February 12, 2026

Karl Storz SE & CO. KG
Winkie Wong
Director Regulatory Affairs
Dr.-Karl-Storz-Straße 34
Tuttlingen, Baden-Wurttemberg 78532
Germany

Re: K253972
Trade/Device Name: KARL STROZ IMAGE1(TC400US) ; X-to-4U Adapter (TC040)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FET, OWN
Dated: December 11, 2025
Received: December 11, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2026.02.12 15:06:17 -05'00'

Tanisha Hithe, Ph.D.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253972

Please provide the device trade name(s).

KARL STORZ IMAGE1 (TC400US);
X-to-4U Adapter (TC040)

Please provide your Indications for Use below.

The IMAGE1, a camera control unit (CCU), when used with compatible camera heads or videoendoscopes and ancillary equipment, is intended to provide real-time visible (VIS) and near-infrared (NIR) fluorescent imaging and documentation of endoscopic and microscopic procedures in adults and pediatrics.

The X-to-4U Adapter, as ancillary equipment, is intended to connect compatible camera heads or videoendoscopes to the IMAGE1 CCU.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary: K253972

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:	Winkie Wong Director of Regulatory Affairs Phone: (424) 218-8618 Email: winkie.wong@karlstorz.com
Date of Preparation:	December 11, 2025
Type of 510(k) Submission:	Traditional
Device Identification:	KARL STORZ IMAGE1 (TC400US); X-to-4U Adapter (TC040)
Regulatory Class:	II
Product Code:	FET: Endoscopic Video Imaging System/Component OWN: Confocal Optical Imaging
Classification Name:	21 CFR 876.1500 (Endoscope and Accessories)
Device Panel:	Gastroenterology & Urology
Predicate Device(s):	KARL STORZ ICG Imaging System, Image1S Camera Control Unit (K233333) The predicate has not been subjected to a design related recall.
Device Description:	The IMAGE1 CCU is the next generation KARL STORZ CCU designed for use by medical professionals in an OR setting to provide real-time visible (VIS) and near-infrared (NIR) fluorescent imaging and documentation of endoscopic and microscopic procedures. The IMAGE1 CCU performs image processing functions including color processing, color filtration, and image enhancement and is compatible with many KARL STORZ C-Line and 4U connector type camera heads. Software extensions and applications can be purchased by the user and downloaded onto the CCU to provide additional features beyond those of the default set. For compatibility with the X-link connector type camera head and videoendoscopes, IMAGE1 requires the X-to-4U adapter. The X-to-4U Adapter provides an electromechanical interface between the X-Line family of Flexible Videoendoscopes and the 4U-Receptacle of the IMAGE1 CCU.
Indications for Use:	IMAGE1, a camera control unit (CCU), when used with compatible camera heads or videoendoscopes and ancillary equipment, is intended to provide real-time visible (VIS) and near-infrared (NIR) fluorescent imaging and documentation of

<table>
<tr><td></td><td>endoscopic and microscopic procedures in adults and pediatrics.

The X-to-4U Adapter, as ancillary equipment, is intended to connect compatible camera heads or videoendoscopes to the IMAGE1 CCU.</td></tr>
<tr><td>Physical and Technological Characteristics:</td><td>
<table>
<tr><th></th><th>Subject Device
KARL STORZ IMAGE1 & Adapter</th><th>Predicate Device K233333
KARL STORZ Image1S CCU</th></tr>
<tr><td>Resolution</td><td>Up to 4K-UHD</td><td>Same as the subject</td></tr>
<tr><td>Brightness control</td><td>Yes</td><td>Same as the subject</td></tr>
<tr><td>Enhancement control</td><td>Yes (S-Clara, S-Chroma, SPECTRA A/B)</td><td>Yes (S-Clara, S-Chroma)</td></tr>
<tr><td>Light Source Control</td><td>Automatic</td><td>Same as the subject</td></tr>
<tr><td>Shutter Control</td><td>Automatic</td><td>Same as the subject</td></tr>
<tr><td>Image/Video Capture</td><td>Yes</td><td>Same as the subject</td></tr>
<tr><td>Zoom</td><td>1x, 1.2x, 1.5x, 1.75x, 2x, 2.25x, 2.5x</td><td>Same as the subject</td></tr>
<tr><td>Adaptive Zoom</td><td>Yes</td><td>Same as the subject</td></tr>
<tr><td>Digital Outputs</td><td>12G/3G-SDI,
DisplayPort,
DVI-D</td><td>HDMIx2, 3/12G-SDI x1,
SDVoE via 10Gig Ethernet</td></tr>
<tr><td>Communication Interface</td><td>KS HIVE (Ethernet)</td><td>KS HIVE (Ethernet), SCB</td></tr>
<tr><td>Peripheral</td><td>Mouse, keyboard, monitor</td><td>Same as the subject</td></tr>
<tr><td>Remote Service</td><td>Yes</td><td>Same as the subject</td></tr>
<tr><td>SW application hosting</td><td>Yes</td><td>No</td></tr>
<tr><td>Software Revision</td><td>1.0</td><td>4.5</td></tr>
</table>
</td></tr>
<tr><td>Non-Clinical Performance Data:</td><td>The following non-clinical performance data were provided in support of the determination for substantial equivalence.

<u>Electrical Safety and Electromagnetic Compatibility (EMC)</u>

The system complies with the following standards:
• IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION / ANSI/AAMI ES60601-1:2005/A2:2021
• IEC 60601-1-2:2014 [Including AMD 1:2021]
• IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION
• IEC 60601-2-18: Edition 3.0 2009-08
• ANSI/AAMI IEC 62366-1:2015 + AMD1:2020 (Consolidated Text)

<u>Reprocessing Validation</u>

The reprocessing data submitted complies with the following standards:
• ISO 17664-2: Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices

<u>Bench Performance Testing</u>

The bench performance data was conducted to establish substantial equivalence between the subject device and the predicate device for comparison and characterization of white light and ICG optical performance characteristics.</td></tr>
</table>

	The following standard was used to establish test methodology in field of view bench tests: • ISO 8600-3:2019 Endoscopes — Medical endoscopes and endotherapy devices - Part 3: Determination of field of view and direction of view of endoscopes with optics The bench testing conducted on the subject devices includes the following: Optical performance testing (White Light) • Color Accuracy and CCER • Distortion • Field of View • Instantaneous Dynamic Range and Detection Linearity • Spatial Frequency Response • White Light Linearity & Dynamic Range • 2D Autolevel Drift and Noise • 2D Autolevel Settling Time • 3D System Zero Parallax • On-Axis and Off-Axis Resolution • Illumination Detection Uniformity • Depth of Field • Signal to Noise Ratio & Sensitivity • Latency • SPECTRA A and B Color Accuracy and Color Contrast Enhancement Ratio • SPECTRA A and B SNR and Sensitivity • SPECTRA A and B Instantaneous Dynamic Range • SPECTRA A and B Dynamic Range • SPECTRA A and B Illumination Detection Uniformity Optical performance testing (ICG Imaging) • ICG Coregistration • Minimum Detectable Concentration of ICG • ICG Fluorescence Minimum Sensitivity and ICG SNR and Noise • ICG Penetration Depth • ICG Spatial Resolution • ICG Color Reproducibility • ICG Linearity and Dynamic Range • ICG Depth of Field • ICG Illumination Detection Uniformity CPU Resource Testing – SW application hosting <u>Software Life Cycle Processes</u> The system complies with the following standard: • IEC 62304:2006 + A1:2016 – Medical device software – Software life cycle processes <u>Software Verification & Validation</u> The system complies with the following guidance: • Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

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 to the predicate device.
Conclusion:	The conclusions drawn from the non-clinical performance data demonstrate that the subject device is as safe as and as effective as the predicate device. As such, we conclude that the substantial equivalence of the subject and the predicate device has been met, and the differences between the subject and the predicate device do not raise new questions of safety and effectiveness.