June 6, 2019

Intuitive Surgical, Inc.
Mr. Manjunath Bisalehalli
Regulatory Affairs Engineer
1266 Kifer Road
Sunnyvale, California 94086

Re: K191043
Trade/Device Name: da Vinci Handheld Camera
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: April 17, 2019
Received: April 19, 2019

Dear Mr. Bisalehalli:

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,

for

Jennifer R. Stevenson
Acting Division Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation & 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191043

Device Name
da Vinci Handheld Camera

Indications for Use *(Describe)*
The da Vinci Handheld Camera is intended for endoscopic viewing of internal surgery sites during minimally invasive surgery. It is designed for use with compatible da Vinci Surgical Systems.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

7 510(k) Summary

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact:	Manjunath Bisalehalli Regulatory Affairs Engineer Phone Number: 408-523-7089 Fax Number: 408-523-8907 Email: Manjun.Bisalehalli@intusurg.com
Date Summary Prepared:	April 17, 2019
Trade Name:	*da Vinci* Handheld Camera
Common Name:	Endoscope and accessories
Classification:	Class II 21 CFR 876.1500, Endoscope and Accessories
Product Codes:	GCJ (Endoscope and accessories)
Classification Advisory Committee:	General and Plastic Surgery
Predicate Device:	Intuitive Surgical Stereo View Endoscopic System (K080155)

Device Description

The *da Vinci* Handheld Camera is a lightweight handheld 2D Camera which can be connected to any third party 5 mm to 10 mm laparoscope to view images on the *da Vinci Xi* Vision cart. The *da Vinci* Handheld Camera consists of the camera head, the light guide, camera connector and the light guide adaptor.

The *da Vinci* Handheld Camera leverages the illuminator, video processor, monitor and video outputs on the *da Vinci Xi* Vision Cart to provide common functions of a laparoscopic video tower. The *da Vinci Xi* Handheld Camera connects to the vision cart in the same way an endoscope does through the endoscope controller. The *da Vinci* Handheld Camera consists of the camera head, endocoupler, cable assembly, light guide, and an adapter. The *da Vinci* Handheld Camera Head Sterilization Tray is intended for use to encase and protect *da Vinci* Handheld Camera Head during sterilization.

Intended Use

The *da Vinci* Handheld Camera is intended for endoscopic viewing of internal surgery sites during minimally invasive surgery. It is designed for use with compatible *da Vinci* Surgical Systems.

Technological Characteristics

The subject device, *da Vinci* Handheld Camera, is technologically very similar to the predicate device, Intuitive Surgical Stereo View Endoscopic System (cleared under K080155). The subject device has the same architecture design, as the predicate except it is a handheld camera.

Performance Data

Performance data (bench and animal testing) demonstrate that the subject device is substantially equivalent to the predicate device and that the design outputs meet the design requirements. The testing includes dimensional measurements, mechanical and functional verification, simulated use in animal model (porcine), and human factors evaluation.

Bench Testing

The subject device, *da Vinci* Handheld Camera, was subjected to a series of bench tests to evaluate the performance and to demonstrate that the design outputs meet the input requirements. The design verification testing assessed the following:

- Physical Specifications
- Mechanical Requirements
- Electrical Requirements
- User Interface Requirements
- Equipment Interface Requirements

Animal Validations

A series of tests were performed using simulated clinical models (animal) to evaluate the performance of the subject device, *da Vinci* Handheld Camera.

Human Factors Evaluation

As part of the Usability Engineering Process for the *da Vinci* Handheld Camera, the Usability Risk Analysis was updated to identify any new usability characteristics related to safety, as well as foreseeable hazards and hazardous situations. Human factors

evaluation was conducted on the *da Vinci* Handheld Camera. Based on the results of those studies, the *da Vinci* Handheld Camera is found to be safe and effective for the intended users, uses, and use environments.

Summary

Based on the intended use, indications for use, technological characteristics, and performance data, the subject device, *da Vinci* Handheld Camera is substantially equivalent to the predicate device, Intuitive Surgical Stereo View Endoscopic System.