April 26, 2021

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

Re: K210918
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, IZI, GCJ
Dated: March 23, 2021
Received: March 29, 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,

Long Chen, 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

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)*

K210918

Device Name

da Vinci Fluorescence Imaging Vision System;
da Vinci Firefly Imaging System

Indications for Use *(Describe)*

Da Vinci Fluorescence Imaging Vision System:

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.

Da Vinci Firefly Imaging System:

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.

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

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Intuitive Surgical, Inc.
Applicant Address	1266 Kifer Road Sunnyvale CA 94086 United States of America
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 Fluorescence Imaging Vision System; 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
K124031	da Vinci Fluorescence Imaging Vision System	NAY
K141077	da Vinci Firefly Imaging System	NAY

Device Description Summary

21 CFR 807.92(a)(4)

Two subject devices, the da Vinci Fluorescence Imaging Vision System and the da Vinci Firefly Imaging System, are bundled in this submission.

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 being made to the described components from the previously-cleared version of the device (K124031).

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 being made to the described components from the previously-cleared version of the device (K141077).

There are two changes being made between the subject devices and the predicate devices. The two changes are equivalent for both the da Vinci Fluorescence Imaging Vision System and the da Vinci Firefly Imaging System. The first change is that a Fluorescence Imaging Kit

will no longer be included with the subject devices. In the predicate devices, this Fluorescence Imaging Kit includes cross-labeled indocyanine green (ICG) fluorescence imaging agent, aqueous solvent, and syringe trays. Historically, the ICG labeling by itself has not included indications for use with an imaging medical device. Therefore, as a part of the previous 510(k) clearances for the da Vinci Fluorescence Imaging Vision System (K124031) and the da Vinci Firefly Imaging System (K141077), ICG was cross-labeled by Intuitive to include indications for use with the predicate devices. The labeling of the imaging agent ICG (trade name SPY AGENT GREEN), as published on the FDALabel Database, now includes indications for use with a fluorescence imaging device.

The second change is that the user manuals for both devices have been revised. The fluorescence imaging-related content in the subject devices user manuals has been updated to remove references to the Fluorescence Imaging Kit, for consistency with the expanded ICG imaging agent indications for use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Da Vinci Fluorescence Imaging Vision System:

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.

Da Vinci Firefly Imaging System:

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.

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)

The technological characteristics are unchanged from the previously-cleared versions of the devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The information required by this section is not applicable. The changes in this 510(k) are limited to the removal of the Fluorescence Imaging Kit and revised labeling. Based on the risk management assessment of these changes, no design verification or validation testing is required to ensure safe and effective performance of the subject devices.