October 20, 2022

Intuitive Surgical Inc.
Melissa Gonzalez
Regulatory Project Manager
1266 Kifer Road
Sunnyvale, California 94086

Re: K222827
Trade/Device Name: da Vinci Firefly Imaging System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: September 14, 2022
Received: September 19, 2022

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 (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/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 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 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,

Mark Trumbore
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

Device Name

da Vinci Firefly Imaging System

Indications for Use *(Describe)*

Upon intravenous administration and use of an ICG drug product consistent with its approved label, the da Vinci Firefly Imaging System is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The da Vinci Firefly Imaging System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near infrared imaging.

Fluorescence imaging of biliary ducts with the da Vinci Firefly Imaging System is intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.

Upon interstitial administration and use of an ICG drug product consistent with its approved label, the da Vinci Firefly Imaging System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

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.

510(k) Summary

Prepared on: 2022-09-16

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Intuitive Surgical, Inc.
Applicant Address	1266 Kifer Road Sunnyvale CA 94086 United States
Applicant Contact Telephone	408-523-8684
Applicant Contact	Mrs. Melissa Gonzalez
Applicant Contact Email	melissa.gonzalez@intusurg.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	da Vinci Firefly Imaging System
Common Name	Endoscope and accessories
Classification Name	System, Surgical, Computer Controlled Instrument
Regulation Number	876.1500
Product Code	NAY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K213710	da Vinci Firefly Imaging System	NAY

Device Description Summary

21 CFR 807.92(a)(4)

The da Vinci Firefly Imaging System provides visualization in two modes: standard, visible-light imaging mode and a near-infrared fluorescence imaging mode, consisting of either a black-and-white surgical image or completely black background with the near-infrared fluorescence depicted in a color overlay. For near-infrared fluorescence imaging, indocyanine green (ICG) fluorescence imaging agent is required.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Upon intravenous administration and use of an ICG drug product consistent with its approved label, the da Vinci Firefly Imaging System is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The da Vinci Firefly Imaging System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct or common hepatic duct), using near infrared imaging.

Fluorescence imaging of biliary ducts with the da Vinci Firefly Imaging System is intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.

Upon interstitial administration and use of an ICG drug product consistent with its approved label, the da Vinci Firefly Imaging System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are unchanged from the previously-cleared versions of the devices.

Technological Comparison

21 CFR 807.92(a)(6)

Imaging Mode and Energy used and/or delivered (Near-Infrared): The subject device has been modified to use an excitation wavelength (785 nm) that targets the center of the allowable absorption spectrum, while maintaining substantially equivalent near-infrared imaging. In terms of imaging modes and energy used and/or delivered, the subject devices are substantially equivalent to the predicate devices.

Labeling: The content in the subject device user manual has been updated to reflect the change from an 805nm laser (predicate) to a 785nm (subject) laser in Table B.1 Warning Label (page 40). There are no other changes to the user manual. The labeling is substantially equivalent to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

To confirm that the change to the subject device does not raise new or different questions of device safety or effectiveness, the following testing activities were required to verify and validate the 785nm Fluorescence System.
- Delta validation testing for the 785nm Fluorescence System with the 8mm Endoscope Plus was limited to the Firefly Clinical Applications test cases. The 785nm Fluorescence Vision System met the acceptance criteria for all of the design requirements and specifications. No issues of safety or effectiveness and no new risks were identified.
- Delta design verification testing was performed with the 785nm Fluorescence System. Verification testing was limited to illumination requirements in Firefly Mode. Additional testing, including white light testing was not required as the white light LED and other components are unchanged compared to the 805nm Fluorescence System most recently cleared under K213710.
- In conjunction with the Design Validation, compatibility testing of the 785nm Fluorescence System with the applicable Endoscopes was tested. The 785nm Fluorescence Vision System and compatible endoscopes met all compatibility acceptance criteria. No issues of safety or effectiveness and no new risks were identified.