July 5, 2018

Intuitive Surgical
Nadine Nasr
Senior Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086

Re: K173721
Trade/Device Name: SureForm 60 and SureForm 60 Reloads
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: June 1, 2018
Received: June 4, 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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,

David Krause -S

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)*
K173721

Device Name
SureForm 60 and SureForm 60 Reloads

Indications for Use *(Describe)*
The Intuitive Surgical Stapler SureForm 60, Stapler SureForm 60 reloads, and other stapler accessories are intended to be used with a compatible da Vinci Surgical Systems 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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7 510(k) Summary

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact:	Nadine Nasr Sr. Regulatory Affairs Specialist Phone Number: 408-523-7093 Fax Number: 408-523-8907 Email: nadine.nasr@intusurg.com
Date Summary Prepared:	December 4, 2017
Trade Name:	SureForm 60 and SureForm 60 Reloads
Common Name:	Endoscope and accessories; Surgical Stapler and implantable staples
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)
Classification Advisory Committee:	General and Plastic Surgery
Predicate Device:	1. Primary: IS4000 *EndoWrist*® Stapler 45 and Stapler 45 Reloads – K170508 2. Secondary: Echelon Flex 60 Powered Plus Articulating Endoscopic Linear Cutter, Echelon 60 mm Endoscopic Linear Cutter Reload, PSEE60A (Stapler) GST60X (Reloads) - K140560

Device Description:

The Intuitive Surgical SureForm 60 and SureForm 60 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 60 is a disposable, fully wristed articulating device. The SureForm 60 Reloads consist of a single-use cartridge that contains multiple, staggered rows of implantable staples, and a stainless steel knife. The reloads are available in four configurations (White, Blue, Green and Black) to accommodate tissues of various thicknesses (e.g., lung, stomach, and bowel). 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: SureForm 60 Reloads Specifications

Attribute	**SureForm 60 Reloads**			
	White	**Blue**	**Green**	**Black**
No. of staple rows and staple line configuration	6 rows total; 3 on each side of transection; 90 staples total	6 rows total; 3 on each side of transection; 90 staples total	6 rows total; 3 on each side of transection; 90 staples total	6 rows total; 3 on each side of transection; 90 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 60 reloads are not compatible with any other Intuitive Surgical stapler instruments, the IS4000 Stapler 30 and 45 instruments and the IS3000 Stapler 45 instrument, and likewise, the IS4000 Stapler 30 and 45 reloads and IS3000 Stapler 45 reloads are not compatible with the SureForm 60.

Intended Use:

The Intuitive Surgical SureForm 60, SureForm 60 reloads, and other stapler accessories are intended to be used with a compatible *da Vinci* Surgical Systems 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).

Indications for Use:

The Intuitive Surgical SureForm 60, SureForm 60 Reloads and Accessories are intended to be used with a compatible *da Vinci* Surgical Systems 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 subject devices, SureForm 60 and SureForm 60 Reloads, are technologically very similar to the predicate devices, IS4000 *EndoWrist*® Stapler 45 and Stapler 45 Reloads (cleared under K170508) and the Echelon Flex 60 Powered Plus Articulating Endoscopic Linear Cutter (PSEE60A) and Echelon 60 mm Endoscopic Linear Cutter Reload (GST60X), cleared under K140560. The subject device has the same architecture design as the predicate except for differences like longer staple line length (60 mm on the subject device vs. 45 mm on the predicate), and use of a Black color reload with higher formed staple height.

Performance Data:

Performance data (bench and animal testing) demonstrate that the subject devices are substantially equivalent to the predicate devices and that the design output meets the design input requirements. The testing included dimensional measurements, mechanical and functional verification, simulated use in animal models, and human factors evaluation.

Bench Testing:

The subject devices, SureForm 60 and SureForm 60 Reloads, were subjected to a series of bench tests to evaluate the performance and to demonstrate that the design outputs meet the input requirements. The design verification testing included:

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

Animal Validation Studies:

A series of studies were performed using simulated clinical models (animal) to evaluate the performance of the subject devices, SureForm 60 and SureForm 60 Reloads. This included Animal Survival Studies (Lobectomy, Lung Wedge Resection, Gastrectomy (Canine), Gastrectomy (Small Porcine), Small bowel anastomosis and Nephrectomy (small and large porcine). Additional animal studies including Staple Line Performance, Buttress Material Compatibility Testing, Maximum Torque Evaluation, Design Validation Testing and Burst Pressure Testing were also performed. A side-by-side comparison between the subject and predicate device (Echelon Flex 60 Powered Plus Articulating Endoscopic Linear Cutter (PSEE60A) and Echelon 60 mm Endoscopic Linear Cutter Reload (GST60X)) was performed in the Animal Survival Studies, 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
Animal Survival Study: Lobectomy	Assess subject device performance as compared to the Echelon Flex 60 Powered Plus 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.
Animal Survival Study: Lung Wedge Resection	Assess subject device performance as compared to the Echelon Flex 60 Powered Plus in a lung wedge resection procedure.	Canine (8 animals)	• All staple lines passed assessment 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 test and control devices.
Animal Survival Study: Gastrectomy – canine	Assess subject device performance as compared to the Echelon Flex 60 Powered Plus in a gastrectomy procedure.	Canine (8 animals)	• All subject staple lines passed intra-operative leak tests. 3 predicate staple lines passed intra-operative leak tests. 1 predicate staple line did not pass the intra-operative leak test until a portion of the staple line was oversewn. • All animals survived through the 14 day survival period. During the terminal procedure 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.
Animal Survival Study: Gastrectomy – porcine	Assess subject device performance as compared to the Echelon Flex 60 Powered Plus in a gastrectomy procedure.	Porcine (8 animals)	• All staple lines passed intra-operative leak tests. • All animals survived through the 14 day survival period. During the terminal procedure 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.
Animal Survival Study: Small bowel anastomosis	Assess the performance of the subject device as compared to the Echelon Flex 60 Powered Plus in a small bowel anastomosis procedure.	Porcine (8 animals)	• All staple lines passed visual assessment intra-operatively. • Early death of one of the animals enrolled in the stud occurred. Gross necropsy determined cause of death to be peritonitis with no apparent involvement of the anastomosis sites, and the findings were confirmed by histopathology.

Study Name	Study Purpose	Type/Number of animals	Study Outcome
			• Another animal also expired during the study. Gross necropsy determined cause of death to be peritonitis due to strangulation of small intestine (containing the predicate anastomosis site) through a mesenteric defect. The predicate anastomosis site was confirmed by histopathology to be uninvolved with cause of death and exhibited normal tissue healing similar to staple lines harvested during the scheduled terminal procedures. • The staple lines in the remaining animals passed leak testing after the 14-day survival period. There were no signs of active 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.
Animal Survival Study: Nephrectomy	Assess subject device performance as compared to the Echelon Flex 60 Powered Plus 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.
Staple Line Performance	Assess staple line performance and staple formation of the subject device compared to the Echelon Flex 60 Powered Plus.	Canine and Porcine (4 Canine and 7 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 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) and Cook	Canine and Porcine (1 Canine, 1 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.

Study Name	Study Purpose	Type/Number of animals	Study Outcome
	Biodesign Staple Line Reinforcement (510(k) cleared under K170945) were 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 Echelon Flex 60 Powered Plus.	Porcine (2 animals)	The subject device met all acceptance criteria, exhibiting similar or superior tissue effects (tissue approximation and hemostasis) when compared to the adjacent Echelon Flex 60 Powered Plus staple lines. The subject device also met the staple formation acceptance criteria with no more than three sub-optimal staples within each test fire.
Design Validation	Design validation testing of the subject device was performed in a clinical laboratory setting closely approximating an intraoperative use situation.	Porcine (2 animals)	The subject device met all acceptance criteria.
Burst Pressure	Assess burst pressure of the subject device as compared to the Echelon Flex 60 Powered Plus.	Porcine (Excised tissue and *in-vivo* model - 1 animal)	The staple lines from the subject device performed substantially equivalent to that of the predicate device as there was no statistically significant difference in staple line burst pressures.

Study Name	Study Purpose	Type/Number of animals	Study Outcome
Venous Burst Pressure	Assess jugular porcine venous staple line burst pressure of the subject device as compared to the Echelon Flex 60 Powered Plus.	Excised Porcine Jugular Veins	All jugular vein seals that were burst pressure tested passed the 45mmHg for 10 seconds pressure acceptance criteria with both the subject and predicate devices. The subject device demonstrated non-inferiority to the Echelon Flex 60 Powered Plus.

Human Factors Evaluation:

As part of the Usability Engineering Process for the SureForm 60 and SureForm 60 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 SureForm 60 and SureForm 60 Reloads. Based on the results of those studies, the SureForm 60 has been found to be safe and effective for the intended users, uses, and use environments.

Summary:

Based on the intended use, indications for use, technological characteristics, and performance data, the subject devices, SureForm 60 and SureForm 60 Reloads are substantially equivalent to the predicate devices, the IS4000 *EndoWrist*® Stapler 45 and Stapler 45 Reloads and the Echelon Flex 60 Powered Plus Articulating Endoscopic Linear Cutter (PSEE60A) and Echelon 60 mm Endoscopic Linear Cutter Reload (GST60X).