April 8, 2026

Scopix , Ltd.
Orly Maor
Regulatory consultant
108 Kalanit St.
Amikam, 3783000
Israel

Re: K260089
Trade/Device Name: TL-10 Laparoscopic Scope Cleaner
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 20, 2025
Received: January 12, 2026

Dear Orly Maor:

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: 2026.04.08 22:33:26 -04'00'

For
Colin Kejing Chen, Ph.D.
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

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.	K260089

Please provide the device trade name(s).

TL-10 Laparoscopic Scope Cleaner

Please provide your Indications for Use below.

The TL-10 is a laparoscopic accessory lens cleaning device intended to provide lens clearing during laparoscopic procedures

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

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

510(k) Summary

Traditional Premarket Notification Submission – 510(k)
TL-10 Laparoscopic Scope Cleaner
510(k) Number _____

Date Prepared: January 9, 2025

I. SUBMITTER

Scopix Ltd.
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Contact Person

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II. DEVICE

Name of Device: TL-10 Laparoscopic Scope Cleaner
Common or Usual Name: TL-10 Laparoscopic Scope Cleaner
Classification Name: Laparoscope, general & plastic surgery
Regulatory Class: Class II, per 21 CFR 876.1500
Product Code: GCJ.
Classification Panel: General & Plastic Surgery

III. PREDICATE DEVICE

The Scopix Ltd. TL-10 Laparoscopic Scope Cleaner, the subject of this premarket notification, is substantially equivalent to the following predicate device:

- TroCare, LLC TroCare TroKit Laparoscope Lens Wiper, cleared under K241796 Product code GCJ, Regulation Number 21 CFR 876.1500.

In addition, the following will be used as a reference device:

- ClearCam, LLC Clear Cam, cleared under K200228 Product code GCJ, Regulation Number 21 CFR 876.1500.

IV. DEVICE DESCRIPTION

The Scopix TL-10 Laparoscopic Scope Lens Cleaner is a sterile, single-use disposable device that fits in a trocar and is intended for cleaning the endoscope lens without requiring removal of the endoscope from the patient's body.

During laparoscopic procedures, a trocar is utilized to introduce the endoscope and additional surgical instruments into the patient's body cavities. The Scopix TL-10 Scope cleaner is positioned in a trocar prior to the introduction of the endoscope. When the endoscope lens is obscured, the surgeon moves the endoscope back and forth through a crisscross arrangement of cleaning strings located at the distal end of the TL-10 cannula; this action removes contaminants from the lens and restores visibility for the ongoing procedure.

V. INDICATIONS FOR USE

The TL-10 is a laparoscopic accessory lens cleaning device intended to provide lens clearing during laparoscopic procedures.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Scopix TL-10 Laparoscopic Scope Cleaner has the same intended use as the predicate and reference devices. Its indications for use are identical to that of the predicate device.
A substantial equivalence table, which summarizes the similarities and differences between Scopix TL-10, and its predicate and reference device, is provided below.

Characteristic	Scopix Ltd. Scopix TL-10 Laparoscopic Scope Cleaner	TroCare, LLC. TroCare TroKit Laparoscope Lens Wiper	ClearCam, LLC. ClearCam	SE Justification
510(k) number	Subject device	K241796	K200228	-
Product Code	GCJ	GCJ	GCJ	Same.
CFR	21 CFR 876.1500	21 CFR 876.1500	21 CFR 876.1500	Same
Intended Use	The TL-10 **is a laparoscopic accessory lens cleaning device** intended to provide lens clearing during laparoscopic procedures.	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	The ClearCam System is **indicated to provide lens clearing during laparoscopic procedures**.	Same as reference and the within the scope of the predicate.

Characteristic	Scopix Ltd. Scopix TL-10 Laparoscopic Scope Cleaner	TroCare, LLC. TroCare TroKit Laparoscope Lens Wiper	ClearCam, LLC. ClearCam	SE Justification
		device is compatible with the da Vinci Si Surgical System.		
Lens Cleaning Materials	Silicon elastic strings	Elastomer squeegee	Silicon	Use of different materials does not impact substantial equivalence
Patient Population	Patient under laparoscopic Surgery	Patient under laparoscopic surgery	Patient under laparoscopic surgery	Same
Anatomical Site	Abdominopelvic cavity	Abdominopelvic cavity	Abdominopelvic cavity	Same
Design Features	Mechanical wiping of the distal lens to provide a clear view	Mechanical wiping of the distal lens to provide a clear view	Mechanical wiping of the distal lens to provide a clear view	Same as the predicate
Compatibility Laparoscope	10 mm	10mm	10mm	Same
Delivery Method	Introduction into abdominopelvic cavity via a trocar	Introduction into abdominopelvic cavity via a trocar	A sheath and handle that slides over the laparoscope	Same
Performance	Able to maintain laparoscopic view when it gets soiled by debris	Able to maintain laparoscopic view when it gets soiled by debris	Able to maintain laparoscopic view when it gets soiled by debris	Same
Sterilization	EtO	EtO	EtO	Same
Biocompatible for Intended Use	Externally communicating devices, in contact with tissue, with limited contact (≤ 24h)	Externally communicating devices, in contact with tissue, with limited contact (≤ 24h)	Externally communicating devices, in contact with tissue, with limited contact (≤ 24h)	Same tests were done as the predicate
How Provided	Single use, sterile	Single use, sterile	Single use, sterile	Same

VII. PERFORMANCE DATA

The following performance data were conducted. The Laparoscopic Scope Cleaner met the predetermined acceptance criteria ensuring substantial equivalence to the predicate. No new safety or effectiveness issues were raised during testing:

- **Biocompatibility**
  Biocompatibility evaluation in compliance with ISO 10993-1 was performed.
  The following tests were conducted:
  - Cytotoxicity Study
  - ISO Intracutaneous /irritation Study
  - Sensitization Test
  - Acute Systemic Toxicity Study
  - Pyrogen Study - Material Mediated Study

  All tests were successfully completed and passed, and the device met the defined acceptance criteria and was found to be biocompatible.

- **Sterilization, Transportation, Packaging and Shelf Life Testing**
  Sterilization validation was performed to demonstrate compliance with ISO 11135-1. In addition, transportation simulation and environmental tests prior to accelerated shelf life that included packaging testing and performance to support the six months labeled shelf life.

  All tests were successfully completed and passed, and the device met the defined acceptance criteria.

- **Performance Testing**
  Performance testing included the following:

Test	Purpose and result
TL-10 Device Compatibility with Commercial Trocars	The purpose of this test was to verify that the device can be easily inserted, extracted, placed, secured, and does not damage the device components and the hosting trocar when an endoscope is used and that the endoscope can moved freely in the TL-10 device. The test PASS.
TL-10 Device Gas Pressure Holding	The purpose of this test was to provide documented evidence that the TL-10, when installed in a trocar, does not interfere with the gas flow, does not cause gas leaking while the surgeon maneuvers the endoscope, or, when the endoscope is removed. The test PASS

Test	Purpose and result
TL-10 Device Cleaning Strings and Components Durability	The purpose of this test was to provide documented evidence that TL-10 can withstand 60 consecutive wiping cycles, comprising 30 cycles with a 10 mm/30 deg endoscope and 30 cycles with a 10 mm/0 deg endoscope, while maintaining the structural integrity of the silicone strings and device components. The test PASS
TL-10 Device Cleaning Strings Disconnection	The purpose of this test was to provide documented evidence that deliberately cut strings, in a simulated worst-case scenario, do not disconnect from the device. The test PASS
Packaging Aseptic Presentation and Ease-of-Opening Evaluation	The purpose of this test was to demonstrate that the sterile barrier system design enables aseptic presentation of the medical device and allows the intended user to open and transfer the product without compromising sterility. The test PASS
Animal Study	Animal Study evaluated the Scopix TL-10 safety and performance. The devices performed as intended without malfunction. The results indicated that the device is safe and effective. The test PASS

All tests were successfully completed and passed, and the device met the defined acceptance criteria.

VIII. CONCLUSIONS

The TL-10 Laparoscopic Scope Cleaner was determined to be substantially equivalent to the predicate and reference devices.