December 16, 2025

Intuitive Surgical Inc.
℅ Jyh-Shyan Lin
Senior Regulatory Affairs Specialist
1266 Kifer Road
SUNNYVALE, CA 94086

Re: K251763
Trade/Device Name: IRISeg
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: November 12, 2025
Received: November 13, 2025

Dear Jyh-Shyan Lin:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251763

Device Name
IRISeg

Indications for Use *(Describe)*
IRISeg is intended for use as a software application that receives DICOM compliant MR or contrast-enhanced CT images, provides manual and machine learning-enabled tools for image analysis and segmentation, and creates an output file that can be used to render a 3D model for preoperative surgical planning and intraoperative display. The use of IRISeg may include the generation of preliminary segmentations using machine learning algorithms. IRISeg is intended for use by qualified professionals. The output file is meant for visual, non-diagnostic use and shall be reviewed by clinicians who are responsible for all final patient management decisions.
The machine learning enabled kidney CT auto-segmentation tool is intended for use for adult patients with contrast-enhanced, axial kidney CT images with slice thickness 3mm or less.

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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K251763: 510(k) SUMMARY

This summary of 510(k) substantial equivalence information is submitted in accordance with the requirements of Safe Medical Device Act (SMDA) 1990 and 21 CFR 807.92.

1. SUBMITTER

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact:	Jyh-Shyan (Jesse) Lin Senior Regulatory Affairs Specialist Phone Number: 408-523-4952 Email: jesse.lin@intusurg.com
Date Prepared:	November 12, 2025

2. SUBJECT DEVICE INFORMATION

Manufacturer Name:	Intuitive Surgical, Inc.
510(k) Number:	K251763
Trade Name:	IRISeg
Common Name:	Automated radiological image processing software Medical image processing software
Classification:	Class II 21 CFR 892.2050 Medical image management and processing system
Primary Product Codes:	QIH
Associate Product Code:	LLZ
Review Panel:	Radiology

3. PREDICATE DEVICE INFORMATION

Manufacturer Name:	Intuitive Surgical, Inc.
510(k) Number:	K242461, last cleared on December 10, 2024
Trade Name:	IRISeg
Common Name:	Automated radiological image processing software Medical image processing software
Classification:	Class II 21 CFR 892.2050 Medical image management and processing system
Primary Product Codes:	QIH
Associate Product Code:	LLZ
Review Panel:	Radiology

No reference devices were used in this submission.

4. DEVICE DESCRIPTION

IRISeg is a standalone software application created by Intuitive Surgical for segmentation of CT and **MR** images and generation of output files that can be rendered as virtual 3D models of anatomical structures. IRISeg is designed to provide qualified professionals ("users") with a machine learning (ML)-based tool for auto-segmentation of kidney anatomy based on CT scans and non-ML manual tools for segmentation based on CT and **MR** scans.

*Note that there have been **no changes to existing tools or introductions of new tools** between the predicate and subject devices.*

Input File

IRISeg can open and load CT or **MR** imaging files in DICOM (Digital Imaging and Communications in Medicine) format, and segmentation label files in NIfTI (Neuroimaging Informatics Technology Initiative) format from an accessible storage location.

Output File

Following the use of IRISeg to segment CT or **MR** imaging files, the software can be used to generate an output file that can be used to render virtual segmented 3D models.

IRISeg Manual Tools

IRISeg includes a variety of tools for users to manually edit segmentation labels, such as Paintbrush tools, Eraser tools, Connected Component Selection, Free Curve Selection, Morphological operations, Mathematical Operations.

Manual tools alone can be used to manually segment (annotate) CT and **MR** scans.

Manual tools can also be used to modify the output of the ML-based auto-segmentation algorithm. The ML-based auto-segmentation does not generate mass labels. Users must segment and label renal masses using manual tools.

IRISeg ML-Based Auto-Segmentation Tool

IRISeg includes an ML-based auto-segmentation algorithm (cleared under K242461 and unchanged in the subject device) for automatic segmentation of four kidney structures from CT imaging. The auto-segmentation algorithm is a neural network based ML algorithm. It is trained on segmented kidney CT models that were sourced from clinical data processed during commercial operation of the cleared IRIS 1.0 system (K182643). Each 3D model was reviewed by one U.S board certified radiologist. The input is a CT image (series of 2D slices). The output of the model is four probability maps for kidney parenchyma, kidney artery, kidney vein, and collecting system. The probability maps are thresholded to generate binary masks for kidney parenchyma, kidney artery, kidney vein and collecting system. The ML-based auto-segmentation does not generate binary masks for kidney masses.

The algorithm output is intended as an initial estimate of the segmentation. The user must use the manual tools to update the initial algorithm output to generate the kidney CT 3D model.

The development of the IRISeg kidney CT ML-based auto-segmentation algorithm followed FDA's Good Machine Learning Practices for Medical Device Development: Guiding Principles, October 2021.

5. INTENDED USE/INDICATIONS FOR USE

IRISeg is intended for use as a software application that receives DICOM compliant **MR** or contrast-enhanced CT images, provides manual and machine learning-enabled tools for image analysis and segmentation, and creates an output file that can be used to render a 3D model for preoperative surgical planning and intraoperative display. The use of IRISeg may include the generation of preliminary segmentations using machine learning algorithms. IRISeg is intended for use by qualified professionals. The output file is meant for visual, non-diagnostic use and shall be reviewed by clinicians who are responsible for all final patient management decisions.

The machine learning enabled kidney CT auto-segmentation tool is intended for use for adult patients with contrast-enhanced, axial kidney CT images with slice thickness 3mm or less.

6. SUMMARY OF SUBSTANTIAL EQUIVALENCE

The subject device has been developed as a standalone software application by modifying the predicate device (K242461). The comparison with the predicate device is based on the intended use, indications for use, general design, technological characteristics and operational principle/workflow. A summary of the subject device compared to the predicate device is provided below.

Comparison of Indications for Use and intended Use

<table>
<tr><th>Predicate Device (K242461)</th><th>Subject Device (K251763)</th></tr>
<tr><td rowspan="2">Intended to receive DICOM compliant contrast-enhanced CT images, provide manual and machine learning-enabled tools for image analysis and segmentation, and creates an output file that can be used to render a 3D model for preoperative surgical planning and intraoperative display.</td><td>SAME intended use.</td></tr>
<tr><td>SIMILAR Indications for use:
Added MR indication for image analysis and non-ML manual segmentation of DICOM compliant MR images.</td></tr>
</table>

Comparison of Device Characteristics

Description	Predicate Device (K242461)	Subject Device (K251763)
Regulation Number	21 CFR §892.2050	21 CFR §892.2050
Classification	Class II	Class II
Product Code	Primary: QIH; Associate: LLZ	Primary: QIH; Associate: LLZ
Prescription use	Rx only	Rx only
Host Hardware Compatibility	General-purpose computer hardware	Same
Intended population	Adult patients (ML algorithm)	Same
Intended Users	Qualified Professionals	Same

Description	Predicate Device (K242461)	Subject Device (K251763)
Intended Clinical Decision Support	The output file can be used to render a 3D model for preoperative surgical planning and intraoperative display. The output file is meant for visual, non-diagnostic use and shall be reviewed by clinicians who are responsible for all final patient management decisions.	Same
Configuration	Label names, label color parameters and label name translation for kidney CT scans	Equivalent to the predicate device DIFFERENCE: Updated label names, label color parameters and label name translation for **MR** scans
Principles of Operations / Workflow	Manual segmentation alone Auto-segmentation followed by manual segmentation.	Equivalent to the predicate device DIFFERENCES: Manual segmentation only for **MR** scans
User interface / Environment	Graphical user interface design. Office setting (Segmentation Software Application running on a general-purpose computer)	Same
Supported Input	DICOM-Compliant CT scans (Axial views, contrast enhanced)	Equivalent to the predicate device DIFFERENCES: addition of DICOM compliant **MR** scans
Supported Output	Segmentation files that can be used to render a 3D model for preoperative surgical planning and intraoperative display	Same
Supported Segmentation Structures	Kidney CT structures: • ML auto-segmentation - Parenchyma, Artery, Vein and Collecting System • Manual segmentation - Parenchyma, Artery, Vein, Collecting System and Mass	Same: Kidney CT structures (Manual and ML auto-segmentation) DIFFERENCES (**MR** structures for manual segmentation): -Kidney **MR** structures -Prostate **MR** structures -Rectal **MR** structures

Description	Predicate Device (K242461)	Subject Device (K251763)
ML Auto-Segmentation Structures and performance	4 kidney CT structures: Parenchyma, Artery, Vein and Collecting System Performance: Machine Learning Auto-Segmentation Testing of kidney CT scans.	Same Same
Manual Tools and manual segmentation performance	Various segmentation and selection tools for manual segmentation. Performance: Manual segmentation testing of kidney CT scans	Same Same (kidney CT scans) Equivalent manual segmentation performance for **MR** scans
2D and 3D Visualization Features	Volume rendering, 3D model visualization, 2D slice visualization.	Same
Segmentation Support Features	Metadata viewing	Same

7. RISK MANAGEMENT (SAFETY)

Risk is managed in compliance with ISO 14971, to identify and provide mitigation of potential hazards throughout the software development life cycle (SDLC). Risks related to IRISeg ML-based auto-segmentation algorithm is managed by following the AAMI CR34971 Guidance on the Application of ISO 14971 to Artificial Intelligence and Machine Learning. Clinical risk analysis, usability risk analysis, comparative task analysis, use-related risk analysis, Cybersecurity Risk Analysis, and Risk Assessment of off-The-Shelf Software are conducted, and the risks are mitigated throughout the SDLC.

8. PERFORMANCE DATA (EFFECTIVENESS)

Performance testing of the kidney ML auto-segmentation algorithm was conducted on the predicate device (cleared under K242461). The algorithm was not modified in the subject device, and therefore the performance of the ML algorithm is as effective as in the predicate device.

Final product testing have been performed in accordance with IEC 62304 Edition 1.1 2015-06 Consolidated Version. Software documentation has been provided according to FDA's Guidance, Content of Premarket Submissions for Device Software Functions" (June 14, 2023). IRISeg underwent final product testing. The software testing of the subject device included functional testing, usability testing, and cybersecurity testing. Acceptance criteria were based on the requirements and intended use of IRISeg. Test results showed that all tests met the acceptance criteria. The testing results demonstrate that IRISeg meets design specifications and user needs.

Cybersecurity Testing

The cybersecurity verification and validation testing were conducted, and cybersecurity was evaluated per FDA's Guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" (June 27, 2025). Specifically, addressing the following cybersecurity testing areas: security requirement testing, threat mitigation testing, vulnerability testing, and penetration testing. The cybersecurity verification and validation test results demonstrate the adequacy of the implemented cybersecurity controls.

Labeling

The device labeling contains instructions for use and any necessary cautions to ensure that the labeling differences, as compared to the predicate device, do not affect the safety and effectiveness of the subject device when used as labeled.

Labeling information including the prescription use ("Rx only"), the name and place of business of the manufacturer, device description, indications for use, directions for use, cybersecurity labeling and transparency labeling (per Transparency for Machine Learning-Enabled Medical Devices: Guiding Principles, June 2024) is provided in the subject device's user manual. The UDI (per 21 CFR 801.50 Labeling requirements for standalone software) is provided on the software About screen.

9. CONCLUSION

The subject device and the predicate device are deemed to be substantially equivalent based on indications for use, general design, technological characteristics, operational principle/workflow and performance testing. The subject device raises no new questions related to safety or effectiveness, as compared to the predicate device.