



9/18/2025

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

Re: K241796

Trade/Device Name: TroCare TroKit Laparoscope Lens Wiper (CP000626)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ

Dear Kenneth Kleinhenz:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on October 4, 2024. Specifically, FDA is updating this substantial equivalence (SE) Letter as an administrative correction to the typo in the indications for use (previously cleared indications for use indicated that the device is compatible with the da Vinci Si Surgical System, whereas the intended indications for use [and associated performance testing] identifies compatibility with the da Vinci Xi Surgical System).

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Colin Kejing Chen, OHT4: Office of Surgical and Infection Control Devices, 301-796-6390, Kejing.Chen@fda.hhs.gov.

Sincerely,

Colin K. Chen Digitally signed by Colin
K. Chen -S
-S Date: 2025.09.18 14:26:57
-04'00'

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



October 4, 2024

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

Re: K241796

Trade/Device Name: TroCare TroKit Laparoscope Lens Wiper (CP000626)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 14, 2024
Received: June 21, 2024

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 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: 2024.10.04 10:51:31 -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

Indications for Use

510(k) Number (if known)
K241796

Device Name
TroCare, LLC TroKit Laparoscope Lens Wiper

Indications for Use (Describe)

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.

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.

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Date Prepared: 15 September 2025

I. SUBMITTER

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

Mfg. Establishment Registration Number: First premarket notification. Company to register with FDA within 30 days of 510(k) clearance.

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: K241796

III. PREDICATE DEVICE

Medeon ClickClean, K192891

IV. DEVICE DESCRIPTION

Design Characteristics

The TroKit Laparoscope Lens Wiper is a sterile, single-use and disposable laparoscopic accessory device that fits 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 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE


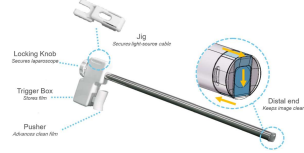


The TroKit Laparoscope Lens Wiper shares indications for use and design principles with the following predicate devices: Medeon ClickClean (K192891), FlowShield (K150705) and the ClearCam System (K200228); all Class II medical device that was cleared for marketing in the United States under K192891, K150705, and K200228.


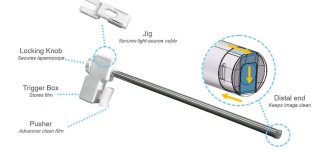


Indications For Use


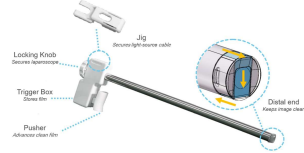


The TroKit Laparoscope Lens Wiper and the Medeon ClickClean (K192891), FlowShield (K150705) and the ClearCam System (K200228) predicate device are substantially equivalent with respect to their indications for use as they are all indicated for the same intended use of protecting laparoscope devices during intraabdominal procedures and/or wiping the lens intraoperatively to avoid repeated egress and ingress into the surgical space for purposes of wiping the lens.

SUMMARY : TABLE OF SUBSTANTIAL EQUIVALENCE

The TroCare TroKit device is substantially equivalent to the Medeon ClickClean (K192891) predicate device and the FlowShield (K150705) and the ClearCam System (K200228) Related devices in the following respects:

Criteria	Subject Device	Predicate Device		Related Device
	TroKit Laparoscope Lens Wiper	Medeon Click Clean	Minimally Invasive Devices FlowShield	ClearCam LLC ClearCam System
		K192891	K150705	K200228
				
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	Stainless steel laparoscope provided with a clear polymer sheath to protect the laparoscope and facilitate cleaning of the lens in vivo	laparoscopic accessory lens clearing device consisting of a sheath and handle that slides over the laparoscope. The handle contains a wire connected to a wiper at the distal end of the sheath that provides lens clearing when activated. Elastomer squeegee used to clean a laparoscope lens in vivo

Criteria	Subject Device	Predicate Device		Related Device
	TroKit Laparoscope Lens Wiper	Medeon ClickClean	Minimally Invasive Devices FlowShield 10mm Endoscopic Cannula and Conical Blunt Obturator	ClearCam LLC ClearCam System
		K192891	K150705	K200228
				
<p>Indications for Use</p>	<p>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.</p>	<p>Laparoscope Lens Shield Device (LENS), a sterile, single-use and disposable laparoscopic accessory lens shield device, for various sizes of laparoscopes including standard and bariatric laparoscope, intended to maintain the intra-operative view of the surgical site during minimally invasive surgery by physically shielding the laparoscope lens from debris, grease, blood, and bodily fluids.</p>	<p>The reusable FloShield 10mm Endoscopic Cannula and Conical Blunt Obturator is an access device indicated for use with a disposable 8.5 – 13mm Cannula Seal manufactured by Applied Medical to provide a passageway for the introduction of endoscopic instruments in general laparoscopic procedures. The access device is compatible with the da Vinci si Surgical System.</p>	<p>The ClearCam System is indicated to provide lens clearing during laparoscopic procedures</p>

Criteria	Subject Device	Predicate Device		Related Device
	TroKit Laparoscope Lens Wiper	Medeon ClickClean	Minimally Invasive Devices FlowShield 10mm Endoscopic Cannula and Conical Blunt Obturator	ClearCam LLC ClearCam System
		K192891	K150705	K200228
				
Design and Materials	Clear polymer that fits around the end of an endoscope	Clear polymer that fits around the end of an endoscope	Clear polymer that fits around the end of an endoscope	Clear polymer that fits around the end of an endoscope
Anatomical Regions of Use	Abdominal	Abdominal	Abdominal	Abdominal
Fits with Laparoscope Size (O.D)	10mm	5mm - 7mm	8.5mm – 13mm	5mm
Single Use	Yes	Yes	Yes	
Materials	Clear Polymer	Clear Polymer	Clear Polymer	Clear Polymer
Sterilization Methodology	EO Gas	EO Gas	EO Gas	EO Gas
Regulation	21 CFR 876.1500	21 CFR 876.1500	21 CFR 876.1500	21 CFR 876.1500
Product Code	GCJ	GCJ	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.

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.