April 17, 2019

CSD Labs GmbH
% Yarmela Pavlovic
Partner
Hogan Lovells US LLP
3 Embarcadero Center
San Francisco, California 94501

Re: K181988
Trade/Device Name: eMurmur ID
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD, DQC
Dated: March 19, 2019
Received: March 19, 2019

Dear Yarmela Pavlovic:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S5

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181988

Device Name
eMurmur ID

Indications for Use *(Describe)*
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.

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

CSD Labs' eMurmur ID (K181988)

SPONSOR

Company name:	CSD Labs GmbH
Company address:	Nikolaiplatz 4 8020 Graz Austria
Contact Person:	Andreas Reinisch
Date Prepared:	March 19, 2019

DEVICE

Trade Name:	**eMurmur ID**
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)**
Diacoustic Medical Devices	SensiCardiac Mobi	K131044 (Primary Predicate)
Discoustic Medical Devices	SensiCardiac	K121617 (Reference Device)

INDICATIONS FOR USE

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.

DEVICE DESCRIPTION

eMurmur ID is a software system comprised of the following components:

1. The eMurmur ID Backend, running on a server environment, hosts the eMurmur ID Heart Sound Analysis Algorithm, an encrypted database for archiving patient and user information, and an application programming interface (API) for communication with the web portal and mobile application.

2. The eMurmur ID Mobile App, which runs on a mobile device. The app permits the following activities:
    a. Electronic recording of heart sound signals via a compatible electronic stethoscope, the Littmann 3200
    b. Visual and acoustic playback of heart and lung sounds
    c. Capturing patient information
    d. Transferring data to and from the eMurmur ID backend through a secure connection
    e. Displaying heart sound analysis results
3. The eMurmur ID Web Portal, which provides the following functionalities:
    a. Capturing and editing patient information
    b. Displaying and editing patient encounters including heart sound analysis results
    c. Visual and acoustic playback of heart and lung sounds
    d. Downloading reports (PDF) and heart and lung sound recordings
    e. Transferring data to and from the eMurmur ID backend through a secure connection

The acquisition of the acoustic data is carried out by the FDA-cleared off-the-shelf electronic stethoscope Littmann 3200 by 3M (MN, USA) (K083903).

For heart sounds to be analyzed by the heart sound analysis algorithm, a 20 second digital recording of the patient's heart sounds and the patient's date of birth are required. Heart sounds are recorded using the compatible, FDA-cleared, off-the-shelf electronic stethoscope Littmann 3200. The heart sounds are transmitted via Bluetooth to a mobile device running the eMurmur ID mobile app. The app then stores and sends the recorded data to the eMurmur ID backend for analysis. The results of the heart sound analysis are returned to the app within a few seconds, where they are displayed to the user together with the heart sound recording. The user can utilize the heart sound analysis results and the acoustic and visual representation of the heart sound recordings as decision support data in their decision-making process regarding the presence and type of a heart murmur.

TECHNOLOGICAL CHARACTERISTICS

eMurmur ID has technological characteristics that are comparable to the predicate and reference devices:

1. Each of the systems host a heart sound analysis algorithm, a web API and a database on a backend server.
2. Each of the systems provide the user with a mobile app, which is used to record heart sounds and patient information. The mobile app transfers the data to the backend through a secure connection and displays the analysis results to the user.
3. Each of the systems require an FDA-cleared off-the-shelf electronic stethoscope for the acquisition of the heart sounds.
4. Each of the devices provide similar heart sound analysis output and similar additional supporting information to the user.

	eMurmur ID (K181988)	SensiCardiac Mobi (K131044) (Primary Predicate)	SensiCardiac (K121617) (Reference Device)
Intended Use / Indications for Use	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.	The SensiCardiac Mobi Diagnostic is an electronic auscultatory device, intended to provide support to the physician in the evaluation of patients' heart sounds. The product acquires and records the acoustic signals of the heart and analyzes these signals. The analysis procedure will identify specific heart sounds that may be present. Identified sounds include S1, S2, and suspected murmurs. The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the order of a licensed physician. It is not intended as a sole means of diagnosis. The interpretation of heart sounds offered by the SensiCardiac Mobi are only significant when used in conjunction with physician over-read as well as consideration of all other relevant patient data.	Sensi is a decision support software package intended to assist medical examiners in heart auscultation. The Sensi Diagnostic Heart Murmur Software distinguishes between normal/physiological and pathological heart murmurs by analyzing the acoustic heart signals captured with an electronic stethoscope. The device will record the acoustic sound of the heart at the four main auscultation positions. The acoustic heart signal is analyzed to identify heart sounds that may be present, identified sounds include S1, S2 and suspected murmurs.
User Population	Healthcare provider licensed or authorized to perform auscultation	Healthcare provider licensed or authorized to perform auscultation	Healthcare provider licensed or authorized to perform auscultation
Acquires and Records Heart Sounds	Yes – acoustic signal of heart by means of electronic stethoscope and mobile app	Yes – acoustic signal of heart by means of electronic stethoscope and mobile app	Yes – acoustic signal of heart by means of electronic stethoscope and Windows desktop app
Analyzes Heart Sounds	Yes – distinguishes between normal/physiological and pathological heart murmurs	Yes – distinguishes between normal/physiological and pathological heart murmurs	Yes – distinguishes between normal/physiological and pathological heart murmurs

	eMurmur ID (K181988)	SensiCardiac Mobi (K131044) (Primary Predicate)	SensiCardiac (K121617) (Reference Device)
User Interface	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.	Recording and analysis are conducted on an iOS mobile app, which is also used for reviewing auscultations.	Recording and analysis are conducted on a Windows desktop app, which is also used for reviewing auscultations.
Backend	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.	Equivalent architecture. The API uses the XML data format instead of JSON. Is equipped with algorithm identical to K121617.	Equivalent architecture. Instead of a mobile app, a desktop app is used. The API uses the XML data format instead of JSON. The equivalence of algorithm performance is demonstrated in a clinical trial.
Safety Features	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	Identical regarding aspects that are verifiable by CSD Labs.	Identical regarding aspects that are verifiable by CSD Labs.

PERFORMANCE DATA

Performance data included software verification and validation testing, electromagnetic compatibility, electrical safety, wireless coexistence, and bench validation testing using existing heart sound databases. It also included a pivotal clinical study. The pivotal clinical study was conducted comparing eMurmur ID to the reference device, SensiCardiac (K121617) — the predecessor to the primary predicate, SensiCardiac Mobi (K131044), which was not yet commercially available for comparison at the time of testing — in a prospective clinical investigation. It verified the hypothesis that eMurmur ID can distinguish between AHA class I (pathologic murmurs) and AHA class III heart sounds (innocent murmurs and/or no murmurs) with a sensitivity and specificity not worse than that of the predicate device.

The study population consisted of 120 subjects across all ages where 50% had a confirmed pathological murmur (class I) and 50% had a confirmed innocent or no murmur (class III). Patient's heart sounds were recorded by the expert physician and analyzed by both eMurmur ID and the predicate device. The findings for both devices were compared to clinical gold standard reference, defined as the expert physician's auscultation-based diagnosis, independently verified by cardiac echocardiography.

The following table shows the results of the primary (sensitivity, specificity) and secondary (accuracy) endpoints of the study with their respective 95% confidence intervals. The results were compared using the 95%-Fleiss confidence interval method for paired binary data.

	eMurmur ID	SensiCardiac
Sensitivity (95% CI)	85.0% (72.9%-92.5%)	58.3% (44.9%-70.7%)
Specificity (95% CI)	86.7% (74.9%-93.7%)	58.3% (44.9%-70.7%)
Accuracy (95% CI)	85.8% (78.0%-91.3%)	58.3% (49.0%-67.2%)

The results of the study met the criteria for successfully demonstrating that eMurmur ID performance was not worse than the predicate device. In fact, the actual study results demonstrated that the eMurmur ID performed statistically significantly better than the predicate with respect to both sensitivity ($p=0.0014$) and specificity ($p=0.0009$), as well as with respect to overall accuracy ($p<0.0001$).

In all instances, eMurmur ID functioned as intended, and the electromagnetic compatibility, bench testing, and clinical performance observed were as expected.

CONCLUSIONS

Performance data demonstrate that the eMurmur ID software system performs in a manner that is comparable to the reference device, meeting the criteria that it be at least non-inferior. eMurmur ID has the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate device. The minor technological differences between eMurmur ID and its predicate device raise no new questions of safety or effectiveness. Thus, eMurmur ID is substantially equivalent.