March 26, 2026

Restore Robotics
Kevin May
Chief Operating Officer
15 Longevity Dr.
Building C
Henderson, Nevada 89014

Re: K252926
Trade/Device Name: Robotic Surgical Instruments - Permanent Cautery Hook (470183); Robotic Surgical Instruments - Permanent Cautery Spatula (470184)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: QSM
Dated: February 13, 2026
Received: February 13, 2026

Dear Kevin May:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 2026.03.26 14:40:15 -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252926

Please provide the device trade name(s).

Robotic Surgical Instruments - Permanent Cautery Hook (470183);
Robotic Surgical Instruments - Permanent Cautery Spatula (470184)

Please provide your Indications for Use below.

The Robotic Surgical Instruments, Permanent Cautery Hook (470183) and Permanent Cautery Spatula (470184), are reusable, non-sterile instruments intended for use with the da Vinci X/Xi Surgical System – Intuitive Surgical, Inc. The Permanent Cautery Spatula and Permanent Cautery Hook are intended to be used with the da Vinci Xi System or the da Vinci X System for precise dissection and division of tissue with monopolar cautery.

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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K252926

510(k) Summary

Prepared on: 2026-02-13

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Restore Robotics
Applicant Address	15 Longevity Dr. Building C Henderson NV 89014 United States
Applicant Contact Telephone	678.619.0011
Applicant Contact	Mr. Kevin May
Applicant Contact Email	kmay@restorerobotics.net

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Robotic Surgical Instruments - Permanent Cautery Hook (470183); Robotic Surgical Instruments - Permanent Cautery Spatula (470184)
Common Name	Robotic Surgical Instruments
Classification Name	Robotic Surgical Instruments
Regulation Number	21 CFR §876.1500
Product Code(s)	QSM, NAY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K131861	da Vinci X Surgical System	NAY
K203632	da Vinci S/Si (IS2000/IS3000) 5mm and 8mm Reusable Instruments, da Vinci Xi/X (IS4000/IS4200) 8mm Reusable Instruments	NAY

Device Description Summary

21 CFR 807.92(a)(4)

The Robotic Surgical Instruments, Permanent Cautery Hook (470183) and Permanent Cautery Spatula (470184), are reusable, non-sterile instruments intended for use with the da Vinci X/Xi Surgical System – Intuitive Surgical, Inc. The Permanent Cautery Spatula and Permanent Cautery Hook are intended to be used with the da Vinci Xi System or the da Vinci X System for precise dissection and division of tissue with monopolar cautery.

Each instrument consists of four primary components: the housing, shaft, wrist, and tip. The shaft and wrist enable multiple axes of articulation, while the tip is designed for direct interaction with tissue. When operated in conjunction with the appropriate robotic system, these instruments provide enhanced dexterity and a greater range of motion than the human hand, facilitating precise tissue manipulation and dissection in minimally invasive procedures.

The remanufactured devices are intended for up to ten (10) additional clinical use cycles beyond the OEM-cleared use life, as supported by validated reprocessing and performance testing. The design, materials, and intended use are identical to the Predicate Device (K131861) in form, fit, and function. The mechanism of action is unchanged and remains based on the same fundamental mechanical architecture and dimensions.

There are no changes to:
- The indications for use

- Clinical applications
- Patient population
- Performance specifications
- Method of operation

In accordance with the Design Control process, a comprehensive risk analysis was conducted to evaluate the impact of remanufacturing. The remanufacturing process includes validated inspection, repair, testing, and cleaning procedures to ensure safety and effectiveness. Design verification and validation activities confirmed that the Subject Devices meet all applicable design input requirements. The following evaluations were performed, or rationales were provided where testing was not required, consistent with applicable standards and FDA guidance:

- Biocompatibility (per ISO 10993)
- Functional performance testing (mechanical and electrical)
- Cleaning validation (including protein, hemoglobin, and TOC residue analysis)
- Electrical safety testing (per IEC 60601-1 and relevant clauses)

Test results support that the remanufactured instruments are as safe and effective as the Predicate Devices and meet all required specifications for intended use.

Additionally, FDA-cleared Reference Device (K203632) is cited to support the validated cleaning and reprocessing methods associated with the proposed ten (10) reuse cycles.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Robotic Surgical Instruments, Permanent Cautery Hook (470183) and Permanent Cautery Spatula (470184), are reusable, non-sterile instruments intended for use with the da Vinci X/Xi Surgical System – Intuitive Surgical, Inc. The Permanent Cautery Spatula and Permanent Cautery Hook are intended to be used with the da Vinci Xi System or the da Vinci X System for precise dissection and division of tissue with monopolar cautery.

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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Subject Devices, Permanent Cautery Hook (470183) and Permanent Cautery Spatula (470184), have the same intended use as the Predicate Device (da Vinci X Surgical System, (K131861). Both are intended for use with the da Vinci X/Xi Surgical System – Intuitive Surgical, Inc. These devices are intended to be used with the da Vinci Xi System or the da Vinci X System for precise dissection and division of tissue with monopolar cautery.

Although the indications for use statements differ in scope, this reflects only the level of description. The Predicate Device describes the surgical system, while the Subject Devices describe the compatible instruments. These differences do not alter the underlying intended use or raise new questions of safety or effectiveness.

The Subject Devices do not introduce any new clinical applications, anatomical targets, user populations, or surgical modalities. Therefore, consistent with 21 CFR 807.92 and FDA's The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications (2014) guidance, these differences in indication wording do not constitute a new or different intended use.

Technological Comparison

21 CFR 807.92(a)(6)

The Subject Devices, Permanent Cautery Hook (470183) and Permanent Cautery Spatula (470184), are identical in design, materials, dimensions, and functional characteristics to the instruments cleared for use with the da Vinci X Surgical System (K131861). Both the

Predicate and Subject Devices enable endoscopic tissue dissection using monopolar electrocautery.

The remanufacturing process does not introduce any new technological characteristics. It restores previously used instruments to their original form, fit, and function through validated inspection, cleaning, repair, and testing procedures. All mechanical, electrical, and performance attributes remain consistent with those of the Predicate Device.

Accordingly, the Subject Devices have the same intended use and technological characteristics as the Predicate Device, and no new questions of safety or effectiveness are raised. The remanufactured Subject Devices perform equivalently to the Predicate Device cleared under K131861, as demonstrated through design verification, cleaning validation, and functional testing.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

In accordance with the Design Control process, a comprehensive risk analysis was conducted to evaluate the impact of remanufacturing. The remanufacturing process includes validated inspection, repair, testing, and cleaning procedures to ensure safety and effectiveness. Design verification and validation activities confirmed that the Subject Devices meet all applicable design input requirements.

The following evaluations were performed, or rationales were provided where testing was not required, consistent with applicable standards and FDA guidance:

- Biocompatibility (per ISO 10993)
- Functional performance testing (mechanical and electrical)
- Cleaning validation (including protein, hemoglobin, and TOC residue analysis)
- Electrical safety testing (per IEC 60601-1 and relevant clauses)

Test results support that the remanufactured instruments are as safe and effective as the Predicate Device(s) and meet all required specifications for intended use.

Additionally, FDA-cleared Reference Device (K203632) is cited to support the validated cleaning and reprocessing methods associated with the proposed ten (10) reuse cycles.