February 17, 2022

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

Re: K213710
Trade/Device Name: da Vinci Fluorescence Imaging Vision System, 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: November 22, 2021
Received: November 24, 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 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.

510(k) Number *(if known)*
K213710

Device Name
da Vinci® Fluorescence Imaging Vision System and
da Vinci® Firefly Imaging System

Indications for Use *(Describe)*

da Vinci Fluorescence Imaging Vision System

Upon intravenous administration and use of an ICG drug product consistent with its approved label, the da Vinci Fluorescence Imaging Vision System is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The da Vinci Fluorescence Imaging Vision 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 Fluorescence Imaging Vision 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 Fluorescence Imaging Vision System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

da Vinci Firefly Imaging System

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.

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510(k) Summary (21 CFR § 807.92(c))

I: SUBMITTER INFORMATION

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

Contact: Connor McCarty
Senior Regulatory Engineer
Connor.McCarty@intusurg.com
805.798.4205

Date Summary Prepared: January 27, 2022

II: SUBJECT DEVICE INFORMATION

Device Trade Name: *da Vinci®* Fluorescence Imaging Vision System and *da Vinci®* Firefly Imaging System
Common Name: System, Surgical, Computer Controlled Instrument
Classification Name: Endoscope and Accessories (21 CFR §876.1500)
Regulatory Class: II
Product Code: GCJ, NAY, IZI
Submission Type: Traditional 510(k)

III: PREDICATE DEVICE INFORMATION

Predicate Devices: Pinpoint Endoscopic Fluorescence Imaging System (K182606);
da Vinci® Fluorescence Imaging Vision System and
da Vinci® Firefly Imaging System (K210918, cleared on April 26, 2021)

IV: DEVICE DESCRIPTION

The *da Vinci* Fluorescence Imaging Vision System is a fully-integrated, adjunct endoscopic imaging system for the *da Vinci Si* Surgical System. The *da Vinci* Fluorescence Imaging Vision System consists of enhanced, existing components of the *da Vinci Si* Surgical System: 8.5 mm or 12 mm endoscopes (0 degree or 30 degree) optimized for NIR fluorescence imaging, the 3D High-Definition (HD) stereoscopic camera head, the fluorescence-capable illuminator for use with the existing video processor unit (light source), and supporting software functions. There are no changes to the device components from the previously cleared version of the device (K210918).

The *da Vinci* Firefly Imaging System is a fully-integrated, adjunct endoscopic imaging system for *the da Vinci Xi* and *da Vinci X* Surgical Systems. The *da Vinci* Firefly Imaging System consists of enhanced, existing components of the *da Vinci Xi* and *da Vinci X* Surgical Systems: an 8 mm endoscope (0 degree or 30 degree) optimized for NIR fluorescence imaging, the fluorescence-capable Endoscope Controller, and supporting software functions. There are no changes to the device components from the previously cleared version of the device (K210918).

V: INDICATIONS FOR USE

da Vinci Fluorescence Imaging Vision System

Upon intravenous administration and use of an ICG drug product consistent with its approved label, the *da Vinci* Fluorescence Imaging Vision System is intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The *da Vinci* Fluorescence Imaging Vision 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* Fluorescence Imaging Vision 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* Fluorescence Imaging Vision System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

da Vinci Firefly Imaging System

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.

VI: COMPARISON OF SUBJECT AND PREDICATE DEVICES

No modifications are being made to the technological characteristics of the subject devices. This 510(k) is being submitted for a labeling change to add the following to the cleared indications for use statement: “Upon interstitial administration and use of an ICG drug product consistent with its approved label, the *da Vinci* Fluorescence Imaging Vision System and 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.” A comparison of the indications for use and key technological characteristics between the subject and predicate devices is provided in **Tables 1A/1B**.

TABLE 1A: Comparison of Subject and Predicate Devices – Indications for Use

SUBJECT DEVICES: ***da Vinci®* Fluorescence Imaging Vision System and *da Vinci®* Firefly Imaging System**	**PREDICATE DEVICE: (K182606) Pinpoint Endoscopic Fluorescence Imaging System**	**PREDICATE DEVICES: (K210918) *da Vinci®* Fluorescence Imaging Vision System and *da Vinci®* Firefly Imaging System**
Upon intravenous administration and use of an ICG drug product consistent with its approved label, the *da Vinci* Fluorescence Imaging Vision System and the *da Vinci* Firefly Imaging System are intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The *da Vinci* Fluorescence Imaging Vision System and the *da Vinci* Firefly Imaging System enable 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* Fluorescence Imaging Vision System and *da Vinci* Firefly Imaging System are 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* Fluorescence Imaging Vision System and 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 intravenous administration of TRADENAME (ICG Drug Product), the Pinpoint Endoscopic Fluorescence Imaging System is used with TRADENAME to perform intraoperative fluorescence angiography and is also indicated for use in fluorescence imaging of biliary ducts and, when indicated, intraoperative cholangiography. The PINPOINT Endoscopic Fluorescence Imaging System is indicated for use to provide real time endoscopic visible and near-infrared fluorescence imaging. The PINPOINT System enables surgeons to perform minimally invasive surgery using standard endoscope 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 PINPOINT System is intended for use with standard of care white light, and when indicated, intraoperative cholangiography. The devices are not intended for standalone use for biliary duct visualization. Upon interstitial administration of TRADENAME (ICG drug product), the Pinpoint system is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.	The *da Vinci* Fluorescence Imaging Vision System and the *da Vinci* Firefly Imaging System are intended to provide real-time endoscopic visible and near-infrared fluorescence imaging. The *da Vinci* Fluorescence Imaging Vision System and the *da Vinci* Firefly Imaging System enable 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* Fluorescence Imaging Vision System and *da Vinci* Firefly Imaging System are 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.

TABLE 1B: Comparison of Subject and Predicate Devices – Key Technological Characteristics

Attribute	**SUBJECT DEVICES:** ***da Vinci®*** **Fluorescence Imaging Vision System and** ***da Vinci®*** **Firefly Imaging System**	**PREDICATE DEVICE: (K182606) Pinpoint Endoscopic Fluorescence Imaging System**	**PREDICATE DEVICES: (K210918)** ***da Vinci®*** **Fluorescence Imaging Vision System and** ***da Vinci®*** **Firefly Imaging System**
Excitation Wavelength	802 – 805nm	805nm	Identical to subject devices
Excitation Power Density	Compliance with IEC 60825 3R	Compliance with IEC 60825 3R	Identical to subject devices
Scope Diameter	8.5mm, 12mm	5.5mm, 10mm	Identical to subject devices
Scope Length	296.85 - 543.6mm	320 – 423mm	Identical to subject devices
Working Distance	20 - 140mm	7 - 70mm	Identical to subject devices
Field of View	60° - 80°	70° - 75°	Identical to subject devices
Scope Viewing Angle	0°, 30°	0°, 30°, 45°	Identical to subject devices
Sensor Type	3 chip RGB CCD; Front and back side illuminated CMOS HD sensor assembly	CMOS HD sensor assembly	Identical to subject devices
Sensor Resolution	1280 x 1024; 1920 x 1080 output image	1920 x 1080 output image	Identical to subject devices

VII: CONCLUSION

The labeling modification has no impact on the safety or effectiveness of the *da Vinci* Fluorescence Imaging Vision System and *the da Vinci* Firefly Imaging System. As such, the subject devices are substantially equivalent to the predicate devices.