May 22, 2026

Ai Health Highway India Pvt. Ltd
Satish Jeevannavar
CEO/Founder
DSI Innovation campus, Block A, 2nd Floor Gharebhavipalya
Hongasandra village, Hosur Road
Bangalore, Karnataka 560068
India

Re: K252915
Trade/Device Name: AiSteth®
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: May 6, 2026
Received: May 6, 2026

Dear Satish Jeevannavar:

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,

STEPHEN C. BROWNING -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular 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.

510(k) Number *(if known)*
K252915

Device Name
AiSteth®

Indications for Use *(Describe)*
The AiSteth® Platform (AiSteth® Device + Mobile applications on Android & iOS) is intended to be used as part of a physical assessment of a patient by healthcare professionals for diagnostic decision support in clinical settings. AiSteth® is intended for use on pediatric and adult patients. It can record, store, amplify, filter and share sounds on the accompanying mobile applications for storage and sharing. It can be used to record heart sounds and cardiac murmurs, bruits, respiratory sounds, and abdominal sounds during physical examination in normal patients or those with suspected diseases of the cardiac, vascular, pulmonary or abdominal organ systems.

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.

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510(k) Summary

Table of Contents

Trade Name- AiSteth® **(K252915)**

1. **Submitter's Identifications**
   Submitter's Name: Ai Health Highway India Pvt. Ltd.
   Address: DSI Innovation campus, Block A, 2nd Floor,
   Gharebhavipalya, Hongasandra village, Hosur Road,
   Bangalore - 560068 Karnataka, India
   Contact Person: Dr. Satish S Jeevannavar
   Contact Title: CEO and Founder
   Contact E-mail Address: satish.sj@aihighway.org
   Telephone: +91 9480490148

2. **Correspondent's Identifications**
   Correspondent Name: Ai Health Highway India Pvt. Ltd.
   Address: DSI Innovation campus, Block A, 2nd Floor,
   Gharebhavipalya, Hongasandra village, Hosur Road,
   Bangalore - 560068 Karnataka, India
   Contact Person: Dr. Satish S Jeevannavar
   Contact Title: CEO and Founder
   Contact E-mail Address: satish.sj@aihighway.org
   Telephone: +91 9480490148

3. **Name of the Device**

510(k) No: K252915

Device Classification Name: Electronic Stethoscope

Trade Name: AiSteth®

Model: AiSteth®

Classification Panel: Cardiovascular

Product Code: DQD

Device Classification: Class II

Regulation Number: 21 CFR 870.1875 - Stethoscope

4. **The Predicate Device:**
   510(k) application number: 151319, Eko Electronic Stethoscope System manufactured by Eko Devices, Inc, Oregon, has been identified as the predicate for AiSteth® to support the substantial equivalence comparison.

510(k)	K151319
Trade/Proprietary Name	Eko Electronic Stethoscope System
Regulation Name	Stethoscope
Regulation Number	21 CFR 870.1875

Product Code	DQD
Device Class	Class II
Classification Panel	Cardiovascular

5. Device Description

5.1 Device introduction

Valvular heart disease (VHD) is a major contributor to global cardiovascular morbidity and mortality, with rheumatic heart disease prevalent in low- and middle-income countries and degenerative valve conditions such as aortic stenosis and mitral regurgitation increasingly common in aging populations. Pathological murmurs are often the first clinical sign of VHD and can be detected through cardiac auscultation.

Although auscultation is inexpensive and widely available, its effectiveness is limited by declining clinician proficiency and variability in interpretation. Echocardiography remains the diagnostic gold standard but is resource-intensive and not feasible as a frontline screening tool. Smart stethoscopes can support clinicians by enhancing the detection of pathological murmurs, improving consistency, and enabling screening and referral in both traditional and remote care settings, including underserved areas.

AiSteth® encompasses the complete platform, incorporating the smart stethoscope, the accompanying mobile application.

AiSteth® helps you see the sound on your smartphone. Its purpose is to offer smart features through a mobile application, enabling you to record, store and share heart sounds, respiratory sounds and abdominal sounds.

The stethoscope is paired with a mobile application. The AiSteth® mobile app is compatible with both iOS and Android devices. The application offers functionalities such as:

● Record, storage, and playback of heart sounds, respiratory sounds, and abdominal sounds during physical examination in patients.

● Export audio and visual data for easy sharing with other healthcare professionals for further assessment.

5.2 Components:

The components of AiSteth® Stethoscope are:

- High sensitivity microphone
- Integrated, non-user removable rechargeable Li-polymer battery.
- Bluetooth Classic module
- LED status indicator (Battery level, Bluetooth Sync, Power).
- ON/OFF push-button

- Chestpiece with Type BF applied diaphragm

Mobile Application (Android & iOS)

- Enables sound recording, visualization, playback (raw & denoised), and secure sharing.

5.3 Equipment functions:

The AiSteth® operates on the principle of electronic auscultation. The signals captured through the chestpiece are securely transmitted via **Bluetooth®** to the AiSteth® mobile application (compatible with iOS and Android). The mobile application visualizes the sound as waveforms and spectrograms, and provides functionality to record, store, playback, and share the data.

For clinical use, healthcare professionals can auscultate in two modes:

1. **Smart Digital Mode** – Sounds are amplified, digitized, and displayed on the paired mobile device for visualization, storage, and sharing.
2. **Traditional Acoustic Mode** – The device can be used as a standard stethoscope, allowing direct auscultation through the chest piece and earbuds without mobile application support.

The device is powered by an integrated, non-user removable rechargeable battery and incorporates LED indicators to show operational status (pairing, connection, charging, and low battery).

This design ensures that AiSteth® functions both as a **traditional stethoscope** and a **smart electronic stethoscope**, thereby maintaining continuity with conventional clinical practice while enhancing diagnostic capabilities through digital technology.

5.4 Instrument type:

AiSteth® is a dual mode electronic stethoscope

- **Smart Mode:** Functions as an electronic stethoscope with digital auscultation, recording, playback, and sharing via a Bluetooth connected app.
- **Traditional Mode:** Operates as a conventional acoustic stethoscope when the Bluetooth mode is disabled.

5.5 Main performance indicators:

1. High-sensitivity sound capture: The AiSteth® uses a high-sensitivity microphone to capture cardiovascular, lung, and abdominal sounds.

2. Audio clarity – Raw and denoised playback: Ability to record and playback both raw and denoised sounds (noise-reduced audio for better clarity). Denoise filters out environmental noise (e.g., fan, conversations), improving clinical auscultation quality.

3. Visualization of sounds: Display of live audio waveforms on the mobile application to assist users in interpreting sound patterns visually.

4. Recording and storage: Ability to record auscultation sounds and store them securely on local or cloud storage.

5. Battery performance: Powered by integrated, non-user removable rechargeable Li-polymer (580 mAh) with up to 48 hours of operational backup. Charging is performed using the provided charging cable via the designated charging port on the chest piece. Charging time approximately 3 hours.

6. Bluetooth connectivity: Reliable wireless communication with Android and iOS devices using Bluetooth classic.

7. Dual mode operation: Functions both as an electronic stethoscope and a traditional stethoscope when the Bluetooth is turned off.

8. Device status indication: LED ring displays ON/OFF status, battery level, and Bluetooth sync status.

9. Ease of use and user interface: Simple single button operation and intuitive mobile app interface for recording and managing patient data.

10. Compatibility and platform support: Mobile application runs on both Android and iOS, supports data export in WAV format, and allows integration with cloud systems.

5.6 The list of accessories:

None

6. Indications for Use

The AiSteth® Platform (AiSteth® Device + Mobile applications on Android & iOS) is intended to be used as part of a physical assessment of a patient by healthcare professionals for diagnostic decision support in clinical settings. AiSteth® is intended for use on pediatric and adult patients. It can record, store, amplify, filter and share sounds on the accompanying mobile applications for storage and sharing. It can be used to record heart sounds and cardiac murmurs, bruits, respiratory sounds, and abdominal sounds during physical examination in normal patients or those with suspected diseases of the cardiac, vascular, pulmonary or abdominal organ systems.

6.1 Intended patient population

AiSteth® is suitable for use during clinical examination of pediatric and adult population in clinical settings, as determined by a qualified healthcare professional.

6.2. Intended User

Any qualified healthcare professional during clinical examination of an individual can use AiSteth®. The Instructions for use (IFU)/User Manual provided along with the device is self-explanatory and does not require additional training.

6.3.Intended Environment

AiSteth® is intended to be used in clinical settings

7. Summary of Substantial Equivalence

The subject device (AiSteth®) and the predicate device (Eko Electronic Stethoscope System) were compared across multiple parameters to demonstrate substantial equivalence.

These include intended use, device description, intended patient population, and intended users, as well as user interface, interoperability, and connectivity features. Technical performance characteristics such as sound amplification, frequency capture, noise cancellation, data transfer capabilities, and test results were also evaluated. In addition, battery performance, charging characteristics, and mobile application user interface were compared to ensure consistent functionality and usability.

Table 2: Comparison of characteristics

Item	Proposed Device (AiSteth®) K252915	Predicate Device (Eko Electronic Stethoscope System – K151319)	Details of equivalence
Intended Use/ Indications for Use	The AiSteth® Platform (AiSteth® Device + Mobile applications on Android & iOS) is intended to be used as part of a physical assessment of a patient by healthcare professionals for diagnostic decision support in clinical settings. AiSteth® is intended for use on pediatric and adult patients. It can record, store, amplify, filter and share sounds on the accompanying mobile applications for storage and sharing. It can be used to record heart sounds and cardiac murmurs, bruits, respiratory sounds, and abdominal sounds during physical examination in normal patients or those with suspected diseases of the cardiac, vascular, pulmonary or abdominal organ systems.	The Eko Electronic Stethoscope System is intended to be used as a part of a physical assessment of a patient by healthcare professionals for diagnostic decision support in clinical settings. Eko is intended for use on pediatric and adult patients. It can electronically amplify, filter and transfer sounds to the accompanying mobile application for storage and sharing. It can be used to record heart sounds and cardiac murmurs, bruits, respiratory sounds and abdominal sounds during physical examination in normal patients or those with suspected diseases of the cardiac, vascular, pulmonary or abdominal organ systems.	Similar
Product code	DQD	DQD	Same

Item	Proposed Device (AiSteth®) K252915	Predicate Device (Eko Electronic Stethoscope System – K151319)	Details of equivalence
Classification name	Electronic Stethoscope	Electronic Stethoscope	Same
Classification	Class II	Class II	Same
Device Description	AiSteth® helps you see the sound on your smartphone. Its purpose is to offer smart features through a mobile application, enabling you to record, store and share heart sounds, respiratory sounds and abdominal sounds. The AiSteth® stethoscope user interface includes a simple push button to switch ON or OFF the smart feature – Bluetooth®. In situations when a smart stethoscope is not required, it can simply act as a regular traditional stethoscope. The AiSteth® smart stethoscope has a light-emitting diode (LED) display ring that indicates the device's status (ON, OFF, battery percentage, and Bluetooth® synchronization) and operates on a rechargeable battery. The AiSteth® stethoscope is paired with a mobile application. The AiSteth® mobile app is	The Eko CORE is a digital stethoscope device designed for use by health care professionals in clinical environments. It enables physicians to transition between traditional and digital auscultation. It can electronically amplify, filter and transfer sounds to the accompanying mobile application for storage and sharing or can transmit the data for telemedicine use. It also enables regular users to listen to their body sounds (lungs, heart, arteries, veins, Gastrointestinal tract, etc.) and record and share it with their physicians. It consists of two primary components: 1) The CORE: an electronic attachment for an analog stethoscope and 2) Eko App, an application that pairs with the CORE attachment.	Similar Eko provides data visualization whereas AiSteth® provides only real-time visualization of the waveform during auscultation.

Item	Proposed Device (AiSteth®) K252915	Predicate Device (Eko Electronic Stethoscope System – K151319)	Details of equivalence
	compatible with both iOS and Android devices. The application offers functionalities such as: ● Record, storage, and playback of heart sounds, respiratory sounds, and abdominal sounds during physical examination in patients. ● Export audio data and pdf reports for easy sharing with other healthcare professionals for further assessment.	• CORE is used to record audio in the stethoscope, convert it to digital data points, and transmit data to a mobile device via Bluetooth®. It includes a volume adjustment button, an analog-to-digital power switch, and an LED light indicator. • The app captures audio data from the CORE and provides data visualization, secure data storage, audio playback, and sharing features. These features enable a healthcare professional to monitor patients, seek out second opinions from a specialist or use the device for telemedicine use.	
Intended Patient Population	Adult and pediatric patients	Adult and pediatric patients	Same
Intended User	Healthcare providers licensed or authorized to perform auscultation.	Healthcare professionals in clinical environments.	Same
Prescribed	Prescription Use only	Prescription Use only	Same
Stethoscope Type	Looks like a traditional stethoscope and facilitates both digital and analog auscultation modes	Attachment to an analog stethoscope and features both digital and analog auscultation modes.	Different The differences in physical design are limited to

Item	Proposed Device (AiSteth®) K252915	Predicate Device (Eko Electronic Stethoscope System – K151319)	Details of equivalence
			external appearance and do not impact the core technological characteristics, functional performance, or clinical utility of the device. The cosmetic design variations do not introduce any new risks, nor do they affect the safety or effectiveness of the proposed device, AiSteth®.
User Interface	On/off power button LED status indicator Mobile App	On/off power button Volume adjustment LED status indicator Mobile App	No volume adjustment is available in AiSteth®. This difference is primarily a convenience feature for the user, allowing adjustment of listening levels during auscultation in Eko's Digital Attachment. AiSteth® is still capable of clearly capturing, recording and

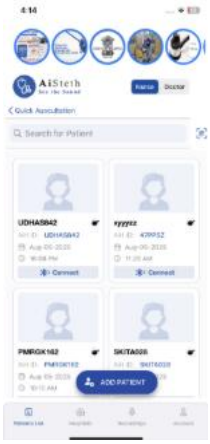
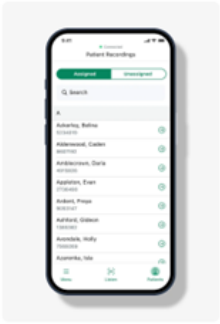
Item	Proposed Device (AiSteth®) K252915	Predicate Device (Eko Electronic Stethoscope System – K151319)	Details of equivalence
			transmitting auscultation sounds at a clinically acceptable quality. Therefore, the absence of this feature does not affect the device's intended use, clinical capability, or raise any concerns regarding safety or effectiveness.
Analog/Digital Interoperability	Yes	Yes	Same
Connectivity	Bluetooth	Bluetooth	Same
Frequency Capture	20Hz-8000Hz	20Hz-2000Hz	Different AiSteth® captures 20 Hz–8 kHz versus 20 Hz–2 kHz for the predicate. This difference does not impact safety or effectiveness, as all clinically relevant sounds within 20 Hz–2 kHz are preserved. Bench verification demonstrates comparable

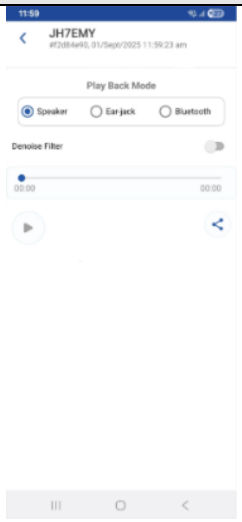
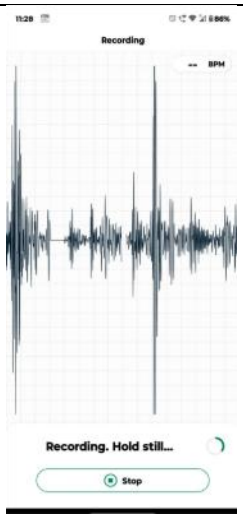
Item	Proposed Device (AiSteth®) K252915	Predicate Device (Eko Electronic Stethoscope System – K151319)	Details of equivalence
			amplitude and waveform characteristics to the predicate within that clinically relevant band. The extended bandwidth of AiSteth® only provides improved audio fidelity and supports advanced analysis.
Sound amplification (Playback)	Default 20X sound amplification	Up to 40X sound amplification	Different Although AiSteth® provides lower sound amplification compared to the predicate, the amplification level is sufficient for clinicians to clearly hear and interpret heart and lung sounds in a clinical environment. The device meets the minimum performance requirements for auscultation and does not

Item	Proposed Device (AiSteth®) K252915	Predicate Device (Eko Electronic Stethoscope System – K151319)	Details of equivalence
			compromise the accuracy of clinical assessment. Therefore, the difference in amplification does not affect the device's safety or effectiveness.
Noise Cancellation during recording	Not available.	The stethoscope has been designed to eliminate distracting background noise during recording. There is an option in the mobile application to switch off the noise cancellation during cancellation.	Different The recordings obtained from AiSteth® ensures no loss of clinically relevant information. Although noise cancellation is not available at the recording level, AiSteth® offers a denoise feature during playback during which the user has the option to reduce the background noise to hear the auscultated sounds more clearly. Thus, the unavailability of noise cancellation does not impact the safety or raise any concerns

Item	Proposed Device (AiSteth®) K252915	Predicate Device (Eko Electronic Stethoscope System – K151319)	Details of equivalence
			regarding the effectiveness of AiSteth®.
Denoise during playback	Denoise feature available during playback (user-controlled)	Not available	Different. The clinician can selectively apply denoise in AiSteth®, allowing flexibility to review both raw and filtered audio. This additional feature is a benefit to the users and does not raise any concerns about safety and effectiveness.
Record and Playback sounds	Record and save sounds to a patient's file or share with a colleague for second opinion.	Record and save sounds to a patient's file or share with a colleague for second opinion. Use recordings as a teaching tool with students, patients, or other clinicians.	Same
Data Transfer to a compatible computing platform	Yes	Yes	Same
Testing performed	Bench comparison with predicate device	Bench comparison with predicate device	Same

Item	Proposed Device (AiSteth®) K252915	Predicate Device (Eko Electronic Stethoscope System – K151319)	Details of equivalence
	Software Verification and Validation Electrical safety EMI/EMC testing Wireless Coexistence Reliability studies Transportation studies	Software Verification and Validation Electrical safety EMC testing Wireless Coexistence	
Battery	Integrated, non user removable rechargeable lithium-polymer battery that lasts up to 30 hours of continuous use; lasts up to a week of regular clinical use	Rechargeable lithium-ion battery that lasts up to 480 minutes of continuous use; generally, lasts up to 2 weeks of regular clinical use	Different The longer battery life AiSteth® does not raise concerns of safety or effectiveness when compared to the predicate device. AiSteth® provides sufficient battery capacity to complete clinical auscultation procedures without interruption, thereby fulfilling the intended use. AiSteth's extended operating duration represents a technological enhancement that offers additional

Item	Proposed Device (AiSteth®) K252915	Predicate Device (Eko Electronic Stethoscope System – K151319)	Details of equivalence
			convenience and reliability for clinicians, but it does not change the fundamental operating principles, intended use, or clinical performance of the device.
Charging	Micro-USB charging	Micro-USB charging	Same
Mobile application UI	 Patient Profile Creation		Similar

Item	Proposed Device (AiSteth®) K252915	Predicate Device (Eko Electronic Stethoscope System – K151319)	Details of equivalence
	 Saving and Playback	 Saving and Playback	Similar
Mobile Application UI	 Waveform Visualization during Recording	 Waveform Visualization during recording	Similar

8. Substantial Equivalence discussion

Similarities between Subject Device & Predicate Device:

The subject device (AiSteth®) and the predicate device (Eko Electronic Stethoscope System) are substantially equivalent in their intended use, product classification, and fundamental technology. Both devices are prescription-use electronic stethoscopes intended for clinicians to record, store, and playback auscultation sounds, with the capability to transfer data to a compatible computing platform for clinical review. The two devices share the same product code, classification name, and regulatory classification as per the FDA medical device

database. They are also similar in terms of intended patient population, intended users, interoperability, connectivity features, mobile application user interface, type of testing performed, as well as battery type and charging method.

Differences between Subject Device & Predicate Device:

The differences between the two devices lie primarily in design and certain user interface features. AiSteth® has a different physical design, lacks a volume adjustment control, and provides amplification during playback rather than hardware-level amplification. Additionally, noise management is implemented differently: Eko Electronic Stethoscope System provides noise cancellation during recording, while AiSteth® offers denoise functionality during playback. AiSteth® also supports longer continuous and clinical usage time compared to the predicate. Furthermore, AiSteth® captures frequencies in the 20 Hz–8 kHz range, compared to 20 Hz–2 kHz in the predicate device, a difference verified in bench testing to have no impact on the safety or effectiveness of auscultation, while offering the advantage of improved audio fidelity and advanced analysis capability.

These differences have been evaluated as a part of extensive bench testing performed on the subject device and the predicate device and do not raise concerns of safety or effectiveness. They do not alter the intended use or core technological characteristics of the device and do not affect the device's ability to capture and provide clinically useful auscultation sounds. Instead, they represent design variations and user convenience features that do not impact safety or performance. Therefore, AiSteth® is substantially equivalent to the predicate device.

9. Non-Clinical Tests Performed

1. ***Bench Comparison with Predicate Device***

   A comparative bench study was conducted to evaluate the performance and functional characteristics of the device against a legally marketed predicate device to demonstrate substantial equivalence in safety and effectiveness.

2. ***Software Verification and Validation (V&V)***

   Comprehensive software testing was performed per IEC 62304 to ensure that the device software meets intended functionality and safety requirements. Verification included unit testing, integration testing, and system-level testing, while validation confirmed that the software performs as expected in real-world scenarios.

3. ***Electrical Safety Testing***

   The device was evaluated per IEC 60601-1 standards for electrical safety, ensuring compliance with voltage, leakage current, insulation, and grounding requirements. The tests confirmed that the device operates safely without posing risks of electric shock or fire hazards.

4. ***Electromagnetic Interference (EMI) and Electromagnetic Compatibility (EMC) Testing***

   Conducted per IEC 60601-1-2, these tests assessed the device's ability to function correctly in the presence of electromagnetic disturbances and to ensure it does not emit interference affecting other medical equipment. The device met all regulatory limits for radiated and conducted emissions, immunity, and electrostatic discharge (ESD) performance.

5. ***Wireless Coexistence Testing***

The device was tested for wireless performance and interference resistance in environments with multiple active wireless technologies. Compliance with ANSI C63.27 standard ensured the device maintains reliable communication without interference from Wi-Fi, Bluetooth, or other RF sources.

6. ***Reliability Studies***

Long-term performance and durability were evaluated through accelerated aging, environmental stress testing, and continuous use simulations. Results confirmed that the device maintains its functional integrity, accuracy, and structural stability over its expected lifespan.

7. ***Transportation Studies***

Packaging and transportation testing were performed per ASTM D4169 standard to assess the device's ability to withstand shipping, handling, vibration, and drop impacts. The device packaging was validated to protect it from mechanical damage and environmental exposure during distribution.

8. Biocompatibility Studies

The device components that come into direct contact with the patient were evaluated for biocompatibility in accordance with ISO 10993 series standards. Testing included cytotoxicity, sensitization, and irritation assessments, confirming that the materials are biocompatible and safe for their intended use. These results demonstrate that the device does not pose any adverse biological risks to patients under normal conditions of use.

9. Battery Testing

To demonstrate the safety and performance of the battery components testing is done as per IEC 62133-2. Based on the results obtained from the study we confirm that the battery used in the AiSteth® device meets the safety requirements of IEC 62133-2 and supports compliance with IEC 60601-1 Clause 15.4.3.4.

The comprehensive testing confirmed that the device meets regulatory safety, performance, and reliability requirements, ensuring compliance with industry standards and demonstrating substantial equivalence to the predicate device.

Sn. No	Testing Performed	Standard Reference
1	Bench Testing	NA
2	Software Verification and Validation	IEC 62304:2015
3	Electrical Safety Testing	IEC 60601-1:2005 IEC 60601-1:2005/AMD1:2012 IEC 60601-1:2005/AMD2:2020
4	EMI/EMC Testing	IEC 60601-1-2:2020

5	Wireless Co-existence Testing	ANSI C63.27-2021
6	Reliability Studies	IEC 60068-2-14:2009 IEC 60068-2-30:2005 IEC 60068-2-2:2007 IEC 60068-2-1:2007
7	Transportation Studies	ASTM D4169-22
8	Biocompatibility Studies	ISO 10993-5:2009 ISO 10993-10:2021 ISO 10993-23:2021
9	Battery Testing	IEC 62133-2:2017, IEC 62133-2:2017/AMD 1:2021

10. Conclusion

AiSteth® has been demonstrated to be as safe and effective as the predicate device. Performance testing, risk analysis, and usability evaluation confirm that the device meets its intended use without raising new questions of safety or effectiveness. Based on the information provided, AiSteth® is substantially equivalent to the predicate device, Eko Electronic Stethoscope System.