EM-TECH Solutions, Inc.
Enayatullah Motahedy
Owner/President
25272 Mcintyre Square
Chantilly, Virginia 20152

August 10, 2026

Re: K254143
Trade/Device Name: EM-TECH Passive Ultrasound Probe Strap
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: ITX
Dated: July 7, 2026
Received: July 8, 2026

Dear Enayatullah Motahedy:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Digitally signed by Michael D. O'hara -S
Date: 2026.08.10 14:36:11 -04'00' For

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
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.	K254143

Please provide the device trade name(s).

EM-TECH PASSIVE ULTRASOUND PROBE STRAP

Please provide your Indications for Use below.

The EM-TECH Passive Ultrasound Probe Strap is intended to passively secure an ultrasound transducer against a patient's body during diagnostic ultrasound examinations performed by trained medical professionals. The device is intended for use in adult patients only.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K254143 510(k) Summary

Prepared on: 2026-07-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	EM-TECH SOLUTIONS INC
Applicant Address	25272 MCINTYRE SQUARE CHANTILLY VA 20152 United States
Applicant Contact Telephone	703-342-7125
Applicant Contact	Mr. ENAYATULLAH MOTAHEDY
Applicant Contact Email	EMOTAHEDY@GMAIL.COM

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	EM-TECH PASSIVE ULTRASOUND PROBE STRAP
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
K092164	Transcranial and Vascular Doppler Diagnostic Ultrasound Transducers, Model EMS-9UA	ITX
K994353	Securline Umbilical Disposable Fetal Monitoring Abdominal Straps (reference device only)	HFM

Device Description Summary

21 CFR 807.92(a)(4)

Device Description Summary

The EM-TECH Passive Ultrasound Probe Strap is a non-powered, reusable medical device accessory intended to passively secure an ultrasound transducer against a patient's body during diagnostic ultrasound examinations performed by trained medical professionals. The device is intended for use in adult patients only.

The device consists of an adjustable elastic body strap, a probe holder pocket, and a hook-and-loop fastening system. The elastic strap is wrapped around the patient's body at the desired imaging location and secured to maintain consistent contact pressure between the ultrasound transducer and the patient's skin. The probe holder pocket positions and retains the transducer without interfering with ultrasound transmission.

The trained operator maintains continuous manual control of probe placement, pressure, angulation, coupling, and image acquisition throughout the procedure.

The device operates through purely mechanical means and contains no electronic components, software, firmware, power sources, or energy-delivery mechanisms. All ultrasound signal generation, processing, and display functions are performed by the ultrasound imaging system, which is a separate device not included in this submission.

The EM-TECH Passive Ultrasound Probe Strap contacts intact skin for limited durations and is intended for use in professional clinical environments. The device is reusable and is cleaned and disinfected between uses in accordance with the provided Instructions for Use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The EM-TECH Passive Ultrasound Probe Strap is intended to passively secure an ultrasound transducer against a patient’s body during diagnostic ultrasound examinations performed by trained medical professionals. The device is intended for use in adult patients only.

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

FDA-cleared K092164, Transcranial and Vascular Doppler Diagnostic Ultrasound Transducers, Model EMS-9UA, is the proposed primary predicate under 21 CFR 892.1570. FDA's record lists primary Product Code OQQ with subsequent codes ITX and IYN. K092164 includes the EMS9UA Transcranial Doppler with Robotic Probe Headband; the cleared headband tracks the Doppler signal and mechanically positions its probe during monitoring. The subject device instead provides passive, non-powered transthoracic probe support and does not change the diagnostic ultrasound system's purpose, acoustic output, or imaging performance. K994353, Securline Umbilical Disposable Fetal Monitoring Abdominal Straps, is reference only for stretch-fabric construction and prolonged intact-skin contact; it is not the predicate.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device is a passive, non-powered mechanical accessory with no electronics, software, energy delivery, or acoustic function. It does not generate, transmit, receive, process, or modify ultrasound and does not alter frequency, power, MI/TI, or beam characteristics. K092164 is powered and uses robotic probe positioning for transcranial Doppler monitoring; the subject device is passive and used for transthoracic echocardiography. The submitted performance evidence addresses the subject device's probe retention, coupling, image quality, user handling, and patient tolerance. K994353 is not relied upon as the predicate.

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

Performance and usability feasibility testing was conducted in 27 adult transthoracic echocardiography cases using the GE S70N phased-array transthoracic cardiac probe. Three RDCS echocardiographers with 2 to 20 years of cardiac-echo experience used the device under continuous manual probe control. The evaluation included standard manual/no-strap and strap-assisted image acquisition. Three board-certified cardiologists independently reviewed 225 de-identified image and video clips using a predefined 1-5 image-quality scale, with scores of 3 or higher considered adequate for the intended imaging task. Of the 225 ratings, 216 (96.0%) were scored 3 or higher. No device slippage, fall-off, device malfunction, use error, or manual fallback was documented in the reviewed completed source fields. Nine ratings were below 3 and were addressed through case-specific review, with most occurring in technically difficult studies. No animal testing was conducted or relied upon for this submission. Based on these results, the subject device performs its intended passive stabilization function, and the performance testing supports a conclusion that the device is substantially equivalent to the identified predicate device.