Intuitive Surgical, Inc.
Gayle Perry
Sr. Regulatory Affairs Engineer
1266 Kifer Road
Sunnyvale, California 94086

Re: K220023
Trade/Device Name: 8mm Monopolar Curved Scissors
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: January 4, 2022
Received: January 5, 2022

Dear Gayle Perry:

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
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
8mm Monopolar Curved Scissors

Indications for Use *(Describe)*
The Intuitive Surgical Endoscopic Instrument Control System (da Vinci Surgical System, Model IS4000) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

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

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact:	Gayle Perry Senior Regulatory Affairs Engineer Cell Number: 650-867-9347 Email: gayle.perry@intusurg.com
Date Summary Prepared:	January 4, 2022
Trade Name:	8mm Monopolar Curved Scissors
Common Name:	Endoscope and accessories
Classification:	Class II 21 CFR 876.1500, Endoscope and Accessories
Product Codes:	NAY
Classification Advisory Committee:	General and Plastic Surgery
Predicate Device:	K131861 – 8mm Monopolar Curved Scissors

Device Description

The Intuitive Surgical *EndoWrist* 8mm Monopolar Curved Scissors instrument is used with the Intuitive Surgical IS4000 *da Vinci Xi* Surgical System or IS4200 *da Vinci X* Surgical System for cutting, cauterizing, coagulation, manipulating and blunt dissection of tissue. The instrument consists of the housing, shaft, wrist, and tip. The shaft and wrist allow for different axes of rotation, and the instrument tip is used to interact with the patient tissue. This instrument is reusable and is provided non-sterile. The instrument is used with a single use tip cover accessory.

Intended Use/Indications for Use:

The EndoWrist Monopolar Curved Scissors is intended to be used with the da Vinci Xi System or the da Vinci X System for endoscopic manipulation of tissue, including: cutting, blunt and sharp dissection, electrocautery.

The Intuitive Surgical Endoscopic Instrument Control System (da Vinci Surgical System, Model IS4000) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and

cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Technological Characteristics:

The subject 8mm Monopolar Curved Scissors is very similar to its predicate device originally cleared under K131861 for use with the IS4000 *da Vinci Xi* System, and subsequently cleared under K171294 for use with the IS4200 *da Vinci X* System. It has the same intended use, same fundamental scientific technology, and similar technological characteristics as the predicate device. The modification to the device consists of a material change to the main tube.

Performance Data:

In accordance with the Design Control process, risk analysis was conducted to evaluate the impact of modification to the predicate device. Design verification and design validation testing were conducted on the subject device to confirm that the design output meets design input requirements and that the device is safe and effective for its intended use.

Design Verification:
The bench testing with the subject device was performed on a *da Vinci* Surgical System. The design verification summarized in this submission verifies mechanical and electrical requirements for the subject instrument, such as:

- instrument reliability and durability,
- leakage,
- electrical safety,
- general and physical requirements to ensure compatibility with the system and tip cover accessory.

Design Validation:
The design validation summarized in this submission validates functional and interaction (compatibility) requirements for the subject device. Design validation addresses how the features of the instrument meet the user needs and intended use as documented in the product requirements document.

Biocompatibility Testing

Biocompatibility tests on the subject device were performed in accordance with ISO 10993-1 and ASTM standards. Based upon the toxicological assessment, the established biocompatibility of the device for its intended clinical use, and the provisions of the current harmonized standard ISO 10993-1:2018, it was determined that the subject device met the requirements of the recognized biocompatibility standards for its intended clinical use.

Summary:

Based on the intended use, indications for use, technological characteristics, performance data, and biocompatibility, the subject 8mm Monopolar Curved Scissors is substantially equivalent to the predicate device.