October 22, 2024

KARL STORZ Endoscopy America, Inc
Mario Trujillo
Regulatory Affairs Specialist
2151 E. Grand Avenue
El Segundo, California 90245

Re: K240506
Trade/Device Name: KARL STORZ Holders
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OCV, GCJ
Dated: September 23, 2024
Received: September 23, 2024

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 (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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.10.22 13:32:12 -04'00'

Long Chen, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240506

Device Name

KARL STORZ Holders

Indications for Use *(Describe)*

The KARL STORZ Holders are manually operated surgical devices intended to hold endoscopes (such as arthroscopes, etc) and accessories during general and neurologic diagnostic and therapeutic 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
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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 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.

<table>
<tr><td>Submitter:</td><td>KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen, Germany</td></tr>
<tr><td>Contact:</td><td>Mario Trujillo
Regulatory Affairs Specialist
Tel.: (424) 218-8481
Email : Mario.Trujillo@karlstorz.com</td></tr>
<tr><td>Date of Preparation:</td><td>October 21, 2024</td></tr>
<tr><td>Device Identification:</td><td>Trade Name: KARL STORZ Holders
Common Name: Endoscope Holder
Classification Name: Endoscope Holder (21 CFR Part 876.1500);</td></tr>
<tr><td>Regulatory Class:</td><td>2</td></tr>
<tr><td>Product Code:</td><td>Primary: OCV
Secondary: GCJ</td></tr>
<tr><td>Predicate Devices:</td><td>Walterlorenz Surgical Assist Arm Scope Holder (K190576)</td></tr>
<tr><td>Device Description:</td><td>The KARL STORZ Holder is a manually operated surgical instrument intended to hold scopes (such as endoscopes, arthroscopes, etc) in a desired position during diagnostic, therapeutic, and surgical procedures (including neurologic procedures). The holder is manufactured from Stainless Steel and functions by the user manually tightening or loosening a knob, which opens and closes around a surgical scope. The device is intended to attach to the several KARL STORZ holding systems, which are a Class 1, table-mounted, mechanical and electromechanical holding arms that have many general surgical functions in addition to scope holding; it can also be used for instrument holding, retraction, and positioning.</td></tr>
<tr><td>Indications For Use:</td><td>The KARL STORZ Holders are manually operated surgical devices intended to hold endoscopes (such as arthroscopes, etc) and accessories during general and neurologic diagnostic and therapeutic procedures.</td></tr>
<tr><td>Substantial equivalence</td><td>The similarities of the subject device to the predicate devices are as follows:
<table>
<tr><th></th><th>Subject Device – K240506
KARL STORZ Holders</th><th>Predicate Device - K190576
WalterLorenz Surgical Assist Arm Scope Holder</th></tr>
<tr><td>Indications for Use</td><td>The KARL STORZ Holders are manually operated surgical devices intended to hold endoscopes (such as arthroscopes, etc) and accessories during general and neurologic diagnostic and therapeutic procedures.</td><td>The WalterLorenz Surgical Assist Arm Scope Holder is a manually operated surgical device intended to hold scopes (such as endoscopes, arthroscopes, etc) and accessories during general diagnostic and therapeutic procedures. The device is also intended to hold endoscopes during diagnostic and therapeutic neurologic procedures.</td></tr>
<tr><td>Material of construction</td><td>Stainless Steel</td><td>Stainless Steel</td></tr>
<tr><td>Devices to be held</td><td>Endoscopes and other surgical instruments</td><td>Endoscopes and other surgical instruments</td></tr>
<tr><td>Mode of operation</td><td>Manual</td><td>Same as subject device</td></tr>
<tr><td>Range of scope diameters</td><td>Up to 23mm</td><td>Up to 10mm</td></tr>
<tr><td>Scratch Protection pads</td><td>Yes</td><td>No</td></tr>
<tr><td>Maximum loading weight</td><td>3kg</td><td>Information not available</td></tr>
<tr><td>Cleaning</td><td>Manual cleaning</td><td>Manual cleaning</td></tr>
<tr><td>Sterilization/ Reprocessing Methods</td><td>Steam Sterilization</td><td>Steam Sterilization</td></tr>
</table></td></tr>
<tr><td>Non-Clinical Performance Data:</td><td>The following non-clinical testing were performed on the subject device:
1) Holding Performance testing
2) Direction of view/Image stability testing</td></tr>
<tr><td>Conclusion:</td><td>The conclusions drawn from the nonclinical tests demonstrate that the subject device, the KARL STORZ Holders, performs as safely and effectively as devices that are currently marketed for the same intended use.</td></tr>
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