May 5, 2025

Aevice Health Pte. Ltd.
Adrian Ang
Chief Executive Officer
18 Howard Road, #06-11 Novelty Bizcentre
Singapore, 369585
Singapore

Re: K243603
Trade/Device Name: AeviceMD
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH, DQD
Dated: November 21, 2024
Received: April 2, 2025

Dear Adrian Ang:

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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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.

Submission Number *(if known)*

K243603

Device Name

AeviceMD

Indications for Use *(Describe)*

The AeviceMD is a non-invasive battery-operated device, including a wearable component, intended to longitudinally acquire, record and store lung sounds from pediatric patients (aged 3 years and above) in a clinical or non-clinical setting. The device stores the data for later playback, review, and analysis by a clinician and comparison with earlier data from the same patient.

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

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

Aevice Health Pte. Ltd.
18 Howard Road, #06-11 Novelty Bizcentre
Singapore 369585
Tel: +65 90058825
Fax: N/A

Company Contact: Adrian Ang
Chief Executive Officer

Contact Person: Adrian Ang
Chief Executive Officer

Contact Email: adrian@aevice.com

Date Prepared: May 3th, 2025

II. DEVICE

Name of Device: AeviceMD
Classification Name: Recorder, Magnetic Tape, Medical; Stethoscope, Electronic
Regulation: 21 CFR §870.2800
Regulatory Class: Class II
Product Classification Code: DSH; DQD

III. PREDICATE AND REFERENCE DEVICES

Predicate Manufacturer: AeviceMD
Predicate Trade Name: Aevice Health Pte. Ltd.
Predicate 510(k): K223382

Reference Device Manufacturer: Eko Devices, Inc.
Reference Device Trade Name: Eko CORE
Reference Device 510(k): K200776

IV. DEVICE DESCRIPTION

The AeviceMD is designed as an electronic stethoscope to acquire and record lung sounds from users for healthcare professionals (HCP) to playback and interpret the sounds recorded. AeviceMD does not contain any alarm feature and it is not intended for emergency use. It is also not a sleep apnea device. The device is not intended for self-diagnosis.

The AeviceMD consists of hardware and embedded software. It is a five-part system that includes the following components:

1. AeviceMD Sensor – an embedded electronic wearable device that detects and records lung sounds and transmits data to an electronic gateway via Bluetooth.

2. AeviceMD Silicone Patch – silicone patch that houses and attaches the Sensor to the user's body (i.e., chest). This silicone patch undergoes biocompatibility testings which allow AeviceMD Sensor to be worn on the skin.

3. AeviceMD Docking Station – gateway device that serves as a computational hub and linkage from the Sensor to the Cloud Platform, and as a charger for the Sensor.

4. AeviceMD App (for patients) / AeviceMD HCP Web App (for healthcare professionals) - The AeviceMD App is a mobile app that downloads the post-processed information from the Cloud Platform and presents users with their recorded lung sounds at the auscultation locations which they can share with their HCP during their next consultation. A separate app, AeviceMD HCP Web App is tailored for HCP to review their patient's data in a clinical setting.

5. AeviceMD Cloud Platform – secure cloud server that receives data from gateway units and analyzes user's data using meaningful output information.

V. INTENDED USE/ INDICATIONS FOR USE

The AeviceMD is a non-invasive battery-operated device, including a wearable component, intended to longitudinally acquire, record and store lung sounds from pediatric patients (aged 3 years and above) in a clinical or non-clinical setting. The device stores the data for later playback, review, and analysis by a clinician and comparison with earlier data from the same patient.

VI. COMPARISON OF DEVICE CLASSIFICATION CHARACTERISTICS WITH PREDICATE AND REFERENCE DEVICES

The table below includes a comparison of the product code, regulation number, device classification name, intended user (including which data or measurements), and intended use environment among the subject device, the predicate device and the reference device.

Parameter:	Subject Device:	Predicate Device:	Reference Device:

	AeviceMD	AeviceMD (K223382)	Eko CORE (K200776)
Product Code	DSH; DQD	DSH; DQD	DQD
Regulation Number	21 CFR 870.2800	21 CFR 870.2800	21 CFR 870.1875
Device Classification Name	Recorder, Magnetic Tape, Medical; Stethoscope, Electronic	Recorder, Magnetic Tape, Medical; Stethoscope, Electronic	Stethoscope, Electronic
Indications for Use	The AeviceMD is a non-invasive battery-operated device, including a wearable component, intended to longitudinally acquire, record and store lung sound from pediatric patients (aged 3 years and above) in a clinical or non-clinical setting. The device stores the data for later playback, review, and analysis by a clinician and comparison with earlier data from the same patient.	The AeviceMD is a non-invasive battery-operated device, including a wearable component, intended to longitudinally acquire, record and store lung sound from adult patients in a clinical or non-clinical setting. The device stores the data for later playback, review, and analysis by a clinician and comparison with earlier data from the same patient.	The Eko CORE is an electronic stethoscope that enables amplification, filtering, and transmission of auscultation sound data (heart, lungs, bowel, arteries, and veins), whereby a clinician at one location on network can listen to the auscultation sounds of a patient on site or at a different location on the network. Eko CORE is intended for use on pediatric and adult patients. The Eko CORE is intended to be used by professional users in a clinical environment or by lay users in a nonclinical environment. The device is not intended for self-diagnosis.
Intended User	Pediatrics only	Adults only	Adults and pediatrics
Intended Use Environment	Clinical and Non-clinical Setting	Clinical and Non-clinical Setting	Clinical and Non-clinical Setting
User Interface	Mobile App Web Portal (For HCP)	Mobile App Web Portal (For HCP)	Mobile App Web Portal (Mentioned on their website for HCP)

Record and Playback Sounds	Yes	Yes	Yes
Data Transfer to Compatible Computing platform	Yes	Yes	Yes
Condition of Use	Reusable	Reusable	Reusable
Rx or OTC	Prescription Only	Prescription Only	Over-the-Counter
Wearable	Yes	Yes	No

Table 1. Comparison of Device Classification Characteristics with Predicate and Reference Devices

Summary of Subject Device Comparison to predicate and reference device

The predicate device and reference device were chosen for the comparison to the subject device as it also longitudinally acquires sounds and allows recording and playback. The subject device identifies as an electronic stethoscope as the auscultation locations consist of the anterior body where a manual stethoscope would be placed during a consultation. These locations are supported by the cleared primary predicate and reference device.

Summary of Technological Characteristics

The AeviceMD has very similar technological characteristics compared to predicate and reference devices. All three devices have the same frequency range and can connect to mobile applications for recording and sharing data with HCP.

Non-Clinical Performance Data

The subject device was subject to non-clinical performance testing. There are no device-specific special control documents/ regulations that apply to the subject device. A list of the standards, guidance and additional testings for the device is listed below:

- ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
- IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 +A1:2012 (or IEC 60601-1: 2012 reprint)
- EN 60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-11: 2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

- IEC 60601-1-6:2010- Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- ANSI AAMI IEC 62366- 1:2015+AMD1:2020(Consolidated Text) Medical devices — Part 1: Application of usability engineering to medical devices
- ANSI AAMI IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes [Including Amendment 1 (2016)] ISO 14971:2019 Medical devices - Applications of risk management to medical devices
- Additional testing: - Non-clinical Frequency Response Test
  - Stethoscope Performance Test against a 510(k) cleared reference stethoscope
  - Human Factors Usability
  - Shipping Validation Test according to ASTM D4169-16
  - Cleaning Validation Testing

VII. CONCLUSIONS

The conclusions drawn from the non-clinical tests demonstrate that the proposed subject device is substantially equivalent to the legally marketed predicate device. The reference device was used to demonstrate effective performance in a pediatric population aged 3 years and above.