January 18, 2019

Intuitive Surgical
Nadine Nasr
Regulatory Technical Lead
1266 Kifer Road
Sunnyvale, California 94086

Re: K183224
Trade/Device Name: SureForm 45, SureForm 45 Reloads
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: NAY, GDW
Dated: November 19, 2018
Received: November 20, 2018

Dear Nadine Nasr:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K183224

Device Name
SureForm 45 and SureForm 45 Reloads

Indications for Use *(Describe)*
The Intuitive Surgical SureForm 45 Stapler, SureForm 45 Reloads and other stapler accessories are intended to be used with a compatible da Vinci Surgical System for resection, transection, and, or creation of anastomoses in General, Thoracic, Gynecologic, Urologic, and Pediatric surgery. The device can be used with staple line or tissue buttressing material (natural or synthetic).

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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K183224

510(k) Summary

[As Required by 21 CFR 807.92(c)]

November 19, 2018

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

Official Contact: Nadine Nasr
Regulatory Technical Lead
Phone Number: 408-523-7093
Fax Number: 408-523-8907

Trade Name: SureForm 45

Common Name: System, surgical, computer controlled instrument

Classification: Class II
21 CFR 876.1500, Endoscope and Accessories

21 CRF 878.4750, Implantable Staple

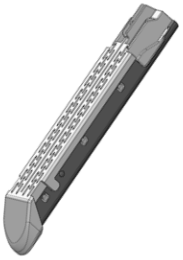
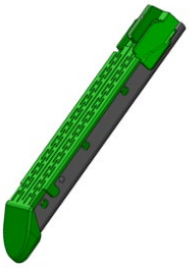
Product Codes: NAY (Endoscope and accessories)
GDW (Implantable Staple)

Predicate Device: SureForm 60 (K173721)

Device Description: The Intuitive Surgical SureForm 45 and SureForm 45 Reloads is a disposable surgical stapler system designed for use exclusively with the Intuitive *da Vinci* Surgical Systems (Models IS4000 and IS4200). It is intended for resection, transection and/or creation of anastomoses in surgery. The instrument achieves its intended use by placing multiple staggered rows of implantable staples in the target tissues (stapling) followed by cutting of the target tissue along the middle of the staple line (transection). The SureForm 45 Stapler Instrument is a disposable, fully wristed articulating device. The SureForm 45 Reloads consist of a single-use cartridge that contains multiple, staggered rows of implantable staples, and a stainless steel knife. As described in **Table 1**, the reloads are available in four

configurations (White, Blue, Green and Black) to accommodate tissues of various thicknesses (e.g., lung, stomach, and bowel).

Table 1: SureForm 45 Reloads Specifications

Attribute	SureForm 45 Reloads			
	White	Blue	Green	Black
No. of staple rows and staple line configuration	6 rows total; 3 on each side of transection; 66 staples total	6 rows total; 3 on each side of transection; 66 staples total	6 rows total; 3 on each side of transection; 66 staples total	6 rows total; 3 on each side of transection; 66 staples total
Unformed staple leg length	2.5 mm	3.5 mm	4.3 mm	4.6 mm
Pictures				

The reloads are single use devices and are shipped sterile to the surgeon with a retainer that protects the staples during shipping and transportation. The SureForm 45 reloads are not compatible with any other Intuitive Surgical stapler instruments (the SureForm 60, IS4000 Stapler 30 and 45 instruments and the IS3000 Stapler 45 instrument), and likewise, the SureForm 60, IS4000 Stapler 30 and 45 reloads and IS3000 Stapler 45 reloads are not compatible with the SureForm 45 instrument.

Indications for Use: The Intuitive Surgical SureForm 45 Stapler, SureForm 45 Reloads and other stapler accessories are intended to be used with a compatible da Vinci Surgical System for resection, transection, and, or creation of anastomoses in General, Thoracic, Gynecologic, Urologic, and Pediatric surgery. The device can be used with staple line or tissue buttressing material (natural or synthetic).

Technological Characteristics: The SureForm 45 System is equivalent to the predicate device (SureForm 60) in terms of its indications for use, design, technology, and performance specifications. Modifications from the predicate are based on a change in the staple line length (45 mm vs. 60 mm). The subject SureForm 45 is the same as the predicate SureForm 60 from a design perspective with the exception of the staple line length itself. The changes to the distal jaw do not substantially change the function of the subject device relative to the function of the predicate device.

Performance Data: The SureForm 45 was evaluated using bench testing and acute *in-vivo* testing (animal model) to demonstrate that the design output meets the input requirements and the device performed as intended.

Design Verification (bench): The subject device, SureForm 45, was subjected to series of bench tests equivalent to those for the predicate device to evaluate performance and to demonstrate that the design outputs meet the design input requirements. Testing was performed with a compatible *da Vinci s*urgical system. The design verification testing included confirmation that the device meets the:

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

Design Validation (animal):

A series of acute clinical validation studies were performed using simulated clinical models (animal) to evaluate the performance of the subject device, SureForm 45 and SureForm 45 Reloads. This included Staple Line Performance, Buttress Material Compatibility Testing, Maximum Torque Evaluation, Design Validation Testing and Burst Pressure Testing. A side-by-side comparison between the subject and predicate device (SureForm 60 and SureForm 60 Reloads) was performed in the Staple Line Performance, Maximum Torque and Burst Pressure Testing to demonstrate substantial equivalence between the subject and predicate device. Buttress Material Compatibility Testing and 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	Type/Number of animals	Study Outcome
Staple Line Performance	Assess staple line performance and staple formation of the subject device compared to the predicate SureForm 60 and SureForm 60 Reloads.	Canine and Porcine (4 Canine, 4 Porcine)	The subject device met all acceptance criteria and exhibited acceptable pass rates in the areas of transection, tissue layer approximation, hemostasis, and staple formation. Wrist angle also had no effect on the quality of staple formation.
Buttress Material Compatibility (Gore, Baxter and Cook)	Confirm the ability of the subject device to produce well-formed staples *in-vivo* as well as a staple line which exhibits clinically acceptable tissue approximation, transection, and hemostasis and not be affected when Gore Seamguard Bioabsorbable Staple Line Reinforcement (510(k) cleared under K053202), Baxter PeriStrip Dry with Veritas Collagen Matrix Staple Line Reinforcement (510(k) cleared under K041669) and Cook Biodesign Staple Line Reinforcement (510(k) cleared under K170945) were used in accordance with the manufacturer's Instructions for Use.	Canine and Porcine (4 Canine, 4 Porcine)	Pass rates in the areas of transection, tissue layer approximation, hemostasis, and optimal staple formation were not adversely affected in a statistically significant manner when buttress material was used in accordance with the manufacturer's Instructions for Use.
Maximum Torque	Evaluate staple line performance at maximum SmartFire torque limits of the subject device as compared to the predicate SureForm 60 and SureForm 60 Reloads.	Canine and Porcine (2 canine, 2 porcine)	The subject device met all acceptance criteria, exhibiting similar tissue effects (tissue approximation and hemostasis) when compared to the adjacent SureForm 60 staple lines. The subject device also met the staple formation acceptance criteria with no more than three sub-optimal staples within each test fire.

Study Name	Study Purpose	Type/Number of animals	Study Outcome
Design Validation	Design validation testing of the subject device was performed in a clinical laboratory setting closely approximating an intraoperative use situation.	Porcine (3 animals)	The subject device met all acceptance criteria.
Burst Pressure (Juglar venous and Stomach)	Assess burst pressure of the subject device as compared to the predicate SureForm 60 and SureForm 60 Reloads.	Porcine (Excised jugular venous and stomach tissue)	The staple lines from the subject device performed substantially equivalent to that of the predicate device. The subject device demonstrated non-inferiority to the predicate SureForm 60 and SureForm 60 Reloads.

Summary: Based on the indications for use, technological characteristics, and performance data, the subject device, SureForm 45 and SureForm 45 Reloads are substantially equivalent to the predicate device, the SureForm 60 and SureForm 60 Reloads.