July 14, 2026

Intuitive Surgical, Inc.
Taian Chen
Senior Regulatory Affairs Specialist
1266 Kifer Rd.
Sunnyvale, California 94086

Re: K261249
Trade/Device Name: Universal Seal (5-12 mm)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: April 15, 2026
Received: April 16, 2026

Dear Taian Chen:

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,

MARK TRUMBORE -S
Digitally signed by MARK TRUMBORE -S
Date: 2026.07.14 07:54:37 -04'00'

Mark Trumbore, 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

?

Please provide the device trade name(s).

?

Universal Seal (5-12 mm)

Please provide your Indications for Use below.

?

The da Vinci Trocar has applications in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments.

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

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

?

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [ ] Adults (22 years old and greater)

?

510(k) Summary (21 CFR 807.92)

1. Contact Information

Date Prepared:	April 15, 2026
510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
510(k) Preparer/Submitter:	Stephanie Rincones Regulatory Affairs Specialist 3 Intuitive Surgical, Inc. Phone: 408-523-2352 E-Mail: stephanie.rincones@intusurg.com
510(k) Primary Correspondent:	Taian Chen Senior Regulatory Affairs Specialist Intuitive Surgical, Inc. Phone: 650-302-8499 E-Mail: taian.chen@intusurg.com

2. Subject Device

Trade Name:	Universal Seal (5 – 12 mm)
Common Name:	Cannula Seal
Classification:	Class II
Regulation:	21 CFR § 876.1500, Endoscope and Accessories
Product Code:	GCJ

3. Predicate Device

Trade Name	Universal Seal (5 – 12 mm)
510(k) Number	K253978

4. Device Description

The Universal Seal (5-12 mm) is a sterile, single-use device. It provides a seal within a port of entry for endoscopes, instruments, and accessories with a diameter range between 5 mm and 12 mm. It also provides an attachment for insufflation accessories and allows for air to flow in or out of the body cavity while minimizing gas leakage.

5. Intended Use

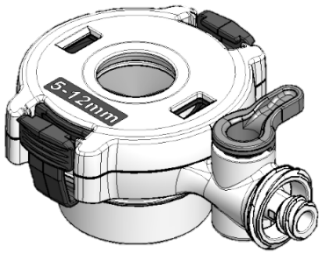
The Universal Seal (5 -12 mm) supports a port of entry for endoscopes, instruments, and accessories.

6. Indications for Use

The da Vinci Trocar has application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments.

7. Technological Characteristics

The subject device is very similar to the predicate device cleared under K253978. It has the same intended use, same indications for use, same fundamental scientific technology, and similar technological characteristics. The table below provides a comparison of technological characteristics between the subject and predicate device. Differences between the devices are highlighted in gray.

Attribute	**Subject Device** Universal Seal (5 – 12 mm)	**Predicate Device** Universal Seal (5 – 12 mm) (K53978)
Representative Image		**SAME** as Subject Device
Mechanism of Action	The Universal Seal (5 – 12 mm) is latched onto a da Vinci Cannula and provides a seal that maintains insufflation during surgical procedure with or without an endoscope, instrument, or accessory inserted through the septum.	**SAME** as Subject Device
Interface Compatibility	The Universal Seal (5 – 12 mm) provides a compatible interface for the insertion of da Vinci endoscopes, instruments and accessories alongside laparoscopic instruments within the diameter range.	**SAME** as Subject Device
Design Features	• Connectors: used to attach an obturator or reducer • Latches: used to connect a cannula • Port connector: used to connect an insufflator to allow a pathway for gas insufflation, desufflation and smoke evacuation • Stopcock: a valve used to open and close the gas pathway from the luer connection • Septum: provides entry for endoscopes, instruments, and accessories while maintaining a seal that minimizes gas leakage	**SAME** as Subject Device
Dimensions	Overall Dimensions: • Housing size (diameter): 1.76 in • Total height: 1.15 in	**SAME** as Subject Device
	Septum: • Inner diameter: minor decrease • Other dimensions: no changes	**SIMILAR** to Subject Device

	Lower Housing: • Luer: ○ Body outer diameter: minor increase ○ External thread length: minor increase and circular boss added ○ Energy director height: minor increase ○ Ultrasonic alignment boss height: minor increase ○ All other dimensions: no changes • All Other Components: ○ No changes	**SIMILAR** to Subject Device
	All Other Components: • No changes	**SAME** as Subject Device
Patient-Contacting Materials	Septum: • Supplier #1: POLYISOPRENE RUBBER, BLACK, PROPRIETARY FORMULATION. MOLD RELEASE AGENT: PROPRIETARY. • Supplier #2: POLYISOPRENE RUBBER, BLACK, PROPRIETARY FORMULATION. MOLD RELEASE AGENT: PROPRIETARY. • Supplier #3: POLYISOPRENE RUBBER, BLACK, PROPRIETARY FORMULATION. MOLD RELEASE AGENT: PROPRIETARY.	**SIMILAR** to Subject Device • Supplier #1: POLYISOPRENE RUBBER, BLACK, PROPRIETARY FORMULATION. MOLD RELEASE AGENT: PROPRIETARY. • Supplier #2: POLYISOPRENE RUBBER, BLACK, PROPRIETARY FORMULATION. MOLD RELEASE AGENT: PROPRIETARY.
	• Protective Flaps: polyurethane • Floating Cylinder (Upper & Lower): polycarbonate, white • Housing (Upper & Lower): polycarbonate, white • Latch: polycarbonate, grey • Stopcock: high density polyethylene, grey • Lubricant: silicone fluid • Duckbill: silicone rubber, black, mold release agent: proprietary; or polyisoprene rubber, black, mold release agent: proprietary	**SAME** as Subject Device
Primary Packaging Materials	Top Web: • Material #1: TYVEK 1059B W/ACT2100 COATING • Material #2: 35644-S FILM Bottom Web: PERFECFORM IONOMER FILM	**SIMILAR** to Subject Device Top Web: TYVEK 1059B W/ACT2100 COATING Bottom Web: PERFECFORM IONOMER FILM
Biocompatibility	All patient-contacting materials are biocompatible per ISO 10993-1.	**SAME** as Subject Device
Sterility	Gamma Radiation, SAL 10^{-6}	**SAME** as Subject Device
Type of Use	Single-Use / Disposable	**SAME** as Subject Device

8. Performance Data

The subject device underwent the series of tests listed below to assess the impact of the material change in comparison with the predicate device. Testing was successfully completed and demonstrated that the subject device continues to meet design input, user need, and intended use requirements.

Design Verification

Bench testing was performed to verify that the subject device continues to meet the following design and functional requirements.

- Absence of natural rubber latex
- Leakage
- Torque limits
- Force limits
- Reliability

Design Validation

Simulated clinical use was performed with a porcine model and a cadaver model to validate that the subject device continues to meet user need and intended use requirements.

Biocompatibility

A biological safety assessment and biocompatibility testing were performed in accordance with the following standard and guidance document to confirm that the subject device continues to meet biological safety requirements for its intended use.

- FDA Guidance, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" (September 8, 2023)*
- ISO 10993-1:2018, *Biological evaluation of medical devices – Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process*

Shelf-Life

Shelf-life testing was performed in accordance with the following standard to confirm that the subject device continues to meet requirements for its labeled shelf life.

- ASTM F1980-21, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*

Transit

Transit testing was performed in accordance with the following standard to confirm that the subject device continues to meet functional requirements following transit.

- ASTM D4169-23e1, *Standard Practice for Performance Testing of Shipping Containers and Systems*

9. Conclusion

Based on the intended use, indications for use, technological characteristics, and performance data, the subject device, the Universal Seal (5-12 mm), is substantially equivalent to the predicate device.