November 15, 2022

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

Re: K210478
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

Dear Rick Ferreira:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated September 30, 2022. Specifically, FDA is updating this SE Letter as an administrative correction. The original SE letter did not include the 510(k) summary enclosure.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Mark Trumbore, OHT4: Office of Surgical and Infection Control Devices, 301-796-5436, Mark.Trumbore@fda.hhs.gov.

Sincerely,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2022.11.15 14:15:23 -05'00'

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

September 30, 2022

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

Re: K210478
Trade/Device Name: 8mm Monopolar Curved Scissors
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: QSM, NAY
Dated: March 29, 2022
Received: March 31, 2022

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 (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: 2022.09.30 16:32:31 -04'00'

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.

Submission Number *(if known)*

K210478

Device Name

8mm Monopolar Curved Scissors (420179)

Indications for Use *(Describe)*

The EndoWrist 8mm Monopolar Curved Scissors instrument is used with the Intuitive Surgical IS3000 da Vinci Si Surgical System for cutting, cauterizing, coagulation, manipulating and blunt dissection 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 TI 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.

The 8mm Monopolar Scissors of this submission are for use only with the Intuitive Si System (Endoscopic Instrument Control System).

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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Food and Drug Administration
Office of Chief Information Officer
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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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 (420179)
Common Name	Endoscope and accessories
Classification Name	Endoscope and Accessories
Regulation Number	21 CFR §876.1500
Product Code	QSM, NAY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K180033	8mm Monopolar Curved Scissors	NAY
K050369	Intuitive Surgical da Vinci Surgical System and Ednowrist Intrume	NAY
K081137	Intuitive Surgicl da Vinci Si Surgical System	NAY
K123329	Intuitive Surgical® da Vinci®, da Vinci S® and da Vinci Si® Surgi	NAY
K170644	Da Vinci S/Si EndoWrist Instruments And Accessories	NAY

Device Description Summary

21 CFR 807.92(a)(4)

The 8mm Monopolar Curved Scissors Instrument is used with the Intuitive Surgical IS3000 da Vinci Si 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.

8mm Monopolar Curved Scissor 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 8mm Monopolar Curved Scissor Instruments, when used with the IS3000 system, are designed to support rapid and precise suturing, dissection and tissue manipulation in surgical procedures.

Summary of Technological Characteristics:
The design, materials, and intended use of the 8mm Monopolar Curved Scissor Instruments, after an additional ten (10) reuse cycles are equivalent to the predicate device. The mechanism of action of the subject 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, or method of operation. The change in device specifications is to extend the useful life of the 8mm Monopolar Curved Scissor Instruments.

Performance Data:
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.

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

The EndoWrist 8mm Monopolar Curved Scissors instrument is used with the Intuitive Surgical IS3000 da Vinci Si Surgical System for cutting, cauterizing, coagulation, manipulating and blunt dissection 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 TI 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.

The 8mm Monopolar Scissors of this submission are for use only with the Intuitive Si System (Endoscopic Instrument Control System).

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are the same as the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The design, materials, and intended use of the 8mm Monopolar Curved Scissors 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.