May 22, 2026

Intuitive Surgical
Crystal Ong
Technical Lead, Regulatory
1266 Kifer Rd.
Sunnyvale, California 94086

Re: K260695
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, GCJ, IZI
Dated: March 3, 2026
Received: March 3, 2026

Dear Crystal 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 (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.05.22 08:36:19 -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

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)*
K260695

Device Name
da Vinci Firefly Imaging System

Indications for Use *(Describe)*
Fluorescence Imaging Vision System (Firefly Imaging System) Indications for Use:
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 extrahepatic 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.

Upon administration and use of pafolacianine consistent with its approved label, the da Vinci Firefly Imaging System is used to perform intraoperative fluorescence imaging of tissues that have taken up the drug.

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.

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510(k) #:

510(k) Summary

Prepared on: 2026-03-03

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Intuitive Surgical
Applicant Address	1266 Kifer Road Sunnyvale CA 94086 United States
Applicant Contact Telephone	408-523-8636
Applicant Contact	Ms. Crystal Ong
Applicant Contact Email	crystal.ong@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(s)	NAY, GCJ, IZI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K251202	da Vinci Surgical System Model IS5000/Gen5	NAY
K231854	1788 4K Camera System with Advanced Imaging Modality	OWN

Device Description Summary

21 CFR 807.92(a)(4)

The Firefly Imaging System is a subset of hardware and software on the da Vinci 5 Surgical System (Model IS5000). The hardware consists of the Endoscope Controller (EC, also referred to as Endoscope System Controller (ESC)) located on the surgical system Tower, a rigid endoscope (0° or 30°), and two sets of surgical displays (the Console's High Resolution Stereo Viewer (HRSV) and the Tower's upper monitor). The EC provides, control, power, and illumination to the endoscope(s) and communicates with the rest of the da Vinci 5 Surgical System via fiber connections. The EC houses the Light Engine, which provides visible light via individual red, green, and blue LEDs and Near Infra-Red (NIR) illumination via a laser. The LEDs are the primary light sources that illuminate the surgical field via light guides integrated into the endoscope(s).

The software that controls the Firefly Imaging System is part of the da Vinci 5 system software. The software ensures a usable image is displayed as well as allows for user adjustments (e.g., in the form of button or slider selections). The system software, in conjunction with the NIR laser, supports Firefly imaging modes.

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, a fluorescence imaging agent is required.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Fluorescence Imaging Vision System (Firefly Imaging System) Indications for Use:

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 extrahepatic 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.

Upon administration and use of pafolacianine consistent with its approved label, the da Vinci Firefly Imaging System is used to perform intraoperative fluorescence imaging of tissues that have taken up the drug.

Indications for Use Comparison 21 CFR 807.92(a)(5)

Yes, the subject device has the same intended use as the predicate device. Indications have been expanded to include compatibility with a new imaging agent. Pre-clinical data included in this premarket application confirms there are no new or different issues of safety or effectiveness.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device is technologically similar to the predicate device. The subject device is the same or similar in design, intended use,principles of operation, technological characteristics and safety features to the predicate device. The principles of operation are unchanged. The technological difference that is the basis of this submission is limited to compatibility with a new imaging agent, pafolacianine.

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

Benchtop comparative testing and validation in a simulated use setting were used to establish substantial equivalence.