



August 5, 2024

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

Re: K241360
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: May 10, 2024
Received: May 14, 2024

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.

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: 2024.08.05 09:17:09 -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

Submission Number (if known)

Device Name

Universal Seal (5-12 mm)

Indications for Use (Describe)

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

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.

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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: May 10, 2024

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) (K231358)

Reference Devices : Single-Site Cannula Seal (K152448) and Stapler Cannula Seal (K113706)

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

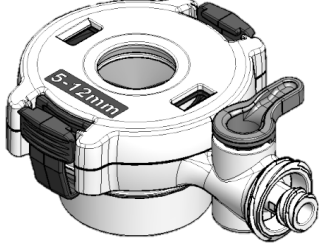
The da Vinci Trocar has application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments.

VI. Technological Characteristics

The subject device is very similar to its predicate device cleared under K231358. It has the same intended use, indications for use, functional-scientific technology, and technological characteristics as the predicate device. The modification is limited to minor material change used on the indirect patient contacting components. Results from performance testing indicate that, Universal Seal (5-12 mm) is substantially equivalent to its predicate, Universal Seal (5-12 mm) cleared through K231358. Table 10-1 provides a comparison 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 10-1 General Aspects of the Universal Seal (5-12 mm)

Attributes	Subject Device Universal Seal (5-12 mm)	Predicate Device Universal Seal (5-12 mm) (K231358)
Manufacturer	Intuitive Surgical, Inc.	SAME as subject device
Product Code	GCJ	SAME as subject device
Regulation Number and Name	21 CFR 876.1500, Endoscopes and Accessories	SAME as subject device
Device Classification	Class II	SAME as subject device
Classification Advisory Committee	General and Plastic Surgery	SAME as subject device
Intended Use	The Universal Seal (5-12 mm) supports a port of entry for endoscopes, instruments, and accessories.	SAME as subject device
Indications for Use	The da Vinci Trocar has application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments.	SAME as subject device
Target Population	Adults and pediatrics	SAME as subject device
Anatomical Site	Abdomen and Thoracic	SAME as subject device
Where Used (hospital, home, ambulance, etc)	Hospital, Surgical Operating Rooms	SAME as subject device

Attributes	Subject Device Universal Seal (5-12 mm)	Predicate Device Universal Seal (5-12 mm) (K231358)
Representative Images		SAME as subject device
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
Compatibility with the environment and other devices	The device is compatible within the surgical operating room and intended to be used with the da Vinci Surgical System, endoscopic instruments, and surgical accessories.	SAME as subject device
Interface Compatibility	The Universal Seal (5-12 mm) provides a compatible interface for the insertion of with da Vinci endoscopes, instruments and accessories alongside with, laparoscopic instruments within the diameter range.	SAME as subject device
Design Features	<ul style="list-style-type: none"> • <u>Connectors</u>: used to attach an obturator or reducer to the Universal Seal • <u>Latches</u>: used to connect the Universal Seal to a compatible da Vinci Surgical System cannula • <u>Port connector</u>: provides a connection point to an insufflator • <u>Stopcock</u>: a valve used to open and close the gas pathway • <u>Septum Assembly</u>: a port of entry for endoscopes, instruments, and accessories 	SAME as subject device

Attributes	Subject Device Universal Seal (5-12 mm)	Predicate Device Universal Seal (5-12 mm) (K231358)
Overall Dimensions	<ul style="list-style-type: none"> <u>Housing size (diameter)</u>: 1.76 in <u>Total height</u>: 1.15 in 	SAME as subject device
Packaging Materials	Primary packaging material: <ul style="list-style-type: none"> Film 	SAME as subject device
Patient-Contacting Materials	<ul style="list-style-type: none"> <u>Protective flaps</u>: polyurethane <u>Floating cylinder</u>: polycarbonate, white <u>Septum</u>: polyisoprene, black, proprietary formulation and mold release <u>Lubricant</u>: silicone fluid <u>Duckbill</u>: polyisoprene, black, proprietary formulation and mold release <u>Housing (upper & lower)</u>: polycarbonate, white <u>Latch</u>: polycarbonate, grey <u>Stopcock</u>: high density polyethylene, grey 	SIMILAR as subject device <ul style="list-style-type: none"> <u>Protective flaps</u>: polyurethane <u>Floating cylinder</u>: polycarbonate, white <u>Septum</u>: polyisoprene, black <ul style="list-style-type: none"> ○ proprietary formulation and mold release, or <u>Lubricant</u>: silicone fluid <u>Duckbill</u>: polyisoprene, black <ul style="list-style-type: none"> ○ proprietary formulation and mold release <u>Housing (upper & lower)</u>: polycarbonate, white <u>Latch</u>: polycarbonate, grey <u>Stopcock</u>: high density polyethylene, grey
Biocompatibility	All materials have been evaluated for biocompatibility 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

VII. Performance Data

The subject device, Universal Seal (5-12 mm) underwent biocompatibility evaluation and testing to assess the impact of material changes in comparison to the predicate device. Biological evaluation was conducted according to 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 assessment, it was concluded that the subject device met the requirements of the recognized standards for biocompatibility for its intended clinical use.

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.