June 4, 2026

TroCare, LLC
% Kenneth Kleinhenz
Regulatory Affairs Consultant
QSR Consulting
4141 Elm Rd.
Hudson, Michigan 49247

Re: K253994
Trade/Device Name: TroKit Laparoscope Lens Wiper
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: December 12, 2025
Received: December 12, 2025

Dear Kenneth Kleinhenz:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

JAMES H. JANG -S

Digitally signed by JAMES H. JANG -S
Date: 2026.06.04 16:46:52 -04'00'

For
Colin Kejing Chen
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253994

Device Name
TroKit Laparoscope Lens Wiper

Indications for Use *(Describe)*
The TroKit Laparoscope Lens Wiper is a laparoscopic accessory lens cleaning device intended to mount onto a trocar and maintain the intra-operative view of the surgical site during minimally invasive surgery by physically shielding and wiping the laparoscope lens from debris, grease, blood, and bodily fluids.

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.

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"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."

Date Prepared: 03 June 2026

I. SUBMITTER

Manufacturer Name: TroCare, LLC
1000 Louisiana Street
Fifty-Third Floor
Houston, TX 77002

Mfg. Establishment Registration Number: No existing devices placed on the market commercially. Company to register with FDA within 30 days of first commercialization.

Official Contact: Kenneth K. Kleinhenz
Regulatory Affairs
Telephone (619) 244-9573
Kleinhenz64@gmail.com

II. DEVICE

Name of Device:	TroCare TroKit Laparoscope Lens Wiper
Common or Usual Name: Classification	Laparoscope, General and Plastic Surgery Endoscope and Accessories (21 CFR 876.1500)
Name Regulatory Class:	II
Product Code:	GCJ
510(K) Identification:	To be assigned

III. PREDICATE DEVICE

TroCare TroKit Laparoscope Lens Wiper, K241796

IV. DEVICE DESCRIPTION

Design Characteristics

The TroKit Laparoscope Lens Wiper is a sterile, single-use and disposable laparoscopic accessory device that is provided in various sizes and is designed to fit onto the distal end of a trocar and with its lens wiper serves to clean the camera lens from blood, tissue, fog, grease, and other surgical debris. The lens wiper itself is a mechanical device within the TroKit that employs a thermoplastic elastomer squeegee. The TroKit is translucent. When the laparoscopic camera is inserted through the trocar into the TroKit its insertion opens the mechanical jaws that house the lens wiper. The wiping is done automatically upon the passage of the laparoscopic camera through the TroKit jaws. The TroKit can be activated and used multiple times during surgery. One device is adequate for one surgery.

Material Composition
The TroCare TroKit Laparoscope Lens Wiper device is fabricated with biocompatible polymers, stainless steel, and titanium alloy.

V. INDICATIONS FOR USE

The TroKit Laparoscope Lens Wiper is a laparoscopic accessory lens cleaning device intended to mount onto a trocar and maintain the intra-operative view of the surgical site during minimally invasive surgery by physically shielding and wiping the laparoscope lens from debris, grease, blood, and bodily fluids.
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VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The TroKit Laparoscope Lens Wiper shares indications for use and design principles with the following predicate device: TroCare TroKit Laparoscope Lens Wiper; a Class II medical device that was cleared for marketing in the United States under K241796.

Indications For Use
The TroKit Laparoscope Lens Wiper and the TroCare TroKit Laparoscope Lens Wiper (K241796) predicate device are substantially equivalent with respect to their indications for use as they are both indicated for the same intended use of protecting laparoscope devices during intra-abdominal procedures and/or wiping the laparoscope lens intraoperatively to avoid repeated egress and ingress into the surgical space for solely for purposes of wiping the lens.

Design and Materials
The design principles of the TroCare TroKit and the TroCare TroKit Laparoscope Lens Wiper (K241796) predicate device are substantially equivalent as they are identical in every way and only differ by their indications for use. The TroCare TroKit Laparoscope Lens Wiper and the TroCare TroKit Laparoscope Lens Wiper (K241796) predicate device are fabricated from the identical materials, consist of the identical constructs, packaged in the identical packaging materials, sterilized with the identical sterilization method and sterilization dose, contain and consist of the identical mechanical features and mechanical specifications, and are provided in the identical shapes and sizes.

SUMMARY : TABLE OF SUBSTANTIAL EQUIVALENCE

The TroCare TroKit device is substantially equivalent to the TroCare TroKit Laparoscope Lens Wiper (K241796) in the following respects:

Criteria	Subject Device		Predicate Device
	TroKit Laparoscope Lens Wiper		TroKit Laparoscope Lens Wiper
			K241796
			
Device Description	Clear polymer sheath to protect the laparoscope and facilitate cleaning of the optical lens in vivo through the use of an elastomer squeegee		Clear polymer sheath to protect the laparoscope and facilitate cleaning of the optical lens in vivo through the use of an elastomer squeegee
Indications for Use	The TroKit Laparoscope Lens Wiper is a laparoscopic accessory lens cleaning device intended to mount onto a trocar and maintain the intra-operative view of the surgical site during minimally invasive surgery by physically shielding and wiping the laparoscope lens from debris, grease, blood, and bodily fluids.		The TroKit Laparoscope Lens Wiper is a laparoscopic accessory lens cleaning device intended to maintain the intra-operative view of the surgical site during minimally invasive surgery by physically shielding and wiping the laparoscope lens from debris, grease, blood, and bodily fluids. The access device is compatible with the da Vinci Xi Surgical System.
Design and Materials	Clear polymer that fits around the end of an endoscope with elastomer squeegee that wipes laparoscope lens.		Clear polymer that fits around the end of an endoscope with elastomer squeegee that wipes laparoscope lens.
Inner Diameter (ID)	5mm Device	10mm Device	10mm
Length	85.70mm	77.09	77.09mm
Height	11.80mm	14.50	14.50mm
Anatomical Regions of Use	Abdominal		Abdominal
Single Use	Yes		Yes
Materials	Clear Polymer		Clear Polymer
Sterilization Methodology	EO Gas		EO Gas
Regulation	21 CFR 876.1500		21 CFR 876.1500
Product Code	GCJ		GCJ

VII. PERFORMANCE DATA

Biocompatibility Testing
The TroKit Laparoscope Lens Wiper was evaluated against the international standard ISO 10993-1 (Biological Evaluation of Medical Devices) and the FDA Guidance Document entitled, "Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process." The battery of testing included:

Cytotoxicity
Sensitization
Irritation
Acute System Toxicity
Material Mediated Pyrogenicity

Non-clinical Testing
The TroKit Laparoscope Lens Wiper was evaluated for mechanical characteristics to demonstrate that it is safe and performs as intended. Mechanical testing of the TroKit devices included push-on and pull-off forces to install and remove the TroKit device from appropriately sized trocars fabricated from various materials to demonstrate substantial equivalence. Push-on and pull-off forces were measured in both a wet and dry environment. Furthermore, the absence of damage and / or deformity of both the trocar and the TroKit device were assessed after maximum push-on and pull-off manipulations were performed. All bench top mechanical testing was repeated on each shape and size of TroKit devices. A porcine animal model was used to simulate in vivo use of the TroKit device as a means to demonstrate that the device is safe (does not dislodge during in vivo manipulations), is robust when used under simulated-use conditions (device does not break and remains fully functional during in vivo manipulations) and performs as intended (device efficiently clears/cleans the optical camera).

Clinical Studies
No clinical studies were performed to support safety or effectiveness of the subject device.

VIII. CONCLUSIONS
The nonclinical testing demonstrates that the subject device is as safe and effective, and performs as well as the legally marketed predicate device.