November 10, 2022

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

Re: K222504
Trade/Device Name: H1 Camera Head
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 18, 2022
Received: August 18, 2022

Dear Winkie 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. 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,

Jianting Wang -S

Jianting Wang
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K222504

Device Name
H1 Camera Head

Indications for Use *(Describe)*
The KARL STORZ H1 camera head, in combination with an appropriately indicated camera control unit (CCU), light source, and monitor, and with an appropriately indicated endoscope, fiberscope, or microscope, is used for real-time visualization in diagnostic and surgical 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.

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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 and the FDA guidance document titled "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" issued on July 28, 2014. All data included in this document is accurate and complete to the best of KARL STORZ SE & Co. KG knowledge.

Submitter:	KARL STORZ SE & Co. KG Dr.-Karl-Storz-Straße 34 78532 Tuttlingen, Germany
Contact:	Mario Trujillo Regulatory Affairs Specialist Tel.: (424) 218-8481 Email: Mario.Trujillo@karlstorz.com
Date of Preparation:	August 5, 2022
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: H1 Camera Head Classification Name: Laparoscope, General & Plastic Surgery (21 CFR Part 876.1500);
Regulatory Class:	2
Product Code:	GCJ
Guidance Document:	Not Applicable
Predicate Device:	Predicate device: KSEA CMOS Camera System (C-cam) (K143640).
Device Description:	The camera head consists of an anodized aluminum, stainless steel enclosure containing a CMOS (Complementary metal-oxide-semiconductor) NTSC image sensor that converts light into electrons, the transistors in each pixel then amplify and move the charge using the more traditional wires forming conventional output signals. The camera head is intended to be attached to the proximal end of the endoscopes and is connected via cable to the compatible CCU for power and operational functions. The camera head is designed to be compatible for use with all standard KARL STORZ Endoscopes, Fiberscopes and Microscope for endoscopic observation in general endoscopic procedures.
Indications For Use:	The KARL STORZ H1 camera head, in combination with an appropriately indicated camera control unit (CCU), light source, and monitor, and with an appropriately indicated endoscope, fiberscope, or microscope, is used for real-time visualization in diagnostic and surgical procedures.

<table>
<tr><td>Technological Characteristics:</td><td>Comparison Table: Subject vs. Predicate and Reference Devices
<table>
<tr><th></th><th>Subject Device

H1 Camera Head</th><th>Predicate Device
K143650
KSEA CMOS
Camera System (C-CAM)</th></tr>
<tr><td>(B1) Sensor Chip Type</td><td>CMOS</td><td>Same as subject</td></tr>
<tr><td>(B2) Aspect Ratio</td><td>4:3</td><td>Same as subject device</td></tr>
<tr><td>(B3) Pixel Count</td><td>1280 x 960 pixels</td><td>168 x 576 pixels</td></tr>
<tr><td>(B4) Sensor Resolution</td><td>1280 x 960</td><td>640 x 480</td></tr>
<tr><td>(B5) Brightness control</td><td>Yes</td><td>Same as subject device</td></tr>
<tr><td>(B6) White Balance</td><td>Yes</td><td>Same as subject device</td></tr>
<tr><td>(B7) Focal Length</td><td>19 mm</td><td>20mm</td></tr>
<tr><td>(B8) Compatible CCU</td><td>C-HUB
C-MAC III
Telepack +</td><td>C-HUB
C-MAC III</td></tr>
</table></td></tr>
<tr><td>Non-Clinical Performance Data:</td><td>The subject device follows the FDA recognized consensus standards and is tested according to the following standards and FDA Guidance:
Electrical Safety and EMC
IEC 60601-1
IEC 60601-1-2
IEC 60601-2-18
IEC 62471
ISO 10993
ISO 8600
Performance Testing
Color Reproduction and Color Contrast Enhancement
Illumination Detection Uniformity
Depth of field
Spatial Resolution
Dynamic Range & Detection Linearity
Distortion
Latency
Signal-to-Noise Ratio (SNR) & Sensitivity
Field of View
Additional bench testing was performed to ensure the device met its design specifications. The bench testing performed verified and validated that the H1 Camera Head has met all its design specification and is substantially equivalent to its predicate devices.</td></tr>
<tr><td>Clinical Performance Data:</td><td>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.</td></tr>
<tr><td>Conclusion:</td><td>The conclusions drawn from the nonclinical tests demonstrate that the subject devices, the H1 Camera Head performs as well as the predicate device.</td></tr>
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