Intuitive Surgical, Inc.
% Ms. Crystal Ong
Sr. Regulatory Engineer
1266 Kifer Road
SUNNYVALE CA 94086

Re: K182643
  Trade/Device Name: IRIS 1.0 System
  Regulation Number: 21 CFR 892.2050
  Regulation Name: Picture archiving and communications system
  Regulatory Class: Class II
  Product Code: LLZ
  Dated: January 18, 2019
  Received: January 22, 2019

Dear Ms. Ong:

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,

Michael D. O'Hara
For
Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure
Indications for Use

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 multidimensional digital images. The IRIS 1.0 System is designed for use by healthcare professionals and is intended to assist the clinician who is responsible for making all final patient management decisions.

Type of Use (Select one or both, as applicable)

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)
510(k) Summary

[As Required by 21 CFR 807.92(c)]

K182643

September 21, 2018

Submitter: Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086

Official Contact: Crystal Ong
Sr. Regulatory Engineer
Ph: 408-523-8636
Fax: 408-523-8907

Trade Name: IRIS 1.0 System

Common Name: Medical Image Processing Software

Classification: Picture archiving and communications system (21 CFR 892.2050), LLZ

Predicate Device: Ceevra Reveal 2.0 (K173274)

Device Description: The IRIS 1.0 System is a software only device that processes medical images and delivers segmented image studies (3D anatomical models) to clinicians. Diagnosis is not performed by the software; the end user (physician) is ultimately responsible for reviewing and interpreting the 3D anatomical models and the original CT study it is based on.

The IRIS 1.0 System will deliver 3D renderings of patient anatomy to the Physician’s iOS device (iPad or iPhone). The physician will be able to view and manipulate the labeled MPRs (multiplanar reconstructions) and the 3D model on their iOS device. The physician also has the option of using the da Vinci® Surgical System TilePro input to display the 3D models in the High Resolution Stereo Viewer (HRSV) via a hardwire connection from the iOS device.

The physician can view and order patient CT studies using the IRIS website or the IRIS iOS interface. The original image study will be anonymized and routed to Intuitive Surgical where image segmentation and quality assurance steps will be performed, before releasing the model to the Physician for review. The Physician can access the 3D Model using the IRIS App on an iOS device, where they will review it, compare it with the original image study, and approve or reject the model.
Another component of the IRIS 1.0 System is the networking and software infrastructure to route the image studies in and out of the hospital, manage ordering information, and manage data in accordance with HIPAA and Cybersecurity requirements. This infrastructure is composed of “Gateway” hardware and software and the cloud storage system used for storage and access of original and segmented image studies.

**Intended Use/Indications for Use:**
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 multidimensional 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.

**Technological Characteristics:** The IRIS 1.0 System is equivalent to the predicate device in terms of its indications for use, design, technology, and performance specifications. Modifications from the predicate include the difference in medical image acceptance (IRIS 1.0 only accepts CT images whereas the predicate uses CT and MR images), difference in mobile device compatibility (IRIS 1.0 is only compatible with iOS devices whereas the predicate can be used with iOS and Android devices) and a difference in alternative viewing platforms (IRIS 1.0 can be connected to the da Vinci Si and Xi surgical systems whereas the predicate can be used with a Virtual Reality headset). The subject device is the same as the predicate for a subset of modalities (CT, iOS devices). These modifications do not affect the substantial equivalence of the subject device as verification and validation testing have established there are no new issues of safety or effectiveness.

**Performance Data:** The IRIS 1.0 System was verified and validated according to a Moderate Level of Concern software device. The subject device met all required specifications and functioned as intended. Safety and performance of the IRIS 1.0 System has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. Additionally, the software validation activities were performed in accordance with IEC 62304:2006/AC: 2015- Medical device software – Software life cycle processes, in addition to the FDA Guidance documents, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”, “Content of Premarket Submission for Management of Cybersecurity in Medical Devices”, and “Display Devices for Diagnostic Radiology; Guidance for Industry and Food and Drug Administration Staff.” In addition, compatibility with the TilePro display was also evaluated and the subject device met all requirements.
Summary: The IRIS 1.0 System raises no new questions of safety or effectiveness. Based on the intended use, technical characteristics, and performance data, the IRIS 1.0 System is equivalent to the predicate device in terms of safety, effectiveness, and performance.