May 31, 2022

CSD Labs GmbH
℅ Allison Komiyama
Principal Consultant
Rqm+
2251 San Diego Ave, Suite B-257
San Diego, California 92110

Re: K220766
Trade/Device Name: eMurmur Heart AI
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD, DQC
Dated: May 6, 2022
Received: May 9, 2022

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220766

Device Name

eMurmur Heart AI

Indications for Use (Describe)

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, pathological heart murmurs and the absence of a heart murmur.

eMurmur Heart AI is indicated for use in a setting where auscultation would 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.

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)

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

CSD Labs' eMurmur Heart AI

SPONSOR

Company name:	CSD Labs GmbH
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Contact Person:	Andreas Reinisch
Date Prepared:	March 14, 2022

CONSULTANT

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Phone:	(412) 816-8253
Contact Person:	Allison Komiyama, PhD, RAC Anike Freeman, MEng, PMP

DEVICE

Trade Name:	**eMurmur Heart AI**
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 ID	K181988

INDICATIONS FOR USE

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, pathological heart murmurs and the absence of a heart murmur.

eMurmur Heart AI is indicated for use in a setting where auscultation would 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.

DEVICE DESCRIPTION

To analyze heart sounds via the **eMurmur Heart AI**, a digital recording of a patient's heart sounds is required. Recordings are made using a supported digital stethoscope, connected to a front-end client like, e.g., the eMurmur app or the eMurmur web portal. The recorded auscultation data are transmitted from the front-end client to the eMurmur backend, which hosts the **eMurmur Heart AI**. After analysis by the **eMurmur Heart AI**, the results of the analysis 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 and type of a heart murmur.

eMurmur is a non-medical device software platform which includes the eMurmur backend, 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.

The **eMurmur** software platform has functions subject to FDA premarket review, i.e., **eMurmur Heart AI**, as well as functions that are not subject to FDA premarket review. 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

The **eMurmur Heart AI** has the same technological characteristics as the predicate device eMurmur ID. It can be accessed via the eMurmur backend, which in turn communicates with the front-end clients, e.g., the eMurmur app and eMurmur web portal.

1. Both systems use the same heart sound analysis algorithm, hosted on a server, requiring a 20 second digital heart sound recording and the patient's age as input.
2. Both systems provide heart sound analysis outputs and additional supporting information to the user.
3. Both systems provide the transfer of auscultation data and the analysis results through a secure connection.
4. Both systems employ equivalent usability and cybersecurity features.
5. Both systems use the electronic stethoscope Littmann 3200 by 3M (MN, USA) (K083903) for the acquisition of the heart sounds that are to be analyzed.

PERFORMANCE DATA

eMurmur Heart AI and the predicate, eMurmur ID (K181988), utilize the same heart sound analysis algorithm, hence no new performance data is required.

All applicable verification measures (unit tests, system tests, inspections) that were performed for the predicate were also performed for the current device, using the same pass/fail criteria.

SUBSTANTIAL EQUIVALENCE

eMurmur Heart AI and eMurmur ID differ only in scope. For the previously cleared device eMurmur ID, all components of the software system (mobile app, web portal, backend, etc.) were treated as a medical device. For **eMurmur Heart AI**, only the relevant component, i.e., the algorithm analyzing heart sounds, is treated as a medical device. The other components which are solely intended to transfer, store, convert and display medical data or results are excluded from the scope of the medical device.

Thus, **eMurmur Heart AI** is substantially equivalent to eMurmur ID, see the table below.

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

	eMurmur Heart AI	**eMurmur ID**
Indications for Use	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, pathological heart murmurs and the absence of a heart murmur. **eMurmur Heart AI** is indicated for use in a setting where auscultation would 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. 'eMurmur' is a non-medical device 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. **eMurmur Heart AI** interacts with the 'eMurmur' software platform.	The eMurmur ID software system is a decision support device for the healthcare provider (the user) in the evaluation of patient heart sounds. eMurmur ID is used to record, display, analyze, and store the acoustic signal of the heart, recorded by means of an electronic stethoscope. The automated analysis will identify specific heart sounds that may be present, including S1, S2, physiological heart murmurs, pathological heart murmurs and absence of a heart murmur. eMurmur ID is indicated for use in a setting where auscultation would typically be performed by a healthcare provider. It is not intended as a sole means of diagnosis. The heart sound interpretations offered by eMurmur ID 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 authorized to perform auscultation
Acquires and Records Heart Sounds	Identical	Acquires acoustic signals of the heart by means of electronic stethoscope and mobile app
Analyzes Heart Sounds	Identical	Distinguishes between normal/physiological and pathological heart murmurs
User Interface	The user interface is not a part of **eMurmur Heart AI** (medical device); the user interface is part of 'eMurmur', a non-medical device.	Android app for recording heart sounds, sending analysis requests and receiving analysis results. Web portal for reviewing and editing user and patient data, OS independent.

Backend	The backend is not a part of **eMurmur Heart AI** (medical device); the backend is part of 'eMurmur', a non-medical device.	Server analyzes (algorithm) and stores (database) patient-related data and communicates with the other components of eMurmur ID. The interface to the other components is a REST/JSON web API.
Accessories	Identical	Electronic stethoscope Littmann 3200
Safety Features	Identical	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
Clinical Performance	Identical	Sensitivity: 85.0% (72.9%-92.5%) Specificity: 86.7% (74.9%-93.7%)

CONCLUSIONS

The medical device **eMurmur Heart AI** has the same intended use, similar indications for use, and the same technological characteristics, and principles of operation as eMurmur ID. Thus, **eMurmur Heart AI** is substantially equivalent to eMurmur ID.

eMurmur Heart AI consists of the same heart sound analysis algorithm as eMurmur ID. Other components that were part of the eMurmur ID medical device (e.g., the app and web portal) have been excluded from the **eMurmur Heart AI** medical device, since these components are software solely intended to transfer, store, convert and display medical data or results.