July 5, 2023

Intuitive Surgical, Inc.
Emily Hovick
Sr. Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086

Re: K231358
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 9, 2023
Received: May 10, 2023

Dear Emily Hovick:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 2023.07.05 14:03:36 -04'00'

Mark Trumbore, Ph.D. Assistant Director
THT4A1: Robotically-Assisted Surgical Devices Team
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary

510(k) Owner:
Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086

Contact Person:
Emily Hovick
Sr. Regulatory Affairs Specialist
Phone: 314-359-8534
Email: Emily.hovick@intusurg.com

Date Summary Prepared: May 09, 2023

## I. SUBJECT DEVICE

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

## II. PREDICATE DEVICE

Intuitive Surgical, Inc, Universal Cannula Seal (5-12 mm), K181395

## III. 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 flow in or out of the body cavity while minimizing gas leakage.

## IV. INTENDED USE/INDICATION FOR USE

The Universal Seal (5-12 mm), as part of the da Vinci Trocar system, supports a port of entry for endoscopes, instruments, and accessories. It is intended to be used with a compatible da Vinci cannula to provide a seal within a port of entry for endoscopes, instruments, and accessories. It is intended to provide an attachment for gas insufflation and desufflation while minimizing gas leakage.

## V. TECHNOLOGICAL CHARACTERISTICS

The subject Universal Seal (5-12 mm) is very similar to its predicate device cleared under K181395. It has the same intended use, same indication for use, same fundamental scientific technology, and similar technological characteristics as the predicate device. The modification to the device consists of indirect patient contacting material changes. Results from performance data

indicate that the Universal Seal (5-12 mm) is substantially equivalent to the predicate Universal Cannula Seal (5-12 mm).

## VI. PERFORMANCE DATA

The subject Universal Seal (5-12 mm) underwent a series of tests to evaluate the impact of the modification to the predicate device. Testing was performed with a compatible da Vinci surgical system. Testing included design verification, reliability testing, design validation, biocompatibility, packaging, 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:

- Leakage
- Torque limits
- Force limits
- Reliability

Design Validation

Simulated clinical use testing was performed with a porcine 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 September 2020
- ISO 10993-1:2018 Biological evaluation of medical devices

Based on the biological safety assessment and biocompatibility testing, it was determined 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.

Transit Testing

Transit testing was performed in accordance with *ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems*

## VII. CONCLUSIONS

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