July 2, 2025

Intuitive Surgical, Inc.
Melissa Gonzalez
Technical Lead, Regulatory Affairs
1266 Kifer Road
Sunnyvale, California 94086

Re: K251490
Trade/Device Name: 8 mm Assist Cannula; 12 mm Assist Cannula
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: May 9, 2025
Received: May 14, 2025

Dear Melissa Gonzalez:

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,

James H. Jang -S
Digitally signed by James H. Jang -S
Date: 2025.07.02 23:37:30 -04'00'

James Jang, Ph.D.
Acting 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.	K251490

Please provide the device trade name(s).

8 mm Assist Cannula;
12 mm Assist Cannula

Please provide your Indications for Use below.

The cannulas, obturators, seals, and related accessories are intended to establish a port of entry for instruments, endoscopes, or accessories. They are intended to be used only in a medical facility by trained medical professionals in accordance with its associated user manual.

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

- ☒ Prescription Use (Part 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

Primary Contact: Melissa S. Gonzalez
Technical Lead, Regulatory Affairs
Phone: 408-523-8684
Email: melissa.gonzalez@intusurg.com

Secondary Contact: Taian Chen
Senior Regulatory Affairs Specialist
Phone: 650-302-8499
Email: taian.chen@intusurg.com

Date Summary Prepared: May 9, 2025

II. Subject Device

Trade Name: 8 mm Assist Cannula and 12 mm Assist Cannula

Common Name: Surgical Cannula

Classification: Class II

Regulation: 21 CFR § 876.1500, Endoscope and Accessories

Product Code: GCJ

III. Predicate Device Information

Predicate Device: 12mm & Stapler Cannula (PN 470375, K142683)

IV. Device Description

The subject device 8 mm and 12 mm Assist Cannulas are used as part of a trocar system to establish a port of entry into the surgical site. The 8 mm and 12 mm Assist Cannulas are intended to be used laparoscopically (independently of the da Vinci Systems), but may be used in conjunction with da Vinci systems to assist robotic procedures.

V. Indications for Use

The cannulas, obturators, seals, and related accessories are intended to establish a port of entry for instruments, endoscopes, or accessories. They are intended to be used only in a medical facility by trained medical professionals in accordance with its associated user manual.

VI. Technological Characteristics

The cannula is a stainless steel hollow tube that serves as a port of entry for endoscopic instruments. A seal is attached to a cannula and an obturator is placed through the seal. The seal attaches to the top of the cannula to create an air-tight system that allows an insufflated body cavity to be maintained. The seal has an insufflation port with a universal luer fitting and stopcock which connects to the da Vinci Insufflator Tube Set with Smoke Evacuation. The following table provides a summary comparison of the technological characteristics between the subject device to the predicate devices and reference device. The differences in technological characteristics do not raise new questions of safety and effectiveness.

Attributes	**Subject Devices** Assist Cannulas (8 mm and 12 mm)	**Predicate Device** 12 mm & Stapler Cannula (K142683)	**Reference Device** 8mm Hex Cannula, Standard (K232610)
Manufacturer	Intuitive Surgical, Inc.	**SAME** as subject device Intuitive Surgical, Inc.	**SAME** as subject device Intuitive Surgical, Inc.
Product Code	GCJ	**SIMILAR** to subject device NAY	**SIMILAR** to subject device NAY
Regulation Number and Name	21 CFR 876.1500, Endoscopes and Accessories	**SAME** as subject device 21 CFR 876.1500, Endoscopes and Accessories	**SAME** as subject device 21 CFR 876.1500, Endoscopes and Accessories
Device Classification	Class II	**SAME** as subject device Class II	**SAME** as subject device Class II
Classification Advisory Committee	General and Plastic Surgery	**SAME** as subject device General and Plastic Surgery	**SAME** as subject device General and Plastic Surgery
Intended Use	To establish a port of entry for instruments, endoscopes, or accessories.	**SAME** as subject device To establish a port of entry for instruments, endoscopes, or accessories.	**SAME** as subject device To establish a port of entry for instruments, endoscopes, or accessories.
Anatomical Site		**SAME** as subject device	**SAME** as subject device

K251490

Attributes	**Subject Devices** Assist Cannulas (8 mm and 12 mm)	**Predicate Device** 12 mm & Stapler Cannula (K142683)	**Reference Device** 8mm Hex Cannula, Standard (K232610)
	Abdomen and Thoracic	Abdomen and Thoracic	Abdomen and Thoracic
Where Used (hospital, home, ambulance, etc)	Hospital, Surgical Operating Rooms	**SAME** as subject device Hospital, Surgical Operating Rooms	**SAME** as subject device Hospital, Surgical Operating Rooms
Compatible Trocar Accessories	**8 mm Assist Cannula** - Universal Seal - da Vinci Insufflator Tube Set with Smoke Evacuation* - 8 mm Cannula Gage Pin - 8 mm Blunt Obturator (Reusable) - 8 mm Bladeless Optical Obturator (Disposable) * connected through the use of the Universal Seal	**SIMILAR** to subject device **12 mm & Stapler Cannula** - Universal Seal - da Vinci Insufflator Tube Set with Smoke Evacuation* * connected through the use of the Universal Seal	**SAME** as subject device **8 mm Hex Cannula** - Universal Seal - da Vinci Insufflator Tube Set with Smoke Evacuation* - 8 mm Cannula Gage Pin - 8 mm Blunt Obturator (Reusable) - 8 mm Bladeless Optical Obturator (Disposable) * connected through the use of the Universal Seal

Attributes	**Subject Devices** Assist Cannulas (8 mm and 12 mm)	**Predicate Device** 12 mm & Stapler Cannula (K142683)	**Reference Device** 8mm Hex Cannula, Standard (K232610)
	12 mm Assist Cannula - Universal Seal - da Vinci Insufflator Tube Set with Smoke Evacuation* - 12 mm & Stapler Blunt Obturator (Reusable) - 12 mm & Stapler Bladeless Obturator (Reusable) *connected through the use of the Universal Seal	**SAME** as subject device **12 mm & Stapler Cannula** - Universal Seal - da Vinci Insufflator Tube Set with Smoke Evacuation* - 12 mm & Stapler Blunt Obturator (Reusable) - 12 mm & Stapler Bladeless Obturator (Reusable) - *connected through the use of the Universal Seal	**NA**
Compatible Devices	**8 mm Assist Cannula:** Compatible with instruments, imaging devices, and surgical accessories ranging in size from 5 mm to 8 mm.	**SIMILAR** to subject device: Compatible with robotic instruments, imaging devices, and surgical accessories ranging in size from 5 mm to 8 mm.	**NA**
	12 mm Assist Cannula: Compatible with instruments, imaging devices, and surgical accessories ranging in size from 5 mm to 12 mm.	**SIMILAR** to subject device: Compatible with robotic instruments, imaging devices, and surgical accessories ranging in size from 5 mm to 12 mm.	**NA**

Attributes	**Subject Devices** Assist Cannulas (8 mm and 12 mm)	**Predicate Device** 12 mm & Stapler Cannula (K142683)	**Reference Device** 8mm Hex Cannula, Standard (K232610)
Inner Diameter	**8 mm Assist Cannula**: Funnel Opening: 1.179” Tube: 0.380” Tip: 0.354”	**SIMILAR** to subject device Funnel Opening: 1.179” Tube: 0.564” Tip: 0.564”	**SAME** as subject device Funnel Opening: 1.179” Tube: 0.380” Tip: 0.354”
	12 mm Assist Cannula: Funnel Opening: 1.179” Tube: 0.564” Tip: 0.564”	**SAME** as subject device Funnel Opening: 1.179” Tube: 0.564” Tip: 0.564”	**NA**
Overall Length	6.336"	**SAME** as subject device 6.336"	**NA**
Overall Design	**8 mm Assist Cannula:** **Funnel:** Bowl shape **Tube:** Ribbed	**SIMILAR** to subject device **Funnel:** Bowl shape with magnetic fin **Tube:** Smooth	**NA**
	12 mm Assist Cannula: **Funnel**: Bowl shape **Tube:** Ribbed	**SIMILAR** to subject device **Funnel:** Bowl shape with magnetic fin **Tube:** Smooth	**NA**
Tip Design	**8 mm Assist Cannula:** Hexagonal with chisel tip	**SIMILAR** to subject device Round with flat tip	**SAME** as subject device Hexagonal with chisel tip
	12 mm Assist Cannula: Round with chisel tip	**SIMILAR** to subject device Round with flat tip	**NA**
Patient Contact Materials	**Funnel**: 17-4 stainless steel	**SAME** as subject device Funnel: 17-4 stainless steel	**NA**

Attributes	**Subject Devices** Assist Cannulas (8 mm and 12 mm)	**Predicate Device** 12 mm & Stapler Cannula (K142683)	**Reference Device** 8mm Hex Cannula, Standard (K232610)
	Tube: 304 Full Hard stainless steel (patient contacting material)	**SIMILAR** to subject device 465 Carpenter Steel (patient contacting material)	**NA**
Biocompatibility	All materials have been evaluated for biocompatibility per ISO 10993-1	**SAME** as subject device All materials have been evaluated for biocompatibility per ISO 10993-1	**NA**
Sterility	Packaged non-sterile; Steam sterilization	**SAME** as subject device Packaged non-sterile; Steam sterilization	**NA**
Use/Disposition	Reusable	**SAME** as subject device Reusable	**NA**
Packaging	Corrugate insert with retention features, inside a corrugate box	**SAME** as subject device Corrugate insert with retention features, inside a corrugate box	**NA**

VII. Performance Data

The following testing was conducted to demonstrate substantial equivalence to the predicate devices.

Performance testing (bench and animal) demonstrates that the subject devices design output meets the design input requirements and that the devices perform as intended. The testing conducted consisted of dimensional measurements, mechanical and functional verification, and simulated use in animal and cadaver models.

Human Factors evaluation for the subject devices included the following activities:

- Known use-related issues for predicate devices and devices similar to the subject devices were analyzed using post-market data and the MAUDE database. All identified use related issues that are relevant to the use of the subject devices were documented in the risk analysis.
- A Comparative Task Analysis (CTA) was conducted to describe all aspects of the user device interaction, through the breakdown of steps into user tasks, and to provide an analysis of comparison to the predicate for each task.
- A Use-Related Risk Analysis (URRA) was conducted to identify all use-related risks for each user task identified as New or Modified from the predicate in the CTA.
- Formative usability evaluations were conducted during the development process to inform the device user interface design and confirm assessment of use-related risks.

VIII. Conclusion

Based on the intended use, indications for use, technological characteristics, and performance data the subject devices, 8 mm Assist Cannula and 12 mm Assist Cannula are substantially equivalent to the predicate device 12 mm & Stapler Cannula.