July 2, 2025

Mendaera, Inc.
Polly Ma
Clinical Engineering Manager and Regulatory Lead
700 S Claremont St Ste 200
San Mateo, California 94402

Re: K250524
Trade/Device Name: Mendaera Guidance System
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: ITX
Dated: February 21, 2025
Received: June 4, 2025

Dear Polly Ma:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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,

YANNA S. KANG -S

Yanna Kang, Ph.D.
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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)*

K250524

Device Name

Mendaera Guidance System

Indications for Use *(Describe)*

The system provides guidance for precise instrument placement of common interventional devices by positioning the device relative to the ultrasound transducer and the resulting image during a diagnostic or therapeutic procedure. This guidance system is intended for use with pediatric and adult patients.

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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510(k) #: K250524

510(k) Summary

Prepared on: 2025-07-01

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Mendaera, Inc.
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Mendaera Guidance System
Common Name	Diagnostic ultrasonic transducer
Classification Name	Transducer, Ultrasonic, Diagnostic
Regulation Number	892.1570
Product Code(s)	ITX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K160806	Verza Guidance System	ITX

Device Description Summary

21 CFR 807.92(a)(4)

The Mendaera Guidance System is a software-controlled, electromechanical system designed to provide guidance for precise placement of common interventional devices during ultrasound-guided percutaneous procedures. The Mendaera Guidance System is intended to be used in percutaneous procedures with live 2D ultrasound imaging.

The primary components of the Mendaera system are the electromechanical arm (“Robot”), Cart, Drape Kit, and Universal Instrument Guide Kit.

The Robot is a handheld component that attaches to a compatible ultrasound probe and is responsible for establishing and maintaining a deterministic trajectory for the interventional device or needle. The Robot has features that allow for rigid, deterministic coupling between the robot and the probe, and the two are secured together via a locking mechanism.

The Cart includes a touchscreen, a graphical user interface ("GUI") for visualizing the live 2D ultrasound image and overlays, and a computer which runs the Mendaera software.
The Drape Kit contains a sterile drape to act as a barrier between the operator or patient and re-usable components of the system.

The Universal Instrument Guide Kit contains the instrument guide, Universal instrument adapter, and gauge inserts. The Universal instrument adapter enables coupling to interventional instruments ranging from 14G to 25G. The adapter and gauge insert both attach to the instrument guide, which connects to the robot. Movement of the interventional instrument is translated to the robot, and allows for the display of an estimate of the instrument position on the live 2D ultrasound image. Rotational motion of the gauge insert and separation of the instrument adapter enables the instrument guide, robot, and ultrasound probe to be removed while leaving the interventional instrument in place.

The Drape Kit and Universal Instrument Guide Kit are provided in two configurations each:
- Universal Instrument Guide Kits: for compatible instruments in long and short lengths
- Drape Kits: for covering all aspects of the handheld or robot only

The robot and cart are provided non-sterile and are reusable. The contents of the Drape Kit and Universal Instrument Guide Kit are provided sterile and are intended for single-use.

The system is used interoperably with compatible, commercially available ultrasound systems. The system is designed to work in both in-plane (longitudinal) and out-of-plane (transverse) configurations. The list of compatible ultrasound systems and associated probes is:
- EchoNous Kosmos (K212100): Lexsa, Torso-One

The device is for use by a medical professional in a physician office, clinic, or hospital environment.

A predetermined change control plan (PCCP) for claiming interoperability with additional ultrasound systems is submitted with this 510(k) submission. The change is a modification of software related to device compatibility and/or interoperability; no hardware changes are included in the PCCP. The software modifications will be to support the integration of the additional compatible ultrasound system(s), enable connection to the ultrasound probe(s), and to meet interoperability requirements, including those related to risk controls. A subset of interoperability-related requirements will be subjected to repeat verification and validation testing as appropriate, as specified in the PCCP. Those test methods include a combination of testing to FDA-recognized editions of voluntary consensus standards, testing following the recommendations in FDA guidances, and bench testing to demonstrate that the overall functionality of the device can operate as specified by the design input requirements for:
- workflow
- latency
- accuracy
- ultrasound image display
- various functional safety features, and
- other general functionality

The same test methods and acceptance criteria will be applied to testing outlined in the PCCP as those used for the cleared device. Labeling, including the Instructions for Use, will be updated as appropriate to list additional compatible ultrasound systems.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The system provides guidance for precise instrument placement of common interventional devices by positioning the device relative to the ultrasound transducer and the resulting image during a diagnostic or therapeutic procedure. This guidance system is intended for use with pediatric and adult patients.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device has the same indications for use as the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

Both the proposed and predicate (K160806) guidance systems provide a means for placement of common interventional devices by positioning the interventional device relative to the ultrasound transducer during a diagnostic or therapeutic procedure. Technological characteristics that differ between the proposed and predicate guidance systems include changes in design, energization, and principles of operation. Additionally, the predicate device only offers in-plane guidance capabilities, so a guidance system that offers out-of-plane guidance capabilities is used as a reference device (K093713). Both the proposed and predicate systems consist of a guide and gauge inserts, and connect to compatible ultrasound probes. Both proposed and predicate guidance systems offer a range of guidance angles, and in both systems, the angle is created through angular adjustment of the guide. For both devices, the instrument trajectory is shown overlaid on the live ultrasound image, but for the predicate, the user must manually set the guide to a predefined position, and then

select the corresponding position on their OEM ultrasound system in order to display the anticipated trajectory on the screen. The proposed device automatically displays the corresponding instrument trajectory for the chosen guide angle. The gauge inserts for both the predicate and proposed system are placed into the guide and the size is selected to accommodate the size of the interventional instrument. The gauge insert sizes for the predicate system range from 12F to 25G while the proposed system ranges from 14G to 25G. The proposed system may be mounted to the ultrasound transducer via a latching feature whereas the predicate system may mount via a bracket. Both devices are attached to an external locating feature on the transducer and secured using a locking mechanism. Similar plastic and metal materials are used to manufacture the predicate and proposed devices. Both the proposed and predicate systems do not compensate for needle deflection and require a user to manually advance the needle through the insert. The PCCP in the subject device with the proposed modification related to extending compatible ultrasound systems from different manufacturers do not raise different questions of safety and effectiveness from the predicate device.

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

Non-clinical testing was completed to confirm that the Mendaera Guidance System is substantially equivalent to the predicate guidance system and that the differences in technological characteristics do not raise any new issues of safety or effectiveness. Comprehensive testing of the device, including mechanical verification, functional verification, reliability testing, electrical safety, electromagnetic compatibility (EMC), biocompatibility of patient-contacting materials, software verification and validation, pre-clinical animal testing, and simulated-use human factors testing, demonstrate that the design output meets the design input requirements and intended use. The proposed guidance system was validated with the EchoNous Kosmos ultrasound system, using the Lexsa and Torso-One probes.

Biocompatibility Testing
Biocompatibility testing was performed for patient-contacting materials in accordance with the following standards and guidances:
- FDA Guidance: “Use of International Standard ISO-10993, “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process,” June 2016
- ANSI/AAMI/ISO 10993-1
All direct patient-contacting components underwent cytotoxicity, intracutaneous irritation, sensitization, acute systemic toxicity, material-mediated pyrogenicity, and indirect hemolysis testing in accordance to ISO 10993-4, ANSI/AAMI/ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 10993-23. Biocompatibility testing was performed by a third party laboratory in compliance with Good Laboratory Practices (GLP).

Reprocessing/Sterilization/Packaging/Shelf Life Testing
Cleaning, disinfection, sterilization, and packaging/shelf life testing was conducted for the Mendaera Guidance System. Testing was performed in accordance with the following standards and guidances:
- ISO 11135
- ANSI AAMI ISO 11607-1
- ANSI/AAMI ST98
- ASTM F1980-21
- ASTM F2096-11
- ASTM D4322-22
- ASTM D4169-22
- ASTM F88/F88M-23

EMC and Electrical Safety Testing
Electrical Safety and Electromagnetic Compatibility testing was to demonstrate compliance with IEC60601-1, IEC60601-1-2, IEC60601-1-6, IEC TS 60601-4-2, and IEC62366-1.

Software Verification and Validation
Software for the Mendaera Guidance System underwent software verification and validation testing and results demonstrate that the device meets design specifications and user needs. Software documentation has been provided according to FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”. The Software Lifecycle Process was also demonstrated to conform with IEC 62304.

Bench Testing
The Mendaera Guidance System underwent design verification testing and testing verified that the overall functionality of the proposed device can operate as specified by the design input requirements including workflow, latency, accuracy, ultrasound image display, robot controls, various functional safety features, and other general functionality.

Animal Testing
Animal testing was performed to demonstrate the technical feasibility and safety of using the Mendaera Guidance System to accomplish its intended use in a live model. Testing demonstrated the proposed device can be used safely and effectively according to its intended use with no new risks identified. Animal testing was performed in compliance with applicable requirements in the GLP regulation (21 CFR Part 58).

Human Factors Validation

A human factors (HF) engineering process was followed in accordance with the following:

- IEC 62366-1
- FDA Guidance: "Applying Human Factors and Usability Engineering to Medical Devices - Guidance for Industry and Food and Drug Administration Staff"

A Human Factors Validation Study was conducted to evaluate the usability of the device, including the critical tasks associated with the use of the system. Based on the results of the testing, the proposed device has been found to be safe for its intended use by the intended users in the intended environment.

Based on the intended use/indications for use, technological characteristics, and performance testing, the Mendaera Guidance System is substantially equivalent (SE) to the predicate device. This SE determination is based on nonclinical testing demonstrating that the system meets state of the art standards for biocompatibility, sterilization, electrical safety, electromagnetic compatibility, software development and packaging. The bench testing verified that the design specifications and customer requirements have been met. A live animal study demonstrated that the system can be used safely and effectively to accomplish its intended use. Finally, the human factors validation provided further assurance that risks due to user errors have been identified and mitigated. These activities demonstrate that the minor technological differences between the Mendaera Guidance System and its predicate device do not raise different issues of safety or effectiveness.