September 10, 2024

Intuitive Surgical, Inc.
Kristy Ann Darling
Regulatory Affairs Lead
1266 Kifer Road
Sunnyvale, California 94086

Re: K241638
Trade/Device Name: 8mm SureForm 30 Curved-Tip Stapler; 8mm SureForm 30 Stapler; 8mm SureForm 30 Reloads
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NAY, GDW, GAG
Dated: June 7, 2024
Received: August 13, 2024

Dear Kristy Ann Darling:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2024.09.10 17:11:03 -04'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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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.

510(k) Number *(if known)*
K241638

Device Name
8mm SureForm 30 Curved-Tip Stapler
8mm SureForm 30 Stapler
8mm SureForm 30 Reloads

Indications for Use *(Describe)*
The Intuitive Surgical 8mm SureForm 30 staplers and reloads and accessories are intended to be used with a compatible da Vinci Surgical system for resection and transection of vasculature and tissue and/or creation of anastomoses in General, Thoracic, Gynecologic, Urologic, and Pediatric surgery.

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.

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"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."

510(k) Summary (21 CFR § 807.92)

I. Submitter Information

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact Person:	Kristy Ann Darling, RAC Regulatory Affairs Lead kristyann.darling@intusurg.com +1 (408) 528-2644
Date Summary Prepared:	September 05, 2024

II. Subject Device

Trade Name:	8mm SureForm 30 Curved-Tip Stapler 8mm SureForm 30 Stapler 8mm SureForm 30 Reloads
Common Name:	Stapler, surgical Stapler, implantable System, surgical, computer controlled instrument
Classification:	II
Regulation:	21 CFR 876.1500 Endoscope and Accessories 21 CFR 878.4740 Surgical Stapler 21 CFR 878.4750 Implantable Staple
Product Code:	NAY, Endoscope and Accessories GAG, Stapler, Surgical GDW, Implantable Staple

III. Predicate Device Information

Predicate Devices:	8mm SureForm 30 Curved-Tip Stapler, K211997 & K222839 8mm SureForm 30 Stapler, K211997 & K222839 8mm SureForm 30 Reloads, K211997 & K222839

IV. Device Description

The 8mm SureForm 30 Staplers are fully wristed, articulating, surgical staplers which are designed for use exclusively with a compatible da Vinci Surgical System (herein referred to as "system"). The staplers are controlled by the surgeon using the Surgeon Console of the system. They are intended for resection, transection and/or creation of anastomoses in surgery and achieves its intended use by placing multiple staggered rows of implantable staples in the target tissue (stapling) followed by cutting of the target tissue along the middle of the staple line (transection).

The 8mm SureForm 30 Reloads consist of a single-use cartridge that contains four staggered rows of implantable titanium alloy (Ti3Al2.5V) staples. The implantable staples are provided in various staple leg lengths (Gray, White, Blue) to accommodate various tissue types. **Table 1** outlines the specifications of the reloads.

Table 1: Reload Specifications

Reloads	No. of rows	No. of Staples	Unformed Staple Leg Length (mm)
8mm SureForm 30 Gray Reload	4	34	2.0
8mm SureForm 30 White Reload	4	34	2.5
8mm SureForm 30 Blue Reload	4	34	3.5

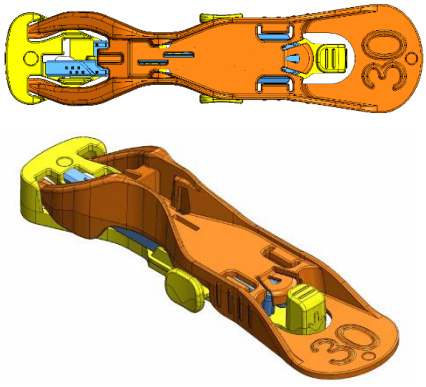
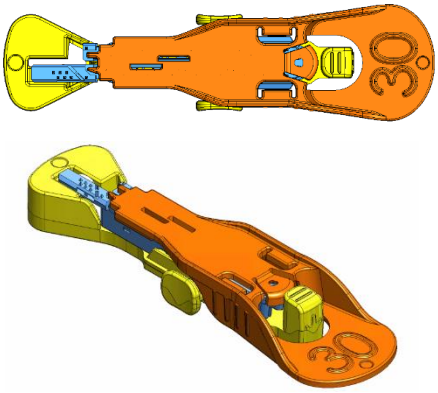
V. Indication for Use

The Intuitive Surgical 8mm SureForm 30 staplers and reloads and accessories are intended to be used with a compatible da Vinci Surgical system for resection and transection of vasculature and tissue and/or creation of anastomoses in General, Thoracic, Gynecologic, Urologic, and Pediatric surgery.

VI. Technological Characteristics

The subject 8mm SureForm 30 Staplers and 8mm SureForm 30 Reloads are very similar to their predicate devices. They have the same intended use, same indication for use, same fundamental scientific technology, and similar technological characteristics as the predicate device. The modifications consist of a new alternate supplier for Tungsten material and corrective actions related to recall number Z-0340-2023. Results from performance data indicate that the 8mm SureForm 30 Staplers and 8mm SureForm 30 Reloads are substantially equivalent to their predicate devices.

8mm SureForm 30 Staplers		
Attributes	**Subject Device** 8mm SureForm 30 Curved-Tip Stapler, 8mm SureForm 30 Stapler	**Predicate Device** 8mm SureForm 30 Curved-Tip Stapler, 8mm SureForm 30 Stapler (K211997 & K222839)
Design	The subject staplers consist of Distal Jaw Assembly, Middle Shaft and Proximal End. Distal Jaw Assembly - modified driver design to improve robustness.	**SIMILAR** to subject device.
Patient Contacting Material	The subject device consists of the same patient contact material, with the exception of the Tungsten material sub-supplier	**SIMILAR** to subject device

8mm SureForm 30 Reloads		
Attributes	**Subject Device** 8mm SureForm 30 Reloads	**Predicate Device** 8mm SureForm 30 Reloads (K211997 & K222839)
Retainer and Bottom Cover	The Retainer and Bottom Cover were redesigned and repurposed into Installation and Removal tools.	The Retainer and Bottom Cover protect the staples during shipping and transportation.
Left: Image of Installation Tool (shown in orange) and Removal Tool (shown in yellow) Right: Image of Retainer (shown in orange) and Bottom Cover (shown in yellow)		
Reload Design	The reload cartridge contains pushers, multiple staggered rows of implantable staples and a stainless-steel component called the switch. Modified switch to reduce friction and improve alignment during reload installation.	**SIMILAR** to subject device.
Packaging	Modified primary packaging dimensions to accommodate new installation and removal tools.	**SIMILAR** to subject device.

8mm SureForm 30 Reloads		
Attributes	**Subject Device** 8mm SureForm 30 Reloads	**Predicate Device** 8mm SureForm 30 Reloads (K211997 & K222839)
Instruction For Use	Added instructions on reload installation and removal. Updated references to align with redesigned and repurposed components: Installation Tool (previously a Retainer) and Removal Tool (previously a Bottom Cover) New and modified warnings	**SIMILAR** to subject device

VII. Performance Data

The subject 8mm SureForm 30 Staplers and 8mm SureForm 30 Reloads underwent a series of tests to evaluate the impact of the modifications made to the predicate devices. Testing was performed with a compatible da Vinci surgical system. Testing included design verification, compatibility verification, transit verification, biocompatibility, design validation, and human factors. The successful completion of testing demonstrated that the subject 8mm SureForm 30 Staplers and 8mm SureForm 30 Reloads design outputs continue to meet design inputs.

Design Verification

Bench testing was performed to verify functional design outputs met the functional design inputs. The design verification in this section addressed the following:

- Mechanical properties such as critical dimensions, mass, materials, and finish
- Mechanical requirements such as range of motion, friction and offset
- Force limits
- Reliability

Transit Verification

Transit testing was performed in accordance with ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems.

Biocompatibility

Biocompatibility testing was completed in accordance with the following standards and guidance documents:

- FDA Guidance: Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process", issued September 2020
- ISO 10993-1:2018 Biological evaluation of medical devices

Design Validation

Simulated clinical use testing was performed to validate that the product specifications continue to meet the user's needs and intended use.

Human Factors

A summative usability study was conducted to assess the use-related risks associated with the device user interface of the 8mm SureForm 30 Staplers and 8mm SureForm 30 Reloads.

VIII. Conclusion

Based on the intended use, technological characteristics, and performance data, the subject 8mm SureForm 30 Staplers and 8mm SureForm 30 Reloads are substantially equivalent to the predicate devices.