February 24, 2026

Intuitive Surgical, Inc.
Taian Chen
Sr. Regulatory Affair Specialist
1266 Kifer Rd.
Sunnyvale, California 94086

Re: K253978
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: December 10, 2025
Received: December 12, 2025

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 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,

MARK TRUMBORE -S
Digitally signed by MARK TRUMBORE -S
Date: 2026.02.24 11:09:43 -05'00'

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 application 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).

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

510(k) Summary (21 CFR § 807.92)

I. Submitter Information

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact Person:	Taian Chen Senior Regulatory Affairs Specialist Phone: 650-302-8499 Email: taian.chen@intusurg.com
Date Summary Prepared:	December 8th, 2025

II. 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

III. Predicate Device Information

Predicate Devices : Universal Seal (5-12 mm) (K241360)

IV. 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.

V. Indications for Use

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

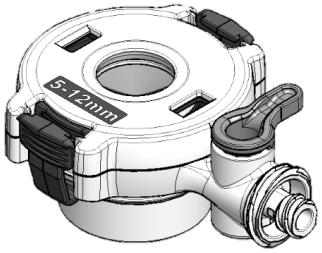
VI. Technological Characteristics

The subject device is very similar to its predicate device cleared under K241360. It has the same intended use, same indications for use, same fundamental scientific technology, and similar technological characteristics as the predicate device. The modification is limited to material change on the indirect patient-contacting components. Results from performance testing concluded that, Universal Seal (5-12 mm) is substantially equivalent to its predicate, Universal Seal (5-12 mm) cleared under K241360. Table 13-1 provides a comparison in technological characteristics between the subject Universal Seal (5-12 mm) and predicate Universal Seal (5-12 mm). Differences between the subject and predicate devices are highlighted in grey.

Table 13-1 General Aspects of the Universal Seal (5-12 mm)

Attributes	**Subject Device** Universal Seal (5-12 mm)	**Predicate Device** Universal Seal (5-12 mm) (K241360)
Mechanism of Action	The Universal Seal (5-12 mm) is latched onto a da Vinci Cannula and is intended to maintain insufflation during procedure with or without an endoscope, instrument, or accessory inserted through the septum of the Universal Seal.	**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 with laparoscopic instruments within the diameter range.	**SAME** as Subject Device
Design Features	• Connectors: used to attach an on obturator or reducer to the Universal Seal • Latches: used to connect the Universal Seal to a compatible da Vinci Surgical System cannula • Port connector: provides a connection point to an insufflator that allows for a gas pathway for insufflation, desufflation, and smoke evacuation	**SAME** as Subject Device

Attributes	**Subject Device** Universal Seal (5-12 mm)	**Predicate Device** Universal Seal (5-12 mm) (K241360)
	• Stopcock: a valve used to open and close the gas pathway from the luer connection • Septum Assembly: a port of entry for endoscopes, instruments, and accessories that maintains and minimizes gas leakage	
Overall Dimensions	• Housing size (diameter): 1.76 in • Total height: 1.15 in	**SAME** as Subject Device
Packaging Materials	Primary packaging material: • Soft Ionomer (Surlyn) Film • 1059 Tyvek	**SAME** as Subject Device
Patient-Contacting Materials	• Protective flaps: polyurethane • Floating cylinder: polycarbonate, white • Septum: polyisoprene, black, proprietary formulation	**SAME** as Subject Device
	• Duckbill: silicone, black, proprietary formulation • Mold release: proprietary mold release	**SIMILAR** to the subject device • Duckbill: polyisoprene, black, proprietary formulation • Mold release: proprietary mold release
	• Lubricant: Silicone fluid, NYEMED (NyeMed 7605)	**SIMILAR** to the subject device • Lubricant: Silicone fluid, NuSil (MED-420)
	• Housing (upper & lower): polycarbonate, white • Latch: polycarbonate, grey • Stopcock: high density polyethylene, grey	**SAME** as Subject Device
Biocompatibility	All patient-contacting materials are biocompatible per 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

Attributes	**Subject Device** Universal Seal (5-12 mm)	**Predicate Device** Universal Seal (5-12 mm) (K241360)
Representative Images		**SAME** as Subject Device

VII. Performance Data

The subject device, Universal Seal (5-12 mm), underwent a series of tests to assess the impact of material changes in comparison to the predicate device. Testing included design verification, reliability testing, design validation, biocompatibility, shelf-life, and transit testing. The successful completion of testing demonstrated that the subject Universal Seal (5-12 mm) design outputs continue to meet design inputs.

Design Verification

Bench testing was performed to verify functional design outputs met the functional design inputs. The design verification in this section addressed the following:

- Stopcock movement
- Leakage
- Torque limits
- Force limits
- Reliability

Design Validation

Simulated clinical use testing was performed with a porcine model and a cadaver model to validate that the product specifications continued to meet the user's needs and intended use.

Biocompatibility

Biocompatibility testing was completed in accordance with the following standards and guidance documents:

- FDA Guidance: Use of International Standard ISO 10993. "*Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process"* issued in September 2023.
- ISO 10993-1:2018: *Biological Evaluation of Medical Devices*

Based on the biocompatibility testing and biological safety evaluation, it was concluded that the subject device met the requirements of the recognized standards for biocompatibility for its intended clinical use.

Shelf-Life

Shelf-life testing was performed through an accelerated aging study to verify that the product can maintain a shelf-life of two years, in accordance with ASTM F1980-22*, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.*

Transit Testing

Transit testing was performed in accordance with ASTM D4169-23e1, *Standard Practice for Performance Testing of Shipping Containers and Systems*.

VIII. Conclusion

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