November 10, 2025

Medical Microinstruments, Inc.
Zainab Amini
RA US Specialist
Via Egidio Giannessi 54
Pisa, 56121
Italy

Re: K252287
Trade/Device Name: Symani Surgical System
Regulation Number: 21 CFR 878.4963
Regulation Name: Electromechanical System For Open Microsurgery
Regulatory Class: Class II
Product Code: SAQ
Dated: October 9, 2025
Received: October 9, 2025

Dear Zainab Amini:

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: 2025.11.10 09:47:50 -05'00'

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.

510(k) Number *(if known)*
K252287

Device Name
Symani Surgical System

Indications for Use *(Describe)*
The Symani® Surgical System is indicated for soft tissue manipulation in open microsurgical procedures to perform:
• Anastomosis, suturing, and ligation microsurgery techniques on small blood vessels and lymphatic ducts between 0.1 and 2.5mm in open free-flap surgery of the breast, mouth, scalp, and extremities and in open lymphatic surgery of the extremities.
• Dissection of soft tissues.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

I. SUBMITTER INFORMATION

Submitter: MEDICAL MICROINSTRUMENTS, INC.
Via Egidio Giannessi 54
Pisa, IT 56121

Contact : Zainab Amini
(904) 896-6812
Zainab.amini@mmimicro.com

Date: 06 November 2025

II. SUBJECT DEVICE INFORMATION

Device Trade Name: Symani® Surgical System
Classification Name: Electromechanical System For Open Microsurgery (21CFR §878.4963)
Regulatory Class: II
Product Code: SAQ
Submission Type: Traditional 510(k)

III. PREDICATE DEVICE INFORMATION:

Predicate Device: Symani Surgical System, K242368

IV. DEVICE DESCRIPTION

Symani is designed to provide surgeons with increased precision while leveraging the surgeon's own surgical experiences. The Symani Surgical System consists of three components, the CMM, Console, and Instruments, with selectable scaling factors between 7x to 20x to improve motion control and scale down any physiological tremor of the operator in a similar fashion to conventional robotic-assisted surgical device (RASD) systems, and the instruments with wristed end-effectors to improve dexterity for tissue manipulation and suturing. The subject device has the same intended use as the predicate device, K242358. Subject device includes two new NanoWrist instruments, Scissors and Forceps.

V. INDICATIONS FOR USE

The Symani® Surgical System is indicated for soft tissue manipulation in open microsurgical procedures to perform:

- Anastomosis, suturing, and ligation microsurgery techniques on small blood vessels and lymphatic ducts between 0.1 and 2.5 mm in open free-flap surgery of the breast, mouth, scalp, and extremities and in open lymphatic surgery of the extremities.
- Dissection of soft tissues.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological characteristics of the subject and predicate devices are different. The subject devices are indicated for soft tissue dissection. The new NanoWrist Scissors is designed to cut soft tissue, and the NanoWrist Forceps is designed for fine pinching and handling soft tissue.

VII. PERFORMANCE DATA

The following performance tests were conducted and submitted within this submission for a determination of substantial equivalence of the subject device compared to the current Symani Surgical System:

- Software;
- Cybersecurity;
- Instrument performance testing;
- Sterilization and shelf-life verification;
- Animal testing
- Biocompatibility

VIII. CONCLUSION

Based on the information provided within this submission, and comparison of the subject vs. predicate device, the subject device Symani Surgical System has the same intended use and different indications for use, and technological characteristics as the predicate device. The performance testing provided within this submission for the introduction of Symani Surgical System's new Instruments and updated indications for use, have demonstrated that the subject device is as safe and effective as the predicate device, K242368. Therefore, the subject device is deemed to be substantially equivalent to the legally commercialized predicate device.