May 1, 2024

Karl Storz SE & Co. Kg
Alita McElroy
Senior Specialist, Regulatory Affairs
Dr.-Karl-Storz-Straße 34
Baden-Wurttemberg
Tuttlingen, 78532
GERMANY

Re: K232370
Trade/Device Name: Percutaneous Nephroscope System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGA
Received: March 29, 2024

Dear Alita McElroy:

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.

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,

Mark J. Antonino -S

Mark J, Antonino, M.S.
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.

Submission Number *(if known)*

K232370

Device Name

Percutaneous Nephroscope System

Indications for Use *(Describe)*

Percutaneous System for adults
The KARL STORZ Percutaneous System is intended to be used during percutaneous removal of kidney stones in adults.

Percutaneous System for adults and pediatrics
The KARL STORZ Percutaneous System is intended to be used during percutaneous removal of kidney stones in adults and pediatrics >1month of age.

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 KSEA's knowledge.

Submitter:	KARL STORZ Endoscopy-America, Inc. 2151 E. Grand Avenue EI Segundo, CA 90245
Contact:	Alita McElroy Senior Regulatory Affairs Specialist Phone: (424) 218-8376 Email: Alita.McElroy@karlstorz.com
Date of Preparation:	August 7, 2023
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: Percutaneous Nephroscope System Classification Name: Kit, Nephroscope (21 CFR 876.1500)
Regulatory Class:	II
Product Code:	FGA
Classification Panel:	Gastroenterology/Urology
Predicate Device(s):	KARL STORZ Adult and Pediatric Nephroscope (K940594)
Device Description:	The Percutaneous Nephroscope System consists of the following: - Minimally Invasive Percutaneous Nephrolithopaxy (MIP) Nephroscopes - HOPKINS Telescopes for Percutaneous Nephrolithotomy (PCNL) - Operating Sheaths - One-Step Dilators - Telescope Bougie Set - Hollow Obturator and Fascial Dilator - Applicators - Biopsy and Grasping forceps - Scissors - Knives - Instrument Port

<table>
<tr><td></td><td>

- Insertion Aid
- Laser Hand Instrument
- Suction tube
- Adaptors
- Luer-Lock tube connectors

The dilators are used to dilate the access tract to the punctured kidney. The operating sheath is inserted in the pre-expanded tract and facilitates insertion of the MIP Nephroscopes or the HOPKINS Telescopes for PCNL. The desired instrument (e.g forceps, scissors, knives) for stone removal is introduced through the working channel of the HOPKINS Telescopes or into the MIP Nephroscopes via an instrument port. A suction tube can alternatively be used via the working channel of the MIP Nephroscopes to suction stone fragments. The laser hand instrument or an insertion aid is used to guide a laser fiber for stone fragmentation. Applicators are used to seal the access tract of the kidney.
</td></tr>
<tr><td>Intended Use and Indications for Use:</td><td>Percutaneous System for adults
The KARL STORZ Percutaneous System is intended to be used during percutaneous removal of kidney stones in adults.

Percutaneous System for adults and pediatrics
The KARL STORZ Percutaneous System is intended to be used during percutaneous removal of kidney stones in adults and pediatrics >1month of age.</td></tr>
<tr><td>Technological Characteristics.</td><td>
<table>
<tr><th></th><th>Percutaneous Nephroscope System

Subject Device</th><th>KARL STORZ Adult and Pediatric Nephroscope System
Predicate Device K940594</th></tr>
<tr><td>Components</td><td>MIP Nephroscopes
HOPKINS Telescopes
Operating Sheaths
Hollow Obturator Fascial Dilator
Telescope Bougie Set
One-Step Dilators
Grasping Forceps
Biopsy Forceps
Knives
Scissors</td><td>Nephroscopes with instrument channel
Telescopes without instrument channel and luer-lock connector tubes
Operating Sheaths
Dilation Set
Hollow Obturator Fascial Dilator
Grasping Forceps
Biopsy Forceps</td></tr>
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	Applicator Insertion Aid Laser Hand Instrument Suction tube Adaptors Luer-lock connector tubes	Knives Scissors Triradiate Graspers Kidney Stone crushers
Scope Type	Rigid, rod lens and fiber-optic	Rigid, rod lens
Scope Outer Diameter	3.3mm- 7.5mm	2.7mm- 6mm, 5 x 3mm
Scope Working Length	20cm- 26cm	10cm -30cm
Instrument channel width	0.8- 5mm	2.5mm- 4.7mm
Scope Direction of View	6°, 7.5°, 10°	0°
Scope Field of View	72°- 102°	65°- 118°
Depth of Field	4mm- 200mm 5.5mm- 200mm 6.6mm- 200mm 7.6mm- 200mm 8.0mm- 200mm	4mm- 200mm 5.1mm- 200mm
Irrigation and Suction	Continuous Flow	Continuous Flow
Vacuum-Cleaner effect	Yes	No
Operating Sheath dimensions	Diameter: 11/12 Fr- 26 Fr Working Length: 7.5cm- 22.8cm	Diameter: 17 Fr- 33 Fr Working Length: 10cm -20cm
Telescope Bougie/Dilation Set	Dilation Cannula Diameter: 3.8mm	Dilation/Puncture Cannula Diameter: 4mm

	dimensions	Working length: 12.6cm Guide wire diameter: 1.9mm, ball end: 3mm working length: 57cm Dilators Diameter: 9, 12, 15, 18, 21, 24, 27, 30Fr Working Length: 27-29cm	Working Length: 15cm Guide wire diameter: 1.9mm, ball end: 2.9mm working length: 57.5cm Dilators Diameter: 9, 12, 15, 18, 21, 24, 27, 30Fr Working Length: 10-18cm
	Hollow Obturator and Fascial Dilator dimensions	Diameter: 6.7mm- 8mm Working Length: 20.8cm - 27cm	Diameter: 5mm- 7mm Working Length: 10cm-15cm
	Biopsy Forceps dimensions	Diameter: 1.67mm - 3.5mm Working Length: 39cm - 40cm	Diameter: 1.67- 3.5mm Working Length: 12cm-31cm
	Grasping Forceps dimensions	Diameter: 1.67mm - 3.5mm Working Length: 40cm	Diameter: 1.67mm- 3.5mm Working Length: 12cm-31cm
	Scissors dimensions	Diameter: 1.7mm - 3.5mm Working Length: 40cm	Diameter: not included in 510k Working Length: 31cm
	Knives dimensions	Diameter: 3.5mm Working Length: 38cm	Diameter: not included in 510k Working Length: 31cm
Non-Clinical Performance Data:	There are no performance standards or special controls developed under Section 514 of the FD&C Act for endoscopes. However, the Percutaneous Nephroscope System is tested in accordance with the following standards and FDA Guidance:		

	ISO Endoscopic Standards • ISO 8600-1 • ISO 8600-3 • ISO 8600-5 • ISO 8600-6 **Biocompatibility Summary** • Cytotoxicity (ISO 10993-5:2009) • Acute Systemic Toxicity (ISO 10993-11:2017) • Irritation (ISO 10993-23:2021) • Maximization Sensitization (ISO 10993-10:2021) **Thermal Safety** • IEC 60601-2-18:2009 (3RD Edition) **Reprocessing (Cleaning and Sterilization)** • AAMI TIR12: 2010 • AAMI TIR30: 2011 • ANSI/AAMI ST77:2013/(R)2018 • ANSI/AAMI ST79:2017 • AAMI/ISO 14937:2009 • DIN EN ISO 11138-1:2017 • ANSI/AAMI/ISO 17655-1:2006/(R)2013 • Reprocessing Medical Device in Health Care Settings: Validation Methods and Labeling Comparative bench testing between the subject and predicate DEVICES demonstrated that the endoscopes in the Percutaneous Nephroscope System meets all its design specification and is substantially equivalent to its predicate device. Additional bench testing was performed for the subject device instruments (forceps and scissors) to ensure the device met its design specifications and is substantially equivalent to the predicate.
Clinical Performance Data:	Published literature was provided to support the safety and effectiveness of the Percutaneous Nephroscope system for use in pediatrics >1month of age.
Conclusion:	The conclusions drawn from the nonclinical test demonstrate that the subject device is as safe and effective as the predicate device.