August 28, 2025

Intuitive Surgical, Inc.
Connor Mccarty
Technical Lead, Regulatory Affairs
1266 Kifer Road
Sunnyvale, California 94086

Re: K252350
Trade/Device Name: da Vinci SP Firefly Imaging System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: July 28, 2025
Received: July 29, 2025

Dear Connor Mccarty:

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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2025.08.28 08:32:17 -04'00'

Mark Trumbore Ph.D.
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.	K252350

Please provide the device trade name(s).

da Vinci SP Firefly Imaging System

Please provide your Indications for Use below.

The da Vinci SP Firefly Imaging System is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The da Vinci SP 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, using near-infrared imaging.

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) #:

510(k) Summary

Prepared on: 2025-07-28

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	805-798-4205
Applicant Contact	Mr. Connor McCarty
Applicant Contact Email	connor.mccarty@intusurg.com

Device Name

21 CFR 807.92(a)(2)

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

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K250786	da Vinci SP Firefly Imaging System	NAY

Device Description Summary

21 CFR 807.92(a)(4)

The da Vinci SP Firefly Imaging System consists of a near-infrared laser light source located in the Endoscope Controller and a connected endoscope. The Firefly imaging system uses near-infrared light in conjunction with the imaging agent Indocyanine Green (ICG), to create fluorescent images of tissue. ICG is administered to the patient according to its manufacturer's labeling, and the system is switched to Firefly imaging. Two modes are available in Firefly imaging: Standard mode and Sensitive mode. When Firefly is active in Standard mode, the system displays the resulting images as a fluorescent (green) overlay on a gray-scale background image. In Sensitive mode, the gray-scale background is no longer illuminated, resulting in increased sensitivity to fluorescent signal.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The da Vinci SP Firefly Imaging System is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The da Vinci SP 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, using near-infrared imaging.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are identical between the predicate and subject devices.

Technological Comparison

21 CFR 807.92(a)(6)

The changes for the subject da Vinci SP Firefly Imaging System are limited to a new intraoperative fluorescence imaging mode called “Sensitive Firefly”. When the surgeon uses the new, additional imaging mode “Sensitive Firefly”, the endoscope emits only near-infrared light onto the surgical site. This allows the image sensors at the endoscope tip to detect ICG imaging agent in surgical site with greater

sensitivity. However, without the additional blue light, the surgeon can only see the fluorescing ICG and not the tissue which is not infused with ICG. Because the strength of ICG perfusion into the surgical site can be dependent on the anatomy, the additional "Sensitive Firefly" imaging mode is designed to provide the surgeon with an option to visualize ICG in situations where concentrations are relatively low and not easily detected in Standard Firefly mode.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Both the subject and predicate devices underwent software verification testing, bench verification testing of the fluorescence-capable endoscope, and clinical validation testing with an animal model. Verification and validation testing on the subject device confirmed that no issues of safety or effectiveness, analogous to the results of the predicate device verification and validation testing. Therefore, the test results demonstrate that the subject device is substantially equivalent to its predicate device.