March 11, 2025

Iconocare Health
Rick Ferreira
President
7825 East Redfield Rd.
Suite 103
Scottsdale, Arizona 85260

Re: K242610
Trade/Device Name: 8mm Monopolar Curved Scissors (470179)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: QSM, NAY
Dated: February 4, 2025
Received: February 4, 2025

Dear Rick Ferreira:

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: 2025.03.11 10:41:30 -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)*

K242610

Device Name

8mm Monopolar Curved Scissors (470179)

Indications for Use *(Describe)*

The Endo Wrist Monopolar Curved Scissors is intended to be used with the da Vinci Xi System or the da Vinci X Surgical 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 and da Vinci Surgical System, Model IS4200) 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.

510(k) #: K242610

510(k) Summary

Prepared on: 2025-02-03

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Iconocare Health
Applicant Address	7825 East Redfield Rd. Suite 103 Scottsdale AZ 85260 US
Applicant Contact Telephone	480-467-8517
Applicant Contact	Mr. Rick Ferreira
Applicant Contact Email	rferreira@alliancehcpartners.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	8mm Monopolar Curved Scissors (470179)
Common Name	876.1500
Classification Name	System, Surgical, Computer Controlled Instrument, Remanufactured
Regulation Number	21 CFR §876.1500
Product Code(s)	QSM

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K220023	8mm Monopolar Curved Scissors	NAY
K171294	da Vinci X Surgical System	NAY

Device Description Summary

21 CFR 807.92(a)(4)

The da Vinci X/Xi 8 mm monopolar scissors instrument (470179) is used in conjunction with its intended surgical robot for cutting, cauterizing, coagulation, manipulating and blunt dissection of tissue. This instrument consists of the housing, shaft, wrist, and tip. The shaft and wrist allow for different axis 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.

Endo Wrist Instruments are designed to provide surgeons with natural dexterity and a greater range of motion than even the human hand. This allows for greater precision when operating in a minimally invasive environment. EndoWrist instruments, in conjunction with the applicable surgical robot, are designed to support rapid and precise suturing, dissection, and tissue manipulation in surgical procedures.

The design, materials, and intended use of the Reusable Surgical Instruments, after an additional ten (10) reuse cycles, are substantially equivalent to the predicate device in form, fit, and function. The mechanism of action of the reusable device is identical to the predicate device in that the same standard mechanical design, materials, and size are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation.

In accordance with the Design control process, risk analysis was conducted to evaluate the impact of the refurbishment of the predicate device. Design verification and design validation testing were conducted on the subject device to confirm that the design outputs meet the design input requirements and that the device is safe and effective for its intended use. This included the following tests and/or rationale-based evaluations:

- Biocompatibility
- Functional performance testing
- Bioburden, cleaning and bacterial endotoxins
- Electrical safety

The performance testing demonstrates that remanufactured devices are as safe and effective as the predicate device and operate as originally intended. K210478 is a reference device to support the testing methodology

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Endo Wrist Monopolar Curved Scissors is intended to be used with the da Vinci Xi System or the da Vinci X Surgical 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 and da Vinci Surgical System, Model IS4200) 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)

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

Technological Comparison

21 CFR 807.92(a)(6)

The da Vinci Xi system is a multiport robotic surgical system that is designed for a wide spectrum of procedures and specialties. This system is compatible with multiple types of surgical instruments. The subject device is the 8 mm monopolar scissors instrument (470179) and is indicated for 10 cycles of use. The subject process proposed by Iconocare will increase the cycles to 10 through a refurbishment process.

The design, materials, and intended use of Reusable Surgical Instruments, after an additional ten (10) reuse cycles are equivalent to the predicate device. The mechanism of action of the reusable device is identical to the predicate device in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. Each individual device is tested for appropriate function of its components prior to packaging and labeling operations.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

In accordance with the Design Control process, risk analysis was conducted to evaluate the impact of modifications to the predicate device. Design verification and design validation testing were conducted on the subject device to confirm that the design outputs meet design input requirements and that the device is safe and effective for its intended use. This included the following tests:
- Biocompatibility
- Validation of Reprocessing
- Functional Performance Testing
- Electrical Safety Testing

The performance testing demonstrates that reprocessed devices are as safe and effective as the predicate and operate as originally intended.