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July 12, 2019

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

Re: K190999
Trade/Device Name: SureForm 45 Curved Tip, SureForm 45 Gray Reload
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: NAY, GDW
Dated: April 15, 2019
Received: April 16, 2019

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/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,

Long Chen, Ph. D.
Assistant Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190999

Device Name
SureForm 45 Curved Tip and SureForm 45 Gray Reload

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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510(k) Summary

[As Required by 21 CFR 807.92(c)]

K190999

July 12, 2019

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 Curved Tip and SureForm 45 Gray Reload

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 (K183224) - primary

EndoWrist 30 Gray Reload (K170508) - secondary

Device Description: The Intuitive Surgical SureForm 45 Curved Tip and SureForm 45 Gray Reload are an addition to the existing SureForm 45 Stapling System (SureForm 45 and SureForm 45 Reloads – White, Blue, Green and Black) cleared January 18, 2019, K183224) and are designed for use exclusively with compatible 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 Curved Tip Stapler Instrument is a disposable, fully wristed articulating device. The SureForm 45 Gray Reload consists of a single-use cartridge that contains multiple, staggered rows of implantable staples, and a stainless steel knife. The specifications for the SureForm 45 Gray Reload are provided in **Table 1**.

Table 1: SureForm 45 Gray Reload Specifications

Attribute	**Gray Reload**
No. of staple rows and staple line configuration	6 rows total; 3 on each side of transection; 66 staples total
Unformed staple leg length	2.0 mm
Pictures	

The Gray Reload is a single use device and is shipped sterile to the surgeon with a retainer that protects the staples during shipping and transportation. The SureForm 45 Gray reloads, as well as the SureForm 45 White, Blue, Green and Black reloads, are compatible with the SureForm 45 and SureForm 45 Curved Tip instruments. The SureForm 45 Gray, White, Blue, Green and Black 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 and SureForm 45 Curved Tip instruments.

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 Curved Tip and SureForm 45 Gray Reload are an addition to the predicate SureForm 45 Stapler System (SureForm 45 and SureForm 45 White, Blue, Green and Black Reloads, K183224, cleared January 18, 2019). The SureForm 45 Curved Tip is equivalent to the predicate device (SureForm 45) in terms of the indications for use, design, materials, technology, and performance specifications. Modifications from the predicate are based on a change in the distal tip. The subject SureForm 45 Curved Tip is the same as the predicate SureForm 45 from a design perspective with the exception of the of the curved anvil tip feature. The curved anvil tip feature allows the surgeon to better visualize the tip of the instrument and facilitates access around and behind tissues.

The SureForm 45 Gray Reload is a new disposable reload for use with the SureForm 45 Instruments (Straight and Curved Tip anvil configurations). It is an addition to the existing family of SureForm 45 Reloads (White, Blue, Green and Black). It is equivalent to the EndoWrist 30 Gray Reload (K170508, cleared March 10, 2017) in terms of the indications for use, design, technology and performance specifications.

The changes to the distal tip and introduction of a new reload do not substantially change the function of the subject device relative to the function of the predicate devices.

Performance Data: The SureForm 45 Curved Tip and Gray Reload were evaluated using bench testing, acute and chronic *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 Curved Tip and Gray Reload, 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 and chronic clinical validation studies were performed using simulated clinical models (animal) to evaluate the performance of the subject device, SureForm 45 Curved Tip and SureForm 45 Gray Reload. 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 devices (SureForm 45 and EndoWrist 30 Gray Reload) was performed in the Staple Line Performance, Maximum Torque and Burst Pressure Testing to demonstrate substantial equivalence between the subject and predicate devices. 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
Acute Testing:			
Staple Line Performance	Assess staple line performance and staple formation of the subject device compared to the predicate EndoWrist 30 Gray Reload.	Porcine (1 animal)	The subject device met all acceptance criteria and exhibited acceptable pass rates in the areas of transection, tissue layer approximation, hemostasis, and 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.	Porcine (1 animal)	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 SureForm 60 and SureForm 60 White Reloads.	Porcine (1 animal)	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 (1 animal)	The subject device met all acceptance criteria.
Burst Pressure (Juglar venous)	Assess burst pressure of the subject device as compared to the predicate EndoWrist 30 Gray Reload.	Porcine (Excised jugular venous 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 EndoWrist 30 Gray Reload.
Chronic Testing:			
Lung Lobectomy	Assess subject device performance as compared to the EndoWrist 30 Gray Reload in a lung lobectomy procedure.	Canine (8 animals)	All staple lines passed assessment 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 subject and predicate devices.
Nephrectomy	Assess subject device performance as compared to the EndoWrist 30 Gray Reload in a nephrectomy procedure.	Porcine (8 animals)	All staple lines passed assessment for leaks intra-operatively. All animals survived through the 28 day survival period. During the terminal procedure, there were no signs of bleeding at the staple lines, and staple lines were well-healed at the end of the survival period for both the subject and predicate devices.

Summary: Based on the indications for use, technological characteristics, and performance data, the subject device, SureForm 45 Curved Tip and SureForm 45 Gray Reload are substantially equivalent to the predicate devices, the SureForm 45 and SureForm 45 Reloads and the *EndoWrist* 30 Gray Reload.