September 4, 2025

Medical Microinstruments, Inc.
Zainab Amini
Sr. Regulatory Affairs Specialist
Via Egidio Giannessi 54
Pisa, Pisa 56121
Italy

Re: K251510
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: May 15, 2025
Received: May 16, 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: 2025.09.04 10:14:35 -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. | K251510 |

Please provide the device trade name(s).

Symani Surgical System

Please provide your Indications for Use below.

The Symani® Surgical System is intended for soft tissue manipulation 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, extremities, and in open lymphatic surgery of the extremities.

The Symani® Surgical System is indicated for use during microsurgical procedures when use of a motion scaling function is deemed appropriate by the surgeon. The System is indicated for use in adults. It is intended to be used by trained physicians in an appropriate operating environment in accordance with the 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) 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:** September 4, 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 Cart with Macropositioner and Micromanipulators (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 and indications for use as the predicate device, K242358.

The Digital Workstation has been added to list of Symani's accessories for displaying surgical images through the 3D Microscopes connected to the Digital Workstation and the overlay information from Symani GUI (when connected to Symani), using Ultra High Definition (UHD) technology to display high-quality resolution images.

## V. INDICATIONS FOR USE

Symani is intended for soft tissue manipulation 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, extremities, and in open lymphatic surgery of the extremities, and is indicated for use during microsurgery procedures when use of a motion scaling function is deemed appropriate by the surgeon. The Symani® Surgical System is indicated for use during microsurgical procedures when use of a motion scaling function is deemed appropriate by the surgeon. The System is indicated for use in adults. It is intended to be used by trained physicians in an appropriate operating environment in accordance with the Instructions for Use.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The introduction of the digital workstation does not introduce new technological characteristics for the other subsystems (i.e., CMM, Console, and Instruments). The subject device includes the Digital Workstation to be used with Symani.

## 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:

- EMI, EMC, Electrical Safety
- Software;
- Cybersecurity;
- Integration test between Symani and Digital Workstation

The following tests have been performed for the Digital Workstation

- EMI/EMC, Electrical, Mechanical, and Thermal Safety
- Software
- Cybersecurity
- Human Factors Testing

## 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 indications for use as the predicate device. The performance testing provided within this submission for the introduction of Symani Surgical System's new accessory of the Symani Surgical System, is as safe and effective as the predicate device, K242358. Therefore, the subject device is deemed to be substantially equivalent to the legally commercialized predicate device.