December 10, 2021

Intuitive Surgical, Inc.
Amrit Jaggi
Senior Regulatory Specialist
1266 Kifer Road
Sunnyvale, California 94086

Re: K211997
Trade/Device Name: 8 mm SureForm 30 Curved-Tip Stapler, 8 mm SureForm 30 Stapler, SureForm 30 Reloads
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NAY, GDW
Dated: November 5, 2021
Received: November 10, 2021

Dear Amrit Jaggi:

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, Ph.D.
Assistant Director
THT4A1: Robotically-assissted Surgical Devices Team
DHT4A: Division of Sugical Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

6 Form FDA 3881 – Indications for Use statement

There is 1 page in this section following this cover sheet.

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)*
New device

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

Indications for Use *(Describe)*
The Intuitive Surgical 8 mm 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.

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510(k) Summary

[As Required by 21 CFR 807.92(c)]

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

Official Contact: Amrit Jaggi
Senior Regulatory Specialist
Phone Number: 949-690-8799
Fax Number: 408-523-8907

Date Prepared: June 25, 2021

Trade Name: 8 mm SureForm™ 30 Curved-Tip Stapler, 8 mm SureForm 30 Stapler, 8 mm SureForm 30 Reloads

Common Name: System, surgical, computer controlled instrument

Classification: Class II
21 CFR 876.1500, Endoscope and Accessories

21 CRF 878.4750, Implantable Staple

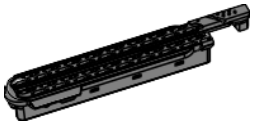
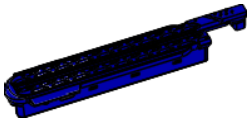
Product Codes: NAY (Endoscope and accessories)
GDW (Implantable Staple)

Predicate Device: SureForm 45 Staplers and Reloads (K190999)

Device Description

The Intuitive Surgical 8 mm SureForm 30 Curved-Tip Stapler and the 8 mm SureForm 30 Stapler are disposable, fully wristed, articulating, surgical staplers and are designed for use exclusively with the Intuitive Surgical da Vinci Xi and X Surgical Systems (Models IS4000 and IS4200 Systems). The staplers are controlled by the surgeon using the Surgeon Console of the IS4000/IS4200 Systems. They are intended for resection, transection and/or creation of anastomoses in surgery. The staplers achieve their 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 8 mm SureForm 30 Reloads consist of a single-use cartridge that contains four staggered rows of implantable titanium alloy (Ti3Al2.5V) staples. The reloads are offered in three configurations (gray, white, and blue). Each color represents a different staple leg height and tissue gap for use with various tissue thicknesses. **Table 1** outlines the specifications of the reloads.

Table 1 8 mm SureForm 30 Reloads Specifications

Attribute	8 mm SureForm 30 Reloads		
	Gray	White	Blue
No. of staple rows and staple line configuration	4 rows total; 2 on each side of the cut line	4 rows total; 2 on each side of the cut line	4 rows total; 2 on each side of the cut line
No. of Staples	34 staples	34 staples	34 staples
Unformed staple leg length	2.0 mm	2.5 mm	3.5 mm
Image			

The reloads are single use devices and are shipped sterile to the surgeon with a retainer and bottom cover that protects the staples during shipping and transportation. The 8 mm SureForm 30 Reloads are not compatible with any other Intuitive Surgical stapler instruments and likewise, the existing Intuitive Surgical stapler reloads are not compatible with the 8 mm SureForm 30 Staplers.

Intended Use

The 8 mm SureForm 30 Staplers and Reloads are intended to resect, transect and/or create anastomoses in surgery.

Indications for Use

The Intuitive Surgical 8 mm 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.

Comparison of Technological Characteristics

The subject device, 8 mm SureForm 30 Staplers and Reloads, and the predicate device, SureForm 45 Staplers and Reloads (K190999) are regulated under the same regulation number, product code, and classification. They have the same intended use, sterility characteristics (EO sterilization), and principles of operation. The subject device, 8 mm SureForm 30 Staplers and Reloads, and the predicate SureForm 45 Staplers and Reloads

differ in some design attributes (the subject device has a narrower diameter and shorter staple line length), indications for use (the subject device is indicated for use on vasculature and tissue), and patient-contacting materials (some same, some different).

Performance Data

Performance test data (bench and animal tests) for the 8 mm SureForm 30 Staplers and Reloads demonstrate that the subject device is substantially equivalent to the predicate device and that the design output meets the design input requirements, user needs, and intended use. The testing is summarized below.

Design Verification (bench):

The 8 mm SureForm 30 Staplers and Reloads were subject to full design verification testing included:

- Physical Specifications
- Mechanical Requirements
- Electrical Requirements
- User Interface Requirements
- Equipment Interface Requirements
- Reliability
- Packaging and labeling

The 8 mm SureForm 30 Staplers and Reloads met all of the bench testing acceptance criteria, demonstrating that that the design output meets the design input requirements.

Design Validation (animal):

A series of acute and chronic clinical validation studies were performed using simulated clinical models (animal) to evaluate the performance of the subject device. Acute clinical validation studies included Staple Line Performance, Hemostasis Testing, Leak Onset Testing, Maximum Torque Evaluation, and Design Validation Testing. Chronic survival studies included Lung Lobectomy Study, Lung Wedge Resection Study, Gastrectomy Study, Small Bowel Anastomosis, and Nephrectomy Study. A side-by-side comparison between the subject and predicate device was performed in the Staple Line Performance, Hemostasis Testing, Leak Onset Testing, Maximum Torque Evaluation, and all Chronic Survival Studies to demonstrate substantial equivalence between the subject and predicate devices. Design Validation Testing demonstrated that the design outputs of the subject device fulfill the design input requirements and that user needs and intended uses are met. A summary of the animal validation studies is provided in **Table 2** below.

Table 2 Summary of Animal Validation Studies

Study Name	Study Purpose	Animal Model	Study Outcome
Acute Testing:			
Staple Line Performance	Assess staple line performance and staple formation of the subject device compared to the predicate	3 canine models 1 porcine model	The subject device met all acceptance criteria and exhibited acceptable pass rates in the areas of transection, tissue layer approximation, hemostasis, and staple formation
Hemostasis	Assess hemostasis performance for the subject device as compared to the predicate device.	2 porcine models	The subject device demonstrated equivalent hemostasis performance to the predicate device.
Leak Onset Pressure	Assess leak onset pressure performance on ex vivo tissue of the subject device as compared to the predicate device.	1 porcine model	All staple lines met all acceptance criteria and exhibited acceptable pass rates in leak onset pressure on thick (stomach) tissue and thin (vein) tissue.
Maximum Torque	Evaluate staple line performance at maximum SmartFire torque limits of the subject device as compared to the predicate device.	2 canine models 1 porcine model	The 8 mm SureForm 30 Stapler and Reloads demonstrated clinically acceptable performance and met all design specifications. The subject device demonstrated equivalent clinical performance when compared to the predicate device in all adjacent fires. No new of issues of safety and efficacy were raised.
Design Validation	Design validation testing of the subject device was performed in a clinical laboratory setting closely approximating an	2 canine models 2 porcine models	The subject device met all acceptance criteria.

Study Name	Study Purpose	Animal Model	Study Outcome
	intraoperative use situation.		
Chronic Testing:			
Lung Lobectomy	Assess subject device performance as compared to the predicate device in a lung lobectomy procedure.	8 canine models	All staple lines passed assessments for leaks intra-operatively. All animals survived through the 28 day + survival period. During the terminal procedures, there were no signs of bleeding or leakage at the staple lines. Staple lines were well-healed at the end of the survival period for both the subject and predicate devices.
Lung Wedge Resection	Assess subject device performance as compared to the predicate device in a lung wedge resection procedure.	8 canine models	All staple lines passed assessments for leaks intra-operatively. All animals survived through the 7 day + survival period. During the terminal procedures, there were no signs of bleeding or leakage at the staple lines. Staple lines were well-healed at the end of the survival period for both the subject and predicate devices.
Small Bowel Anastomosis	Assess subject device performance as compared to the predicate device in a small bowel anastomosis procedure.	8 porcine models	All staple lines passed assessments for leaks intra-operatively. All animals survived through the 14 day + survival period. During the terminal procedures, there were no signs of bleeding or leakage at the staple lines. Staple lines were well-healed at the end of the survival period for

Study Name	Study Purpose	Animal Model	Study Outcome
			both the subject and predicate devices.
Nephrectomy	Assess subject device performance as compared to the predicate device in a nephrectomy procedure.	8 porcine models	All staple lines passed assessments for leaks intra-operatively. All animals survived through the 28 day + survival period. During the terminal procedures, there were no signs of bleeding or leakage at the staple lines. Staple lines were well-healed at the end of the survival period for both the subject and predicate devices.
Gastrectomy	Assess subject device performance as compared to the predicate device in a gastrectomy procedure.	8 canine models	All staple lines passed assessments for leaks intra-operatively. All animals survived through the 14 day + survival period. During the terminal procedures, there were no signs of bleeding or leakage at the staple lines. Staple lines were well-healed at the end of the survival period for both the subject and predicate devices.

Human Factors Evaluation:

As part of the Usability Engineering Process for the 8 mm SureForm 30 Staplers and 8 mm SureForm 30 Reloads, 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 8 mm SureForm 30 Staplers and 8 mm SureForm 30 Reloads. Based on the results of those studies, the 8 mm SureForm 30 Staplers and Reloads has been found to be safe and effective for the intended users, uses, and use environments.

Summary: Based on the indications for use, technological characteristics, and performance data, the subject device, 8 mm SureForm 30 Staplers and Reloads are substantially equivalent to the predicate devices, the SureForm 45 Staplers and SureForm Reloads.