions of safety and effectiveness and can be evaluated through performance testing.
Non-Clinical Performance Data:	The TIPCAM®1 Rubina System was tested for electrical/mechanical/thermal safety and EMC according to the following standards: • IEC 60601-1 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) • IEC 60601-1-2:2014 (4th Edition) • IEC 60601-2-18:2009 • IEC 62471:2009 The following additional bench testing for performance verification and validation purposes was performed: • Photobiological Safety per IEC 62471:2006 • Color Reproduction and Color Contrast Enhancement • Distortion • Depth of Field • Detection Linearity • Illumination Detection Uniformity • Signal-to-Noise Ratio (SNR) & Sensitivity • Latency • Spatial Resolution • Dynamic Range • Direction of View per ISO 8600-3:2019

	• Field of View per ISO 8600-3:2019 • System Horizontal Parallax The subject device software was validated per the FDA guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" as a moderate level of concern. The subject device materials and manufacturing are identical to that of the predicate, therefore, biocompatibility testing was leveraged from K150525 to support the biocompatibility of the subject device. Cleaning and sterilization validation of the subject device was leveraged from the predicate device K150525, as the subject device is substantially similar in specifications to that of the predicate, and the sterilization process remains identical to the predicate. The bench testing noted above confirmed that the TIPCAM®1 Rubina system has met all its design specification and is as safe and effective as the predicate device, SPIES 3D System.
Clinical Performance Data:	Clinical testing was not required to demonstrate the substantial equivalence to the predicate device. Non-clinical bench testing was sufficient to assess safety and effectiveness and to establish the substantial equivalence of the modifications.
Conclusion:	The subject device has the same intended use as the predicate. The technological differences between the subject and predicate do not raise different questions of safety and effectiveness. The conclusions drawn from the non-clinical performance data demonstrated that the subject device is as safe as and as effective as the predicate device. Therefore, the subject device is substantially equivalent to the predicate.