



September 25, 2026

Aevice Health Pte. , Ltd.
Adrian Ang
CEO
3 Tai Seng Ave., Tai Seng Exchange Tower B #04-32
Singapore, 536465
Singapore

Re: K260140
Trade/Device Name: Aevice Wheeze Detection Module
Regulation Number: 21 CFR 868.1900
Regulation Name: Diagnostic pulmonary-function interpretation calculator
Regulatory Class: Class II
Product Code: PHZ
Dated: August 21, 2026
Received: August 21, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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,

**Binoy J.
Mathews -S**

Digitally signed by Binoy
J. Mathews -S
Date: 2026.09.25 10:14:29
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For

James J. Lee, Ph.D.
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

Indications for Use

510(k) Number (if known)

K260140

Device Name

Aevice Wheeze Detection Module

Indications for Use (Describe)

The Aevice Wheeze Detection module is a decision support software system used in evaluation of lung sounds in adults and pediatrics (2 years and older).

It analyzes the acoustic signal of the lung such as lung sound recorded by FDA cleared compatible electronic stethoscope, such as AeviceMD, and identifies recordings where a specific abnormal lung sound suggestive of “Wheeze” is suspected. It is not intended to detect other abnormal or normal lung sounds.

A licensed health care professional’s advice is required to understand the meaning of the Aevice Wheeze Detection result. Healthcare providers should consider the device result in conjunction with recording and other relevant patient data.

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) SUMMARY – K260140

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. 3 Tai Seng Avenue #04-32, Tower B Tai Seng Exchange
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Chief Executive Officer

Contact Person: Adrian Ang
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Date Prepared: 25 September 2026

II. DEVICE

Name of Device: Aevice Wheeze Detection Module
Classification Name: Diagnostic pulmonary function interpretation calculator
Regulation: 21 CFR 868.1900
Regulatory Class: Class II
Product Classification Code: PHZ

III. PREDICATE DEVICE

Predicate Manufacturer: Tyto Care Ltd.
Predicate Trade Name: Tyto Insights for Wheeze Detection
Predicate 510(k): K232237

IV. DEVICE DESCRIPTION

The Aevice Wheeze Detection Module is a standalone software system designed to analyze lung sound recordings when provided. Compatible host-supplied acoustic sound data such as data from the FDA-cleared electronic stethoscope AeviceMD (K223382 and K243608) will be analyze and identify recordings where an abnormal breath sound suggestive of wheeze is suspected in the input acoustic sound files.

The module operates independently of any specific system and platform. Information from the module has to be retrieved by other FDA cleared host system which displays the output results. The results retrieved by the host system are intended to support clinical decision-making regarding the potential presence of wheeze. The Aevice Wheeze Detection Module is not intended for emergency use, and is not intended for self-diagnosis

V. INTENDED USE/ INDICATIONS FOR USE

The Aevice Wheeze Detection module is a decision support software system used in evaluation of lung sounds in adults and pediatrics (2 years and older).

It analyzes the acoustic signal of the lung such as lung sound recorded by FDA cleared compatible electronic stethoscope, such as AeviceMD, and identifies recordings where a specific abnormal lung sound suggestive of “Wheeze” is suspected. It is not intended to detect other abnormal or normal lung sounds.

A licensed health care professional’s advice is required to understand the meaning of the Aevice Wheeze Detection result. Healthcare providers should consider the device result in conjunction with recording and other relevant patient data.

VI. COMPARISON OF DEVICE CLASSIFICATION CHARACTERISTICS WITH PREDICATE DEVICE

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 and the predicate device.

Table 1. Substantial Equivalence Summary

Parameter	Subject Device: Aevice Wheeze Detection Module	Predicate Device: Tyto Insights for Wheeze Detection (K232237)	Summary
Product Code	PHZ	PHZ	Identical.
Regulation Number	21 CFR 868.1900	21 CFR 868.1900	Identical.
Device Classification Name	Diagnostic pulmonary function interpretation calculator	Diagnostic pulmonary function interpretation calculator	Identical.
Indications for Use	The Aevice Wheeze Detection module is a decision support software system used in evaluation of lung sounds in adults and pediatrics (2 years and older). It analyzes the acoustic signal of the lung such as lung sound recorded by FDA cleared compatible electronic stethoscope, such as AeviceMD, and identifies recordings where a specific abnormal lung sound suggestive of “Wheeze” is suspected. It is not intended to detect other abnormal or normal lung sounds.	The “Tyto Insights for Wheeze Detection” is an over-the-counter artificial intelligence (AI) enabled decision support software system used in the evaluation of lung sounds in adults and pediatrics (2 years and older). It automatically analyzes the acoustic signal of the lung as recorded by the FDA cleared compatible Tyto Stethoscope and identifies recordings where a specific abnormal lung sound suggestive of “Wheeze” is suspected. It is not intended to detect	Similar. Both are decision support software systems in evaluation of sounds and that healthcare professional’s advice is required to understand the result. The difference is only the compatible FDA-cleared electronic stethoscope that the module may obtain acoustic lung sound data from. The difference between the proprietary software of the subject device and the predicate does not

	A licensed health care professional's advice is required to understand the meaning of the Aevice Wheeze Detection result. Healthcare providers should consider the device result in conjunction with recording and other relevant patient data.	other abnormal or normal lung sounds. A licensed health care professional's advice is required to understand the meaning of the Tyto Insights for Wheeze Detection result. Healthcare providers should consider the device result in conjunction with recording and other relevant patient.	bring safety and effectiveness concern as the predicate device uses similar methodology of performance testing of the software accuracy as compared to the predicate device.
Target Population	Adults and Pediatrics (Aged 2 years and above)	Adult and Pediatrics (Aged 2 years and above)	Identical.
Intended Use Environment	Clinical and Non-clinical settings	Clinical and Non-clinical settings	Identical.
Type of Use	Prescription Only	Over-The-Counter	Subject device intended to be used under clinician oversight; Difference does not raise new questions of safety or effectiveness.
Form	Stand-alone Software	Stand-alone Software	Identical
Device Composition	• Software-only medical device • Machine-learning-based wheeze detection algorithm • Lung-sound input processing • No hardware components	• The TytoCare Lung Sounds Analyzer Application Server (APS) • The TytoCare Lung Sounds Analyzer Algorithm Server (ALS) • The TytoCare Lung Sounds Analyzer Web Server (WBS) provides a graphic indication whether a wheeze is detected in the recording It can be utilized both in patient and clinician side.	Similar, The subject device is software-only and does not include the hardware components of the predicate device. This difference does not affect safety or effectiveness because the subject device is intended to analyze lung-sound recordings acquired using compatible FDA-cleared electronic stethoscopes, and its software functions and clinical performance were independently verified and validated for the intended use.

Analyzes Lung Sounds	Acquire from compatible FDA-cleared electronic stethoscope, such as AeviceMD (K223382 and K242608), Littmann3200 (K083903) or Welch Allyn Meditron (K991367)	Acquire from compatible FDA-cleared, Tyto Stethoscope, electronic stethoscope (K181612)	Similar. Both the subject device and predicate device requires recorded lung sound input from a compatible electronic stethoscope.
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Signal length	The length of the signal is dictated by the recording process of the compatible Stethoscope. The subject device processes the recordings in segments of 5.12 seconds while signals shorter than 5.12 seconds that will not be processed. A minimum recording of 60 seconds is recommended.	The length of the signal is dictated by the recording process of the compatible Stethoscope. The subject device processes the recordings in segments of up to 12 seconds while signals shorter than 6 seconds will not be processed.	Similar that both process recordings in segments. Different in the signal length that is required for processing by the software. However, the difference does not raise new questions on the safety and effectiveness as there are FDA-cleared devices that have different signal lengths for processing based on their proprietary software. Performance testing has been conducted to establish that there are no new safety and effectiveness concerns raised.
Output	Binary output: - Positive (Wheeze suspected), - Negative (Wheeze not suspected)	- Positive (Wheeze suspected), - Negative (Wheeze not suspected), - The Tyto Insights for Wheeze Detection was not able to analyze the recording	Similar to predicate device that provides insights into whether wheeze is detected or not detected from the recorded lung sounds. However, the subject device does not include a user interface or directly display analysis results to the end user. The absence of a display does not alter the core wheeze detection software, the conditions of use, or the intended user population. Instead, the module can be integrated into an appropriate clinical workflow within a FDA-cleared host system that is responsible for receiving the output. Hence, there is no risk related to interaction with users introduced. Both devices provide wheeze suspected/not

			suspected outputs. Unlike the predicate, the subject device does not provide an acoustic-quality-based “unable to analyze” output. This difference does not raise different questions of safety and effectiveness because the subject device includes technical input validation, was clinically validated using representative patient recordings, and labeling mitigates risks associated with poor recording quality and false-positive/false-negative results. Therefore, the difference with the predicate device does not raise safety and effectiveness concerns.
Clinical Performance	Sensitivity: 73.15% [95% CI: 69.82%–76.24%] Specificity: 84.12% [95% CI: 82.25%–85.83%] Supplemental patient-cluster bootstrap (95% CI): Sensitivity 73.05% [64.75%–80.50%]; Specificity 84.18% [80.00%–88.09%]	Sensitivity and specificity were evaluated as the secondary endpoints. Estimate two-sided (95% CI): Sensitivity: 0.5465 [0.4304 – 0.6549] Specificity: 0.9895 [0.9684 – 0.996]	Performance testing was conducted on the subject device using methods similar to those applied to the primary predicate device. The test results demonstrate that the Aevice Wheeze Module is safe and effective.

Summary of Technological Characteristics

The AeviceMD has similar technological characteristics compared to predicate device. Both are software standalone software that requires acoustic lung sound recordings as input and in turn will be processed via the backend for binary classification results of presence of wheeze (wheeze/ no wheeze). The concern regarding the difference between the proprietary software does not bring safety and effectiveness concerns as the predicate device uses similar methodology of performance testing of the software accuracy as compared to the predicate device.

Non-Clinical Performance Evaluation

There are no device-specific guidance documents, special controls documents, and/or requirements in a device-specific regulation that is applicable to the subject device. A list of the standards and guidance for the device are listed below to support substantial equivalence to subject device:

- *ISO 14971:2019 Medical devices — Application of risk management to medical device*
- *IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes*
- FDA Guidance for “*Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions*”, dated February 3, 2026
- FDA Guidance for “*Content of Premarket Submissions for Device Software Functions*”, dated June 14, 2023.

Software Verification and Validation

- Software verification and validation were performed for the Aevice Wheeze Detection Module in accordance with FDA’s “*Content of Premarket Submissions for Device Software Functions*” guidance. The device software was determined to require a Basic Documentation Level. Software documentation and testing included applicable software requirements, risk management, architecture/design documentation, verification and validation, and testing of input validation, error handling, algorithm implementation, output generation, and interfaces with compatible host systems. The results demonstrated that the software performs as intended and meets its specified requirements.

Cybersecurity

- Cybersecurity documentation and testing were provided in accordance with FDA’s “*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*” guidance. Cybersecurity activities included assessment of cybersecurity risks and threats, implementation and verification of applicable security controls, software component documentation, and cybersecurity risk-management activities. The cybersecurity information supports that identified cybersecurity risks have been appropriately addressed for the intended use of the device.

Clinical Performance Data

A clinical performance validation study was conducted to evaluate the ability of the Aevice Wheeze Detection Module to identify the presence of wheeze in lung-sound recordings obtained from patients using compatible FDA-cleared electronic stethoscopes. The validation was performed using an independent dataset that was not used for development or optimization of the final algorithm. The algorithm and decision threshold were locked prior to evaluation of the validation dataset.

The clinical validation was conducted using a multisite and multisource dataset consisting of 2,336 lung-sound recordings from 131 unique pediatric and adult patients. The validation dataset included 730 recordings with wheeze and 1,606 recordings without wheeze, as determined by the applicable clinical reference standard. The dataset included recordings obtained using the AeviceMD Electronic Stethoscope, 3M Littmann Electronic Stethoscope Model 3200, and Welch Allyn Meditron electronic stethoscope.

Clinical recordings were obtained from multiple clinical and non-clinical settings and data sources. The validation data included recordings acquired in the United States and Singapore, as well as recordings from an online database originating from additional geographic locations. The validation population included 62 pediatric patients and 69 adult patients, with recordings obtained in emergency department, clinical, and home-use settings.

The predefined acceptance criteria for the overall validation population were

sensitivity $\geq 70\%$, and specificity $\geq 80\%$. The Aevice Wheeze Detection Module achieved an overall sensitivity of 73.15%, and specificity of 84.12%, thereby meeting the predefined overall performance acceptance criteria.

Performance by Age Group

Population	No. of Subjects (N)	No. of Recordings (n)	Sensitivity, % (95%CI)	Specificity, % (95%CI)
Overall	131	2336	73.15% [69.82%, 76.24%]	84.12% [82.25%, 85.83%]
Pediatrics (2-18)	62	1056	67.70% [62.67%, 72.34%]	86.71% [84.00%, 89.03%]
Adults (>18)	69	1280	78.34% [73.89%, 82.22%]	82.12% [79.49%, 84.48%]

* 95% confidence intervals used the Wilson method, without adjustment for repeated recordings within patients.

Because multiple recordings were obtained from individual patients, a supplemental patient-cluster bootstrap analysis was performed to account for correlation among repeated recordings from the same patient. The analysis consisted of 10,000 bootstrap repetitions, with patients sampled with replacement and all recordings associated with each sampled patient retained within each bootstrap iteration. The reported results were the averages across these bootstrap repeats, with the 2.5th and 97.5th percentiles of the repeat estimates used as the lower and upper limits of the 95% confidence intervals. The resulting cluster-adjusted sensitivity was 73.05% (95% CI: 64.75–80.50%), and the cluster-adjusted specificity was 84.18% (95% CI: 80.00–88.09%). These estimates were similar to the original recording-level point estimates.

Metric	Recording-Level Estimate (95% CI)	Patient-Cluster Bootstrap Estimate (95% CI)
Sensitivity	73.15% [69.82%, 76.24%]	73.05% [64.75% – 80.50%]
Specificity	84.12% [82.25%, 85.83%]	84.18% [80.00% – 88.09%]

* Recording-level used 95% confidence intervals used the Wilson method, without adjustment for repeated recordings within patients.

The clinical validation demonstrated that the Aevice Wheeze Detection Module can identify wheeze in lung-sound recordings obtained from the indicated pediatric and adult population using compatible FDA-cleared electronic stethoscopes. The observed performance, including the supplemental analysis accounting for repeated recordings within patients, supports the use of the Aevice Wheeze Detection Module as an adjunctive decision-support tool for the identification of suspected wheeze. Device results are intended to be interpreted by healthcare professionals in conjunction with the underlying lung-sound recording and other relevant patient and clinical information.

VII. CONCLUSION

The predicate device Aevice Wheeze Detection Module has the same intended use, similar indication for use and similar technological characteristics as the predicate device, Tytocare Insights for Wheeze.

Clinical performance validation test was used to evaluate the technical performance of the wheeze detection module via a similar methodology used by the predicate device was established. Hence, the Aevice Wheeze Detection Module is as safe and effective as the primary predicate device.