July 27, 2018

Intuitive Surgical, Inc.
Ms. Cheryl Wu
Regulatory Affairs Engineer
1266 Kifer Road
Sunnyvale, California 94086

Re: K181395
Trade/Device Name: Universal Cannula Seal (5-12 mm)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: May 25, 2018
Received: May 29, 2018

Dear Ms. Wu:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181395

Device Name

Universal Cannula 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

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

Contact: Cheryl Wu
Regulatory Affairs Engineer
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Date Summary Prepared: July 26, 2018

Trade Name: Universal Cannula Seal (5-12 mm)

Common Name: Endoscope and accessories

Classification: Class II
21 CFR 876.1500, Endoscope and Accessories

Product Codes: GCJ

Classification Advisory Committee: General and Plastic Surgery

Predicate Device(s): K133845 – 8MM Trocar Kit
K170508 – EndoWrist® Stapler 45 and Stapler 45 Reloads

Intended Use:

To provide a port of entry for endoscopic instruments.

Indications for Use:

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

Device Description:

The Universal Cannula Seal (5-12 mm) is a sterile, single-use (disposable) seal used with *da Vinci* cannula, obturators, and reducers. The Universal Cannula Seal has an opening that is sized to allow specific diameter ranges of instruments and surgical accessories to pass

through to the surgical site while maintaining an air-tight system and an insufflated body cavity. Identical to the predicate seals, the subject seal has an insufflation port with a universal luer fitting and an insufflation lever.

Technological Characteristics:

The Universal Cannula Seal is equivalent to the predicate devices in terms of its intended use, design, technology, and performance specifications. The Universal Cannula Seal combines the instrument and accessory size compatibility ranges from both predicate seals. Modifications also include a change in material formulation and a change in packaging configuration.

These modifications do not affect the intended use or the fundamental technology of the subject device relative to that of the predicate device.

Performance Data:

In accordance with the Design Control process, risk analysis was conducted to evaluate the impact of the modifications on the predicate devices**.** Design verification and design validation testing were conducted on the subject devices to confirm that the design outputs meet design input requirements and that the devices are safe and effective for its intended use. The testing identified no new issues of safety or effectiveness and no new risks.

Design Verification:

The subject device was subjected to a series of bench tests to evaluate performance and to demonstrate that the design outputs meet the design input requirements. Testing was performed with a compatible *da Vinci* surgical system. The design verification testing included confirmation that the subject device meets physical, mechanical, user interface, labeling, and packaging requirements. The verification test cases included:

- Number of seals per package
- Single use disposable product
- Diameter/instrument compatibility markings
- Position and use of insufflation valve
- Standard luer fitting attachment
- Insufflation valve open and close
- Stopcock rotation
- No Natural rubber latex
- Stopcock axial load
- Depression of seal latches
- Seal latch strength
- Installation of seal onto cannula

- Rotation of seal on cannula
- Obturator compatibility
- Torque limits
- Force limits
- Flow rate without device
- Leak test seal without device
- Leak test seal with compatible devices
- Seal removal force

Reliability/Life Testing:

The subject device underwent reliability (life) testing to confirm that the subject device meets the design inputs throughout its intended life of one procedure.

Design Validation:

The design validation testing summarized in this submission validates general, functional, and interaction (compatibility) requirements for the subject device. Tests with an animal model and a cadaver were performed to confirm that the subject device functions in accordance with its intended use.

Human Factors:

In conformance with applicable FDA Guidance and international standards on human factors and usability engineering, a thorough analysis and internal risk assessment has been reviewed for the subject device. No new usability risk scenarios are associated with the differences between the subject device and the predicate devices. Therefore, additional human factors studies were not performed.

Sterilization:

Sterilization validation and Bacterial Endotoxins Testing have been performed on the subject device and demonstrates compliance with applicable FDA Guidance for sterile devices.

Biocompatibility Testing:

Biocompatibility testing was successfully completed in accordance with applicable FDA Guidance and international standards related to ISO 10993-1.

Packaging Verification:

Package transit verification testing was performed to demonstrate that the packaging maintains package integrity and product functionality in simulated storage and shipping

conditions. Shelf life testing was performed to verify the Universal Cannula Seal and its packaging for the time specified.

Summary:

Based on the intended use, indications for use, technological characteristics, and performance data, the subject device Universal Cannula Seal (5-12 mm) is substantially equivalent to currently marketed predicate devices in terms of safety, effectiveness, and performance.