August 19, 2025

Rebotix
% Ryan Burke
Consulting Director
AJW Technology Consultants, Inc.
11705 Boyette Rd #503
Riverview, Florida 33569

Re: K250539
Trade/Device Name: Remanufactured EndoWrist Tenaculum Forceps (420207)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: QSM, NAY
Dated: July 22, 2025
Received: July 22, 2025

Dear Ryan Burke:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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: 2025.08.19 10:31:15 -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250539

Device Name

Remanufactured EndoWrist Tenaculum Forceps (420207)

Indications for Use *(Describe)*

The EndoWrist Tenaculum Forceps instrument is used with the Intuitive Surgical IS2000 da Vinci S Surgical System and the Intuitive Surgical IS3000 da Vinci Si Surgical System for grasping and manipulation of tissue.

The Endoscopic Instrument Control System is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic shears, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, 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, transoral otolaryngology surgical procedures restricted to benign and malignant tumors classified as T1 and T2, and for benign base of tongue resection 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 (except for transoral otolaryngology surgical procedures). 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.

510(k) #: K250539

510(k) Summary

Prepared on: 2025-07-21

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Rebotix
Applicant Address	539 Pasadena Avenue South St. Petersburg FL 33707 United States
Applicant Contact Telephone	727-343-5503
Applicant Contact	Chris Gibson
Applicant Contact Email	Chris@rebotixrepair.com
Correspondent Name	AJW Technology Consultants, Inc.
Correspondent Address	11705 Boyette Rd #503 Riverview FL 33569 United States
Correspondent Contact Telephone	813-645-2855
Correspondent Contact	Mr. Ryan Burke
Correspondent Contact Email	rburke@ajwtech.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Remanufactured EndoWrist Tenaculum Forceps (420207)
Common Name	Endoscope and accessories
Classification Name	System, Surgical, Computer Controlled Instrument, Remanufactured
Regulation Number	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
K203632	420207 Tenaculum Forceps	NAY
K081137	420207 Tenaculum Forceps	NAY
K050369	420207 Tenaculum Forceps	NAY

Device Description Summary

21 CFR 807.92(a)(4)

The subject device is a remanufactured 420207 Tenaculum Forceps with a grasping end effector to be used with the Intuitive Surgical da Vinci Endoscopic Instrument Control System (IS 2000 / IS 3000) for grasping and manipulating tissue during and endoscopic procedure. The mechanism of action and principles of operation for the subject device are identical to the predicate device, as there has been no modification to the mechanical design, materials, or dimensions. There are no changes to the claims, intended use, clinical applications, patient population, or method of operation.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The EndoWrist Tenaculum Forceps instrument is used with the Intuitive Surgical IS2000 da Vinci S Surgical System and the Intuitive Surgical IS3000 da Vinci Si Surgical System for grasping and manipulation of tissue.

The Endoscopic Instrument Control System is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic shears, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, 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, transoral otolaryngology surgical procedures restricted to benign and malignant tumors classified as T1 and T2, and for benign base of tongue resection 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 (except for transoral otolaryngology surgical procedures). 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 indications for use of the remanufactured Tenaculum Forceps is the same as the predicate OEM device.

Technological Comparison 21 CFR 807.92(a)(6)

The remanufactured Tenaculum Forceps have the same technological characteristics including design, material, chemical composition, principle of operation, energy source, performance, and host system compatibility as the predicate OEM device. The use counter has been reset to permit an additional controlled set of uses.

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

The Remanufactured Tenaculum Forceps have the same intended use and technological characteristics as the predicate OEM Tenaculum Forceps. An assessment of hazards that could potentially be introduced by the life extension of the Tenaculum Forceps was performed, along with a risk analysis of the remanufacturing process. Actions taken to address identified risks included life testing to verify device performance and durability through additional uses, electrical safety evaluation (per IEC 60601-1), biocompatibility testing (per ISO 10993-1), reprocessing validation (per OEM instructions), and cybersecurity assessment (per FDA Guidance on Cybersecurity in Medical Devices). The remanufactured EndoWrist ProGrasp Forceps (model: 420093, K241872) was used as a reference for the testing methods.

Based on the detailed comparison of Indications for Use, Technological Characteristics, and Performance Characteristics, it can be concluded that the proposed Remanufactured Tenaculum Forceps is demonstrated to be substantially equivalent to the predicate devices, with no different questions of safety or efficacy having been raised.