December 19, 2025

Csd Labs
% Allison Komiyama
VP, MedTech Innovation
Rqm+
2790 Mosside Blvd.
#800
Monroeville, Pennsylvania 14156

Re: K252284
Trade/Device Name: eMurmur Heart AI (2.2)
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD, DQC
Dated: December 2, 2025
Received: December 2, 2025

Dear Allison Komiyama:

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,

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)*
K252284

Device Name

eMurmur Heart AI (2.2)

Indications for Use *(Describe)*

The eMurmur Heart AI software is a decision support system for the automated evaluation of recorded patient heart sounds. It identifies the first (S1) and second (S2) heart sounds, the presence of abnormal heart murmurs, and the absence of abnormal heart murmurs, with the latter including cases of no murmurs and innocent murmurs. eMurmur Heart AI also determines the average loudness of individual heart sound components, including S1, systole, S2, and diastole, as well as their respective loudness ratios.

eMurmur Heart AI is indicated for use in settings where auscultation can be performed properly by a healthcare provider. It is not intended as a sole means of diagnosis. The heart sound interpretations offered by eMurmur Heart AI are only significant when considered in conjunction with healthcare provider over-read and including all other relevant patient data. eMurmur Heart AI is intended for use on 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) SUMMARY**

**K252284**

**CSD Labs' eMurmur Heart AI**

## SPONSOR

| | |
|---|---|
| Company name: | CSD Labs GmbH |
| Company address: | Krenngasse 12<br>8010 Graz<br>Austria |
| Contact Person: | Andreas Reinisch |
| Date Prepared: | December 18, 20252284 |

## CONSULTANT

| | |
|---|---|
| Company name: | RQM+ |
| Contact Person: | Allison Komiyama, PhD, RAC |

## DEVICE

| | |
|---|---|
| Trade Name: | **eMurmur Heart AI** (2.2) |
| Common or usual name: | Computer Aided Auscultation, Heart Sounds Analyzer |
| Classification name: | Electronic Stethoscope; Phonocardiograph; |
| Regulation number: | 21 CFR 870.1875, 870.2390 |
| Product code: | DQD, DQC |
| Device class: | Class II |
| Reviewing panel: | Cardiology |

## PREDICATE DEVICE

| **Company** | **Product** | **510(k)** |
|---|---|---|
| CSD Labs GmbH | **eMurmur Heart AI** | K220766 |

## INDICATIONS FOR USE

The **eMurmur Heart AI** software is a decision support system for the automated evaluation of recorded patient heart sounds. It identifies the first (S1) and second (S2) heart sounds, the presence of abnormal heart murmurs, and the absence of abnormal heart murmurs, with the latter including cases of no murmurs and innocent murmurs. **eMurmur Heart AI** also determines the average loudness of individual heart sound components, including S1, systole, S2, and diastole, as well as their respective loudness ratios.

**eMurmur Heart AI** is indicated for use in settings where auscultation can be performed properly by a healthcare provider. It is not intended as a sole means of diagnosis. The heart sound interpretations offered by **eMurmur Heart AI** are only significant when considered in conjunction with healthcare provider over-read and including all other relevant patient data. **eMurmur Heart AI** is intended for use on pediatric and adult patients.

## DEVICE DESCRIPTION

To analyze heart sounds using **eMurmur Heart AI**, a digital recording of a patient's heart sounds is required. Recordings are made using any supported digital stethoscope, connected to a front-end client. The recorded auscultation data are transmitted from the front-end client to the eMurmur backend, which hosts **eMurmur Heart AI**. After analysis by **eMurmur Heart AI**, the results are returned to the front-end client where they are displayed to the user. The user can utilize the **eMurmur Heart AI** results to support their decision-making process regarding the potential presence of an abnormal heart murmur, and to assist them when investigating potential changes among longitudinally recorded heart sounds.

eMurmur is a multiple function software platform which includes the eMurmur apps and eMurmur web portal. The platform is used to stream, record, display, replay, and store auscultation data, recorded by means of supported digital stethoscopes, i.e., functions that are not subject to regulatory oversight.

The eMurmur multiple function software platform also has functions subject to FDA premarket review, i.e., **eMurmur Heart AI**. For this application, FDA assessed those functions only to the extent that they could adversely impact the safety and effectiveness of the functions subject to FDA premarket review.

## TECHNOLOGICAL CHARACTERISTICS

**eMurmur Heart AI** performs automated heart sound analysis to support users in the evaluation of heart sounds. **eMurmur Heart AI** features the following technological characteristics:

1. It is hosted on a server and accessed through the eMurmur backend, which communicates with front-end clients over secure, encrypted connections. The eMurmur backend features state-of-the-art cybersecurity features.
2. It requires a digital heart sound recording - made with any supported digital stethoscope - and the patient's age as input. The list of supported stethoscopes for eMurmur Heart AI may be extended by following a Predetermined Change Control Plan (PCCP).
3. It provides heart sound analysis results along with additional supporting information to the user.
4. It interfaces with the eMurmur Transformer, a software accessory that enables compatibility with multiple digital stethoscope models for use with eMurmur Heart AI.

## PERFORMANCE DATA

**eMurmur Heart AI** (version 2.2) is an upgraded version of its predicate device **eMurmur Heart AI** (version 1.0). All applicable verification methods that were performed for the predicate were also performed for the current device.

The dataset used to validate and obtain clearance for the predicate device was augmented with new, previously unseen data, to minimize the risk of overestimating device performance. The resulting dataset was not used during training of eMurmur Heart AI (2.2). The dataset includes heart sound recordings from both pediatric and adult subjects. Of these, 50% had a confirmed abnormal murmur, while the remaining 50% were confirmed to have no abnormal murmur. The ground truth classification was determined by three board-certified cardiologists based on majority consensus.

During validation, the dataset was analyzed by both eMurmur Heart AI (2.2) and its predicate device eMurmur Heart AI (1.0), and their findings were compared against the same ground truth. Non-inferiority is established using confidence intervals for paired data with continuity correction for the true difference in sensitivity or specificity. The results demonstrate that eMurmur Heart AI (2.2) achieves performance non-inferior to that of the predicate device. The detailed validation outcomes, including 95% confidence intervals, are summarized in the table below.

| | **eMurmur Heart AI** (2.2) | **eMurmur Heart AI** (1.0) (predicate) |
|---|---|---|
| Sensitivity | 90.0% (78.8%-95.9%) | 86.7% (74.9%-93.7%) |
| Specificity | 90.0% (78.8%-95.9%) | 88.3% (76.8%-94.8%) |
| Accuracy | 90.0% (82.8%-94.5%) | 87.5% (79.9%-92.6%) |

## SUBSTANTIAL EQUIVALENCE

**eMurmur Heart AI** (2.2) is an upgraded version of its predicate device. The intended use of **eMurmur Heart AI** (2.2) remains the same as the intended use of the predicate **eMurmur Heart AI** (1.0). Both are intended to analyze heart sounds and aid the user in the evaluation of patient heart sounds.

**eMurmur Heart AI (**2.2) has similar indications for use as the predicate. The upgrade introduces a new feature that determines the average loudness of individual heart sound components, including S1, systole, S2, and diastole. This new feature has been validated, its technological characteristics have no negative effect on the safety and effectiveness of **eMurmur Heart AI** (2.2).

***Table 1.*** **Substantial Equivalence Summary Comparison Table**

| | **eMurmur Heart AI (**2.2) | **eMurmur Heart AI (**1.0) (predicate) |
|---|---|---|
| **Indications for Use** | The **eMurmur Heart AI** software is a decision support system for the automated evaluation of recorded patient heart sounds. It identifies the first (S1) and second (S2) heart sounds, the presence of abnormal heart murmurs, and the absence of abnormal heart murmurs, with the latter including cases of no murmurs and innocent murmurs. | The **eMurmur Heart AI** software is a decision support system in the evaluation of recorded patient heart sounds. The automated analysis by **eMurmur Heart AI** identifies specific heart sounds that may be present, including S1, S2, physiological heart murmurs, pathologic heart murmurs and the absence of a heart murmur.<br><br>**eMurmur Heart AI** is indicated for use in a setting where auscultation would |

| | | |
|---|---|---|
| | **eMurmur Heart AI** also determines the average loudness of individual heart sound components, including S1, systole, S2, and diastole, as well as their respective loudness ratios.<br><br>**eMurmur Heart AI** is indicated for use in settings where auscultation can be performed properly by a healthcare provider. It is not intended as a sole means of diagnosis. The heart sound interpretations offered by **eMurmur Heart AI** are only significant when considered in conjunction with healthcare provider over-read and including all other relevant patient data. **eMurmur Heart AI** is intended for use on pediatric and adult patients. | typically be performed by a healthcare provider. It is not intended as a sole means of diagnosis. The heart sound interpretations offered by **eMurmur Heart AI** are only significant when considered in conjunction with healthcare provider over-read and including all other relevant patient data. |
| **User Population** | Identical. | Healthcare provider licensed or trained to perform auscultation. |
| **Analyzes Heart Sounds** | • Detects the presence of abnormal heart murmurs or the absence of abnormal heart murmurs (including cases of no murmurs and innocent murmurs).<br>• Detects S1 and S2 heart sounds.<br>• Determines the loudness of individual heart sound components, including S1, systole, S2, and diastole, as well as their respective loudness ratios. | • Detects the presence or absence of a heart murmur.<br>• Distinguishes between normal (physiological) and pathologic heart murmurs.<br>• Detects S1 and S2 heart sounds. |
| **Accessories** | • Any supported digital stethoscope model.<br>• eMurmur Transformer, a software accessory that enables compatibility with multiple digital stethoscope models. | Digital stethoscope 'Littmann 3200'. |
| **Cybersecurity** | Encrypted internet traffic, data stored in the database on the backend is encrypted, data in the database is duplicated to another database in a different datacenter, no protected health information is stored on the user's devices, user needs to authenticate, user can only access authorized data. Private networking exposes only the eMurmur backend API and no other resources, e.g., eMurmur Heart AI or the eMurmur database, to the internet. | Encrypted internet traffic, data stored in the database on the backend is encrypted, data in the database is duplicated to another database in a different datacenter, no protected health information is stored on the user's devices, user needs to authenticate, user can only access authorized data. |
| **Performance Data** | Sensitivity: 90.0% (78.8%-95.9%)<br>Specificity: 90.0% (78.8%-95.9%)<br>Accuracy: 90.0% (82.8%-94.5%) | Sensitivity: 86.7% (74.9%-93.7%)<br>Specificity: 88.3% (76.8%-94.8%)<br>Accuracy: 87.5% (79.9%-92.6%) |

## PREDETERMINED CHANGE CONTROL PLAN (PCCP)

eMurmur Heart AI has an FDA-authorized Predetermined Change Control Plan (PCCP), which enables the addition of new stethoscope models for use with eMurmur Heart AI while maintaining the device's intended use, safety, and effectiveness. Modifications under the PCCP are limited to device compatibility updates and do not alter the functionality of eMurmur Heart AI.

Planned modifications: update of the eMurmur Transformer to support new stethoscope models.

Recordings made with supported stethoscopes are processed by the eMurmur Transformer software, before being analyzed by eMurmur Heart AI. The eMurmur Transformer ensures consistent analysis across all supported recording devices. Adding a new stethoscope model does not affect already supported stethoscope models. eMurmur Heart AI itself is not affected by the modification.

For each modification, testing and validation activities are performed to ensure continued performance of eMurmur Heart AI. To that end, recordings are collected from patients at multiple locations using the new stethoscope model to be added. The sample size is determined with a power of 80% and a confidence level of 95%. The ground truth classification - "abnormal murmur present" or "healthy" - is determined by three board-certified cardiologists through majority consensus.

Validation of a modification is considered successful only if results demonstrate non-inferior eMurmur Heart AI performance for the new stethoscope compared to the performance of an already supported stethoscope model. Non-inferiority is established using confidence intervals for unpaired data with continuity correction for the true difference in sensitivity or specificity.

If validation is not successful, then the modification is not implemented - meaning the respective stethoscope model will not be supported by eMurmur Heart AI.

Users are informed about the implemented modification through updated labeling. Specifically, a table is provided that lists all supported stethoscopes. Whenever a new stethoscope model is added in accordance with this PCCP, the new stethoscope model will be included in the table. The table is accessible through the User Manual.

## CONCLUSION

The medical device **eMurmur Heart AI** has a the same intended use, and similar indications for use, technological characteristics, and principles of operation as the predicate. The minor differences that exist between **eMurmur Heart AI** and the predicate don't raise new questions of safety or effectiveness. Performance data demonstrate, that the safety and effectiveness of **eMurmur Heart AI** are equivalent compared to the predicate. Thus, **eMurmur Heart AI** is substantially equivalent.