July 12, 2023

AusculThing Oy
Jani Virtanen
Process owner, Regulatory and Quality Affairs
Ruusutorpanpuisto 4 A 15
Espoo, 02600
Finland

Re: K230823
Trade/Device Name: AusculThing ACC
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD, DQC
Dated: June 12, 2023
Received: June 12, 2023

Dear Jani Virtanen:

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,

for Hetal B. Patel -S

Robert Kazmierski
Acting 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)*

K230823

Device Name

AusculThing ACC

Indications for Use *(Describe)*

The AusculThing ACC software is a decision-support SW for the healthcare provider (the user) in the evaluation of patient heart sounds. The ACC is used to record, display, and analyze acoustic signals of the heart recorded by means of an electronic stethoscope. It is intended for use on adult and pediatric patients. The automated analysis will categorize heart sounds as either “abnormal” if any heart murmur of any intensity is identified in any position across the precordium, or “normal” if either no murmurs or benign murmurs are identified. ACC 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 interpretation offered by the software is only significant when used in conjunction with physician over-read and including all other relevant patient data. The device is intended for Rx use only. The AusculThing ACC shall be used together with Thinklabs One electronic stethoscope.

Type of Use *(Select one or both, as applicable)*

[X] 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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# 5. 510(k) Summary

**Submitter information**

| | |
|---|---|
| Name: | AusculThing Ltd. |
| Address: | Ruusutorpanpuisto 4 A 15<br>02600 Espoo, Finland |
| Phone: | +358 50 3801 134 |
| Contact person: | Jani Virtanen, D.Sc.<br>Regulatory and Quality Affairs, Process Owner |
| Submission date: | 15 March 2023 |

**Device information**

| | |
|---|---|
| Trade name: | AusculThing ACC |
| Common name: | Decision support SW, Computer Aided Auscultation, Heart Sound Analyzer |
| Classification name: | Electronic Stethoscope, Phonocardiograph |
| Regulation number: | 21 CFR 870.1875, 870.2390 |
| Product code: | DQD, DQC |
| Classification panel: | Cardiology |

**Predicate devices**

| | | |
|---|---|---|
| Primary predicate: | K181988 | Emurmur ID |

## 5.1 Device Description

AusculThing ACC is a decision support SW that collects heart sounds from adult and pediatric patients. The ACC software receives the data using a Thinklabs One electronic stethoscope.The SW is running on a mobile device, where the electronic stethoscope is connected to. The SW guides the user how relevant heart sound recordings should be obtained from different parts of the body. After recording, the ACC analyzes the recordings in conjunction automatically using an AI -based algorithm, which is trained using a proprietary echocardiogram validated high-quality data database. An image below shows the basic architecture of the use environment for the ACC.

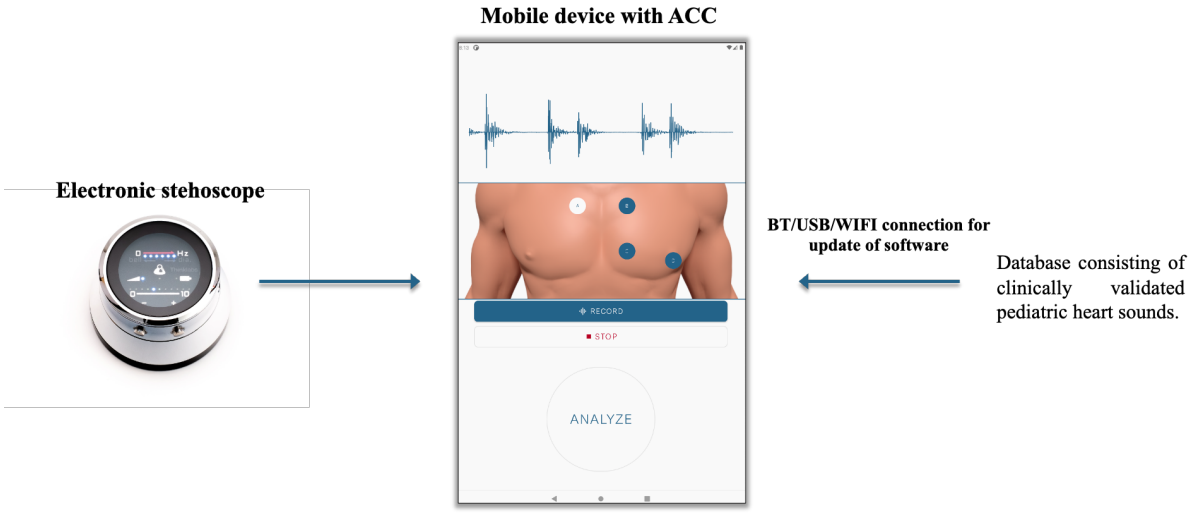


***Image 5.1.*** *Basic structure of the ACC use environment.*

The basic functionality of the ACC SW is to give a user an instant, automated, analysis of the patient under evaluation and differentiate between normal and pathological sounds. For the abnormal heart sounds, the ACC delivers information on suspected murmurs.

The ACC software is a SW that allows a user to upload heart sounds/phonocardiogram (PCG) data to the device for analysis and visualization. The AusculThing ACC Mobile App runs on a mobile device. The app permits the electronic recording of heart sound signals via a compatible electronic stethoscope (Thinklabs One). The app also permits visual and acoustic playback of heart sounds in the mobile device. After analysis, results are returned to the user in the App. The Murmur detection algorithm is based on a neural network model that uses heart sounds to detect the presence of pathological heart sounds.

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.

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## 5.2 Intended use

The AusculThing ACC software is a decision-support SW for the healthcare provider (the user) in the evaluation of patient heart sounds. The ACC is used to record, display, and analyze acoustic signals of the heart recorded by means of an electronic stethoscope. It is intended for use on adult and pediatric patients. The automated analysis will categorize heart sounds as either "abnormal" if any heart murmur of any intensity is identified in any position across the precordium, or "normal" if either no murmurs or benign murmurs are identified. ACC 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 interpretation offered by the software is only significant when used in conjunction with physician over-read and including all other relevant patient data. The device is intended for Rx use only. The AusculThing ACC shall be used together with Thinklabs One electronic stethoscope.

## 5.3 Technological characteristics

AusculThing ACC has technological characteristics that are comparable to the predicate device:

1. Both systems host a heart sound analysis algorithm.

2. Both systems provide the user with a mobile app, which is used to record heart sounds and patient information. Both systems perform an analysis to the data and display the analysis results to the user.

3. Both systems require an FDA-cleared off-the-shelf electronic stethoscope for the acquisition of the heart sounds.

4. Both devices provide similar heart sound analysis output and similar additional supporting information to the user.

The predicate device in this 510(k) Premarket Notification submission is eMurMur ID (K181988) which function and indication are substantially equivalent for the Ausculthing ACC software. On a table below is presented the technical characteristics of the ACC software and eMurMur ID.

The ACC does not raise different questions of safety or effectiveness in comparison to the predicates. While some of the predicate devices feature additional technological capabilities (e.g., the predicate device additional parameters on heart sound), this does not raise different questions of safety or effectiveness because in all cases the subject device features are a subset of those cleared predicate devices.

| | **ACC** | **Emurmur ID** |
|---|---|---|
| **Device type** | Software only | Software only |
| **Physiological input** | Heart sounds | Heart sounds |

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| | | |
|---|---|---|
| **Classification product code** | DQD, DQC | DQD, DQC |
| **510(k) number** | K230823 | K181988 |
| **Patient population** | Adult and pediatric | Adult and pediatric |
| **Intended use / Indications for Use** | The AusculThing ACC software is a decision-support SW for the healthcare provider (the user) in the evaluation of patient heart sounds. The ACC is used to record, display, and analyze acoustic signals of the heart recorded by means of an electronic stethoscope. It is intended for use on adult and pediatric patients. The automated analysis will categorize heart sounds as either "abnormal" if any heart murmur of any intensity is identified in any position across the precordium, or "normal" if either no murmurs or benign murmurs are identified. ACC 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 interpretation offered by the software is only significant when used in conjunction with physician over-read and including all other relevant patient data. The device is intended for Rx use only. The AusculThing ACC shall be used together with Thinklabs One electronic stethoscope. | 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.<br><br>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. |
| **Prescribed** | Prescription only | Prescription only |
| **User interface** | App (iOS/Android) for recording heart sounds, performing analysis of recordings locally on the device and presenting the analysis results. | App for recording heart sounds, sending analysis requests and receiving analysis results. Web portal for reviewing and editing user and patient data. |
| **Murmur detection** | Yes (Classification) | Yes (Classification) |
| **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 |
| **Analyzes heart sounds** | Yes – distinguishes between normal and pathological heart murmurs | Yes – distinguishes between normal/physiological and pathological heart murmurs |
| **Intended user** | Healthcare provider licensed or | Healthcare provider licensed or |

| | | |
|---|---|---|
| | authorized to perform auscultation | authorized to perform auscultation |
| **Backend** | The mobile device analyzes the data and communicates with the other components of AusculThing ACC. Results from the analysis can be shared via email. | 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. |
| **Safety features** | No protected health information is stored on the user's devices. User has authentication on the app and the mobile device. | 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. |

## 5.4 Performance data - Non-clinical Testing

Performance data included software verification and validation testing, no performance data under non-clinical testing have been included.

## 5.5 Performance data - Clinical Testing

The algorithm in this submission has been validated using proprietary data captured with the ACC. A total of 519 recordings were captured from a study population consisting of 133 patients. Of the population 84 were below 18 years of age and 49 were above. Out of the 133 patients 84 had a confirmed heart defect. All data was collected in a clinical study in accordance with GCP/ISO14155.

In the table below the content (age distribution, gender, diagnoses and auscultation findings) of the validation data is described. Some of the patients have multiple diagnoses.

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| | | R01.0 : Benign murmur | Q21.0 : Ventricular Septal Defect | Q21.10 : Atrial Septal Defect | Q21.11 : Patent foramen ovale | Q23.0 : Stenosis congenita valva e aorta | Q23.11 : Valvae aortae biscupidalis | Q22.1 : Stenosis congenita valva pulmonalis (inc. ToF) | Q25.1 : Coarctation of the aorta | Q25.0 : Patent ductus arteriosus | Q23.10 : Insufficientia congenita valvae aortae | Q22.2 : Insufficientia congenita valvae pulmonalis | Q23.3 : Insufficientia congenita valvae mitralis | Q25.7 : Stenosis pulmonalis | I35.0 : Stenosis valvae aortae | I37.0 : Stenosis valvae pulmonalis | I34.2 : Stenosis valvae mitralis | I35.1 : Insufficientia valvae aortae | I37.1 : Insufficientia valvae pulmonalis | I34.0 : Insufficientia valvae mitralis | I36.1 : Insufficientia valvae tricuspidalis | Normal (no murmur nor heart defect) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Age group** | 0 - 1 months | 0 | 3 | 0 | 0 | 0 | 0 | 1 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1 - 6 months | 6 | 4 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 |
| | 6 - 12 months | 3 | 2 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 1 - 4 years | 5 | 0 | 0 | 0 | 1 | 1 | 1 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 4 - 12 years | 9 | 4 | 0 | 0 | 6 | 2 | 2 | 3 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 7 |
| | 12 -18 years | 3 | 1 | 0 | 0 | 2 | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 3 |
| | 18 - 55 years | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 0 | 0 | 1 | 0 | 1 | 0 | 1 |
| | 55 -80 years | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 20 | 0 | 0 | 3 | 0 | 5 | 3 | 1 |
| | >80 years | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 8 | 0 | 0 | 1 | 0 | 1 | 0 | 0 |
| **Sex** | Male | 16 | 5 | 1 | 0 | 6 | 3 | 3 | 2 | 0 | 2 | 0 | 0 | 2 | 22 | 0 | 0 | 4 | 0 | 8 | 3 | 9 |
| | Female | 18 | 9 | 0 | 0 | 3 | 1 | 3 | 1 | 6 | 0 | 0 | 0 | 1 | 12 | 0 | 0 | 1 | 0 | 0 | 0 | 7 |
| **Systolic findings** | - | 24 | 14 | 1 | 0 | 9 | 4 | 6 | 3 | 6 | 2 | 0 | 0 | 3 | 33 | 0 | 0 | 5 | 0 | 8 | 3 | 1 |
| **Diastolic finding** | - | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Systolic gradus** | 1 | 13 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 10 | 4 | 1 | 0 | 1 | 2 | 2 | 2 | 1 | 0 | 0 | 0 | 1 | 7 | 0 | 0 | 0 | 0 | 1 | 0 | 1 |
| | 3 | 0 | 6 | 0 | 0 | 3 | 2 | 3 | 1 | 1 | 1 | 0 | 0 | 2 | 11 | 0 | 0 | 2 | 0 | 4 | 1 | 0 |
| | 4 | 0 | 2 | 0 | 0 | 4 | 0 | 1 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Diastolic gradus** | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Punctum Maximum** | A | 4 | 0 | 0 | 0 | 6 | 2 | 1 | 1 | 0 | 1 | 0 | 0 | 0 | 8 | 0 | 0 | 1 | 0 | 0 | 0 | 0 |
| | B | 4 | 0 | 0 | 0 | 0 | 0 | 4 | 0 | 3 | 0 | 0 | 0 | 3 | 15 | 0 | 0 | 3 | 0 | 2 | 2 | 0 |
| | C | 8 | 13 | 0 | 0 | 2 | 1 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 7 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | D | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 1 | 0 | 6 | 0 | 0 |
| | Unspecified | 14 | 1 | 1 | 0 | 1 | 1 | 1 | 2 | 2 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 1 | 16 |

Heart sounds were recorded from all patients either by a cardiologist. An echocardiogram was conducted by a cardiologist on all patients to establish the golden standard for diagnosis to which the algorithm performance was compared. The table below shows the amount of recordings made in each hospitals.

| Population | Hospital District | Hospital | Audio recordings obtained by | Patient count |
|---|---|---|---|---|
| Children | Kuopio University Hospital | Puijo Hospital | Cardiologist | 14 |
| | Oulu University Hospital | Oulu University Hospital | Cardiologist | 70 |
| Adults | Hospital district of Helsinki and Uusimaa | Lohja Hospital | Cardiologist | 20 |
| | | Hyvinkää Hospital | Cardiologist | 29 |

The obtained accuracy, sensitivity and specificity were compared to the predicate device performance metrics as provided in the predicate device 510k summary (K181988) and are shown in the following table:

| | **ACC** | **eMurmur ID** |
|---|---|---|
| Sensitivity | 90.5% (82.3%-95.1%) | 85.0% (72.9%-92.5%) |
| Specificity | 96.0% (86.3%-98.9%) | 86.7% (74.9%-93.7%) |
| Accuracy | 92.5% (86.7%-95.9%) | 85.8% (78.0%-91.3%) |

The results from the study demonstrate that ACC does not perform worse than the predicate device in the given test setting.

Conclusions

The ACC Analysis Software is as safe and effective as the predicate device. Performance data demonstrate that the AusculThing ACC software performs in a manner that is comparable to the reference device, meeting the criteria that it be at least non-inferior. The ACC Analysis Software has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between AusculThing ACC and its predicate device raise no new questions of safety or effectiveness when used as labeled. Thus, the ACC Analysis Software is substantially equivalent.