December 10, 2024

Intuitive Surgical Inc.
% Jyh-Shyan (Jesse) Lin
Senior Regulatory Affairs Specialist
1266 Kifer Road
SUNNYVALE, CA 94086

Re: K242461
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: August 19, 2024
Received: August 19, 2024

Dear Jyh-Shyan (Jesse) 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.

Submission Number *(if known)*

K242461

Device Name

IRISeg

Indications for Use *(Describe)*

IRISeg is intended for use as a software application that receives DICOM compliant 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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510(k) SUMMARY

This summary of 510(k) safety and effectiveness 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 Lin Senior Regulatory Affairs Specialist Phone Number: 408-523-4952 Email: jesse.lin@intusurg.com
Date Prepared:	November 15, 2024

2. SUBJECT DEVICE INFORMATION

Manufacturer Name:	Intuitive Surgical, Inc.
510(k) Number:	K242461
Trade Name:	IRISeg
Common Name:	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:	System, Image Processing, Radiological

3. PREDICATE DEVICE INFORMATION

Manufacturer Name:	Intuitive Surgical, Inc.
510(k) Number:	K182643, last cleared on February 22, 2019
Trade Name:	IRIS 1.0 System
Common Name:	Medical image processing software
Classification:	Class II 21 CFR 892.2050 Medical image management and processing system
Product Code:	LLZ
Review Panel:	System, Image Processing, Radiological

No reference devices were used in this submission.

4. DEVICE DESCRIPTION

IRISeg Version 3.1 ("IRISeg") is a standalone software application created by Intuitive Surgical for segmentation of contrast-enhanced kidney CT images and generation of output files that can be rendered as virtual 3D models of kidney organs. IRISeg is designed to provide qualified professionals ("users") with manual and machine learning (ML)-based tools for segmentation of kidney anatomy based on CT scans.

Input File

IRISeg can open and load CT imaging files in DICOM (Digital Imaging and Communications in Medicine) format, and label map files (2D segmented labels) in NIfTI (Neuroimaging Informatics Technology Initiative) format from an accessible storage location.

Output File

Following the use of IRISeg to segment kidney CT imaging files, the software can be used to generate an output file that can be used to render virtual segmented kidney 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.

IRISeg manual tools can be used to modify the output of the ML-based auto-segmentation algorithm or to label structures from scratch without the use of ML-based auto-segmentation. The ML-based auto-segmentation does not generate mass labels. Users must segment and label renal masses with the manual tools.

IRISeg ML-Based Auto-Segmentation Tools

IRISeg includes an ML-based auto-segmentation algorithm 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 3D 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 IRISeg kidney CT ML-based auto-segmentation algorithm follows 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 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 segmentation software application of the predicate device, the IRIS 1.0 System (K182643). 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 segmentation software application (part of the predicate device) is provided below.

Comparison of Indications for Use and intended Use

<table>
<tr><th>Predicate Device (K182643) -
Segmentation Software Application as
part of IRIS 1.0 System</th><th>Subject Device
IRISeg</th></tr>
<tr><td rowspan="2">Intended use for providing tools for image analysis and segmentation of kidney CT images.

The IRIS 1.0 System is intended as a medical imaging system that allows the processing, review, analysis, communication, and media interchange of multi-dimensional digital images acquired from CT imaging devices. It is also intended as software for preoperative surgical planning, and as software for the intraoperative display of the aforementioned multi-dimensional digital images. The IRIS 1.0 System Is designed for use by health care professionals and is intended to assist the clinician who is responsible for making all final patient management decisions.</td><td>SAME intended use.</td></tr>
<tr><td>DIFFERENCE in Indications for use:
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.

IRISeg is intended for use by qualified professionals.</td></tr>
</table>

Comparison of Device Characteristics

Description	Predicate Device (K182643) - IRISeg as part of IRIS 1.0 System	Subject Device IRISeg
Regulation Number	21 CFR §892.2050	21 CFR §892.2050
Classification	Class II	Class II
Product Code	Primary: LLZ	Primary: QIH; Associate: LLZ
Prescription use	Rx only	Rx only
Host Hardware Compatibility	General-purpose computer hardware	General-purpose computer hardware
Intended population	Adult patients	Adult patients
Intended Users	Healthcare Professionals	Qualified Professionals
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.	Equivalent to the predicate device
Principles of Operations / Workflow	Manual segmentation alone Auto-segmentation followed by manual segmentation.	Equivalent to the predicate device
User interface / Environment	Graphical user interface design. Office setting (Segmentation Software Application running on a general-purpose computer)	Equivalent to the predicate device
Supported Input	DICOM-Compliant CT scans Axial views, contrast enhanced	Equivalent to the predicate device
Supported Output	Segmentation files that can be used to render a 3D model for preoperative surgical planning and intraoperative display	Equivalent to the predicate device
Supported Segmentation Structures	5 Kidney CT structures: Parenchyma, Artery, Vein, Collecting System and Mass	Equivalent to the predicate device
ML Auto-Segmentation Structures	5 Kidney CT structures: Parenchyma, Artery, Vein, Collecting System and Mass	4 Kidney CT structures: Parenchyma, Artery, Vein and Collecting System

Description	Predicate Device (K182643) - IRISeg as part of IRIS 1.0 System	Subject Device IRISeg
Manual Tools	Various segmentation and selection tools for manual segmentation.	Equivalent to the predicate device
2D and 3D Visualization Features	Volume rendering, 3D model visualization, 2D slice visualization.	Equivalent to the predicate device
Segmentation Support Features	Metadata viewing	Equivalent to the predicate device

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 data demonstrate that the subject device is substantially equivalent to the segmentation software application in the predicate device IRIS 1.0 System (cleared under K182643), and the design output meets the design input requirements. The performance testing included software verification, machine-learning algorithm performance testing, cybersecurity testing, and design validation testing.

Software Verification and Validation

Software verification and validation 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 software verification and validation testing. The software testing included unit testing, integration testing, functional testing, usability testing, segmentation performance testing, as well as the testing for clinical and usability risks. Acceptance criteria were based on the requirements and intended use of IRISeg. Test results showed that all tests met the acceptance criteria. The software testing results demonstrate the IRISeg meets design specifications and user needs.

Machine Learning Auto-Segmentation Testing

IRISeg includes a ML-enabled kidney CT auto-segmentation algorithm. Intuitive conducted the bench performance testing using clinical kidney CT images to help demonstrate that the proposed device achieved the expected segmentation accuracy performance. Performance testing of the algorithm was

done using clinical kidney CT scans. A total of 81 kidney CT scans were used to evaluate the algorithm. The test dataset did not include more than one imaging study from any particular patient. No imaging study used to verify performance was used for training; independence of training and testing data were enforced at the level of the scanning institution, namely, studies sourced from a specific institution were used for either training or testing but could not be used for both. The data used in testing ensured diversity in patient population, scan parameters and scanner manufacturers. Subgroup analysis was performed to ensure model performance was generalizable.

Performance was evaluated by comparing segmentations generated by the kidney CT machine learning algorithm against segmentations generated by a consensus of three U.S Board Certified Radiologists for the same imaging study. The performance of the machine learning model is characterized by the Sørensen–Dice coefficient (DSC) or the Mean Distance to Agreement (MDA) metric. All testing results are presented on a 95% two-sided t-statistic confidence interval basis. Overall testing results across the entire test dataset are summarized below.

Test Case	Artery DSC	Parenchyma DSC	Vein DSC	Collecting System MDA
Overall Testing (N=81)	[0.87, 0.90]	[0.95, 0.97]	[0.87, 0.89]	[1.3, 1.9]

Overall Testing Results

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" (September, 2023). 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 safe and effective use of IRISeg.

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 IRISeg and the segmentation software application (part of the predicate device, IRIS 1.0 System (K182643)) are deemed to be substantially equivalent based on indications for use, technological characteristics, and performance testing. IRISeg raises no new questions related to safety or effectiveness.