August 28, 2024

Intuitive Surgical Operations, Inc.
Heena Khandelwal
Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086

Re: K241913
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: June 28, 2024
Received: July 1, 2024

Dear Heena Khandelwal:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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: 2024.08.28 11:43:09 -04'00'

Mark Trumbore, Ph.D.
Assistant Director, THT4A1: Robotically-Assisted Surgical Devices 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

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.

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510(k) Summary

1. Submitter

510(k) Owner: Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086

Official Contact: Heena Khandelwal
Regulatory Affairs Specialist
Email: heena.khandelwal@intusurg.com

Date Summary Prepared: June 28, 2024

2. Subject Device Information

Manufacturer Name: **Intuitive Surgical, Inc.**

Trade Name: *da Vinci* Handheld Camera

Common Name: Endoscope and accessories

Classification: Class II
21 CFR 876.1500, Endoscope and Accessories

Product Code: GCJ

Review Panel: General and Plastic Surgery

3. Predicate Device Information

Manufacturer Name:	Intuitive Surgical, Inc.
510k Number:	**K191043,** last cleared on June 6, 2019
Trade Name:	*da Vinci* Handheld Camera
Common Name:	Endoscope and accessories
Classification:	Class II 21 CFR 876.1500, Endoscope and Accessories
Product Code:	GCJ
Review Panel:	General and Plastic Surgery

4. 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 compatible *da Vinci* Surgical System Vision cart. The *da Vinci* Handheld Camera consists of the camera head, the light guide, and the light guide adapter. The *da Vinci* Handheld Camera Light Guide is a detachable device that connects to the third party laparoscope via a Handheld Camera Light Guide Adapter and to the *da Vinci* Handheld Camera connector prior to connecting it to the Endoscope controller of compatible *da Vinci* Surgical System. The camera is reusable and is not provided sterile to the users.

The *da Vinci* Handheld Camera connects to a compatible *da Vinci* Surgical System Vision Cart's Endoscope Controller. The *da Vinci* Handheld Camera, Light Guide and Light Guide Adapter are designed for use during optical first entry and laparoscopic tasks during

robotic procedures, prior to docking the compatible *da Vinci* Surgical System patient cart. It is intended to be used by surgeons, circulating nurses (non-sterile user) and scrub nurses (sterile user), in a hospital operating room (OR).

5. Indications for Use/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.

6. Indication for use Comparison:

The indication for use is identical between the predicate and subject device.

7. Technological Comparison with the Predicate Device

The subject da Vinci Handheld Camera device is technologically identical to the predicate, however, only changes are being made to the labeling and da Vinci SP1098 System software user interface to enable compatibility with the subject Handheld camera. There are no changes to the subject device design, material, and fundamental technology.

7. Non-Clinical and/or Clinical Test Summary

Verification and validation testing consisting of design validation, software user interface verification, cybersecurity verification and human factors evaluation, on the subject device confirmed that no issues of safety or effectiveness and no additional unexpected risks were identified. The subject device met the same acceptance criteria as the predicate device. The successful completion of testing demonstrates that the subject device is substantially equivalent to its predicate device.

Animal Validation

In-vivo testing with a live porcine model was used to evaluate the safety and efficacy of the subject Handheld Camera when used with SP Access Port Kit (cleared via K202571) in a representative simulated clinical setting. Live porcine models are appropriate for vision assessments as it is representative with respect to the tissue appearance and behavior. Testing was performed to evaluate various vision parameters of the subject device when used with the SP Access Port Kit during a series of simulated surgical tasks. Design validation activities demonstrated that the design outputs fulfill the user needs and that the intended use have been met.

Bench Verification

The design input, mechanical components, and device features are identical between the subject and predicate Handheld Camera K191043. Therefore, design and Reliability verification was not performed, and test results provided in the predicate submission K191043 remains valid and applies to the subject device.

Cybersecurity Verification

The cybersecurity requirements for the subject *da Vinci* Handheld Camera was modified to include compatibility with the *da Vinci* SP1098 Surgical System. Delta Cybersecurity verification was performed using SP1098 System software version B70_P5 (cleared via K232773) to confirm the subject *device* meet Cybersecurity requirements. There were no modifications to the system software related to Cybersecurity in the scope of this submission. Testing confirmed the subject device meets Cybersecurity requirements and identified no issues of safety or effectiveness and no new risks.

Software User interface verification

SP1098 System software user interface verification was performed to verify compatibility with the subject *da Vinci* Handheld Camera when installed on the *da Vinci* SP Surgical system. Testing was performed on SP1098 System P5 software version (B70_P5) which was cleared in K232773. Testing confirmed that the test article met design inputs as documented in the user interface specification of the *da Vinci* SP Surgical System.

Human Factors

Human Factors Engineering process conducted for the subject devices included the following activities:

- Known use-related issues for predicate devices and devices similar to the subject devices were analyzed using post-market data and the MAUDE database. All identified use-related issues that are relevant to the use of the subject devices were documented in the risk analysis.
- A Comparative Task Analysis (CTA) was conducted to describe all aspects of the user-device interaction, through the breakdown of steps into user tasks, and to provide an analysis of comparison to the predicate for each task.
- A Use-Related Risk Analysis (URRA) was conducted to identify all use-related risks for each user task identified as New or Modified from the predicate in the CTA.
- Formative usability evaluations were conducted during the design development process to modify or identify use-related hazards, develop risk mitigation strategies and refine the device user interface design.

Results from the performance data indicate that the subject *da Vinci* Handheld Camera is substantially equivalent to the predicate *da Vinci* Handheld Camera (K191043).

8. Conclusion

Based on the intended use, indications for use, operating principles, technological characteristics and performance data, the subject *da Vinci* Handheld Camera is substantially equivalent to the predicate device **(K191043).**