Intuitive Surgical, Inc.
Connor Mccarty
Sr. Regulatory Engineer
1266 Kifer Road
Sunnyvale, California 94086

Re: K212101
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, IZI
Dated: October 22, 2021
Received: October 25, 2021

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 (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 W. Trumbore Ph.D., GWCPM
Acting Assistant Director
THT4A1: Robotically-Assisted Surgical Device Team
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)*

K212101

Device Name

da Vinci SP Firefly Imaging System

Indications for Use *(Describe)*

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.

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.

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510(k) Summary

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	NAY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K210918	da Vinci Firefly Imaging System	NAY

Device Description Summary

21 CFR 807.92(a)(4)

The da Vinci SP Firefly Imaging System is a fully-integrated, adjunct imaging system for the da Vinci SP Surgical System. The da Vinci SP Firefly Imaging System consists of enhanced, existing components of the da Vinci SP Surgical System: the endoscope controller, the endoscope, and supporting software functions. The endoscope controller provides a light source, either visible light or a near-infrared (NIR) excitation laser. The endoscope transmits visible light or NIR light from the endoscope controller to illuminate the surgical site. The near-infrared light is used to fluoresce an intravenously-injected imaging agent, indocyanine green (ICG), which is imaged by the endoscope and displayed at the Surgeon Console.

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 of the subject device are a subset of the indications of the predicate device. The indications for use differ between the subject and predicate device based on the parent device indications for use. The parent da Vinci SP Surgical System indications for use do not include surgical procedures utilizing bile duct imaging, and so this indication for the subject device is not included. The intended use is identical between the predicate and subject devices: both devices are intended to provide real-time endoscopic visible and near-infrared fluorescence imaging.

Technological Comparison 21 CFR 807.92(a)(6)

The technological characteristics of the endoscope controller component of the predicate and subject devices are identical. The parent system software and endoscope components differ between the predicate and subject devices.

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

The da Vinci SP Firefly Imaging System underwent a series of bench tests to verify requirements and risk mitigations. Based on the subject device impact on the parent da Vinci SP Surgical System, bench testing was limited to endoscope design verification, illumination reliability testing, and a human factors evaluation. The da Vinci SP Firefly Imaging System underwent validation testing using an animal model (porcine) to evaluate its safety and effectiveness for use in surgery.

Bench testing and clinical 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.