March 16, 2023

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

Re: K222839
Trade/Device Name: EndoWrist Stapler 30 System, EndoWrist Stapler 45 System, SureForm 45 System, SureForm 60 System, 8 mm SureForm 30 System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NAY, GDW, GAG
Dated: February 22, 2023
Received: February 22, 2023

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 -S

Digitally signed by Mark Trumbore -S
Date: 2023.03.16 15:07:08 -04'00'

Mark Trumbore, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
EndoWrist Stapler 45 System, EndoWrist Stapler 30 System, SureForm 60 System, SureForm 45 System, 8 mm SureForm 30 System

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

The Intuitive Surgical EndoWrist Stapler 30 Instrument and Stapler 30 Reloads are intended to be used with a compatible da Vinci Surgical System for resection, transection and/or creation of anastomoses in General, Thoracic, Gynecologic, and Urologic surgery. The device is indicated for adult and pediatric use. The device can be used with staple line or tissue buttressing material.

The Intuitive Surgical SureForm 60, SureForm 60 Reloads and accessories are intended to be used with a compatible da Vinci 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).

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).

The Intuitive Surgical 8 mm SureForm 30 Curved-Tip and 8 mm SureForm 30 Reloads and accessories are intended to be used with a compatible da Vinci Surgical System for resection, 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.

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5. 510(K) SUMMARY K222839

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: March 13, 2023

Trade Name: EndoWrist ™ Stapler 30 Curved-Tip Stapler, EndoWrist Stapler 30 Stapler, EndoWrist Stapler 30 Reloads
EndoWrist Stapler 45 Stapler, EndoWrist Stapler 45 Curved-Tip Stapler, EndoWrist Stapler 45 Reloads
SureForm™ 45 Stapler Curved-Tip, SureForm 45 Stapler, SureForm 45 Reloads
SureForm 60 Stapler, SureForm 60 Reloads
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
21 CFR 878.4740, Surgical Stapler

Product Codes: NAY (Endoscope and accessories)
GDW (Implantable Staple)
GAG (Stapler, Surgical)

Predicate Device: EndoWrist ™ Stapler 30 Curved-Tip Stapler, EndoWrist Stapler 30 Stapler, EndoWrist Stapler 30 Reloads (K170508)
EndoWrist Stapler 45 Stapler, EndoWrist Stapler 45 Curved-Tip Stapler, EndoWrist Stapler 45 Reloads (K170508)
SureForm 45 Staplers and Reloads (K183224 and K190999)
SureForm 60 Stapler, SureForm 60 Reloads (K173721)
8 mm SureForm 30 Curved-Tip Stapler, 8 mm SureForm 30 Stapler, 8 mm SureForm 30 Reloads (K211997)

Device Description

The Intuitive Surgical EndoWrist Stapler 30 Staplers, EndoWrist Stapler 45 Staplers, SureForm 45 Staplers, SureForm 60 Stapler, and 8 mm SureForm Staplers are 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 Reloads consist of a single-use cartridge that contains multiple staggered rows of implantable titanium alloy (Ti3Al2.5V) staples. The reloads are sterile, single use devices that are offered in various configurations by product family. Each color represents a different staple leg height and tissue gap for use with various tissue thicknesses. **Table 1Reload Specifications** outlines the specifications of the reloads.

Table 1 Reload Specifications

Reloads	No. of rows	No. of Staples	Unformed Staple Leg Length
EndoWrist Stapler 45 White Reload	6 row	66 staples	2.5 mm
EndoWrist Stapler 45 Blue Reload	6 row	66 staples	3.5 mm
EndoWrist Stapler 45 Green Reload	4 row	44 staples	4.3 mm
EndoWrist Stapler 30 Gray Reload	6 row	48 staples	2.0 mm
EndoWrist Stapler 30 White Reload	6 row	48 staples	2.5 mm
EndoWrist Stapler 30 Green Reload	6 row	48 staples	4.3 mm
EndoWrist Stapler 30 Blue Reload	6 row	48 staples	3.5 mm
SureForm 60 White Reload	6 row	90 staples	2.5 mm
SureForm 60 Blue Reload	6 row	90 staples	3.5 mm
SureForm 60 Green Reload	6 row	90 staples	4.3 mm
SureForm 60 Black Reload	6 row	90 staples	4.6 mm
SureForm 45 Gray Reload	6 row	66 staples	2.0 mm
SureForm 45 White Reload	6 row	66 staples	2.5 mm
SureForm 45 Blue Reload	6 row	66 staples	3.5 mm
SureForm 45 Green Reload	6 row	66 staples	4.3 mm
SureForm 45 Black Reload	6 row	66 staples	4.6 mm
8 mm SureForm 30 Gray Reload	4 row	34 staples	2.0 mm
8 mm SureForm 30 White Reload	4 row	34 staples	2.5 mm
8 mm SureForm 30 Blue Reload	4 row	34 staples	3.5 mm

Intended Use:

The EndoWrist Stapler 30 Staplers and Reloads, EndoWrist Stapler 45 Staplers and Reloads, SureForm 45 Staplers and Reloads, SureForm 60 Stapler and Reloads, and 8 mm SureForm 30 Staplers and Reloads all have the identical intended use to resect, transect and/or create anastomoses in surgery.

Indications for Use

The Intuitive Surgical EndoWrist Stapler 45, Stapler 45 Reloads and other Stapler Accessories (including the bladeless obturators) are intended to be used with a compatible da Vinci Surgical System for resection, transection and/or creation of anastomoses in General, Thoracic, Gynecologic and Urologic surgery. The device can be used with staple line or tissue buttressing material (natural or synthetic).

The Intuitive Surgical EndoWrist Stapler 30 Instrument and Stapler 30 Reloads are intended to be used with a compatible da Vinci Surgical System for resection, transection and/or creation of anastomoses in General, Thoracic, Gynecologic, and Urologic surgery. The device is indicated for adult and pediatric use. The device can be used with staple line or tissue buttressing material.

The Intuitive Surgical SureForm 60, SureForm 60 Reloads and accessories are intended to be used with a compatible da Vinci 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).

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).

The Intuitive Surgical 8 mm SureForm 30 Curved-Tip and 8 mm SureForm 30 Reloads and accessories are intended to be used with a compatible da Vinci Surgical System for resection, transection of vasculature and tissue, and/or creation of anastomoses in General, Thoracic, Gynecologic, Urologic, and Pediatric Surgery.

Comparison of Technological Characteristics

The subject devices are identical to their predicate devices in terms of design, technology, and performance specifications.

Performance Data:

Usability testing was conducted to demonstrate that surgeons can correctly select and safely use the device, according to the revised labeling. Testing met all acceptance criteria.

Summary:

The subject of this 510(k) is to add a contraindication to warn users against the use of these devices on tissues that are necrotic, friable, or have altered integrity. Based on the intended

use, indications for use, technological characteristics, and performance data, the subject devices EndoWrist Stapler 30 Staplers and Reloads, EndoWrist Stapler 45 Staplers and Reloads, SureForm 45 Staplers and Reloads, SureForm 60 Staplers and Reloads, and 8 mm SureForm 30 Staplers and Reloads are substantially equivalent to the currently marketed predicate devices.