January 20, 2023

Medaica Inc.
% Dave Yungvirt
Official Correspondent
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K223166
Trade/Device Name: Medaica M1 Telehealth Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: October 7, 2022
Received: October 7, 2022

Dear Dave Yungvirt:

We have reviewed the 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,

Robert T. Kazmierski -S

for

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)*

K223166

Device Name
Medaica M1 Telehealth Stethoscope

Indications for Use *(Describe)*

The Medaica M1 Telehealth Stethoscope is an electronic stethoscope that enables transmission of auscultation sound data, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient on site or at a different location on the IP network with the signal carried on an IP connection between the two locations.
The Medica M1 Telehealth Stethoscope is intended to be used by professional users in a clinical environment or by lay users in a nonclinical environment. The device is for medical diagnostics purposes only. The device is not intended for self-diagnosis.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary

| | |
|---|---|
| **Submitter Name and Address** | Medaica Inc.<br>170 S. Green Valley Pkwy Ste 300<br>Henderson, NV 89012 |
| **Contact Person** | Stephen Randall, CEO<br>**Email:** stephen-randall@medaica.com<br>**Phone:** (917) 480 9995 |
| **Establishment Registration Number** | n/a |
| **Date Prepared** | October 3, 2022 |
| **Device Trade Name** | Medaica M1 Telehealth Stethoscope |
| **Device Common Name** | Electronic Stethoscope |
| **Classification** | **Name:** Electronic Stethoscope<br>**Product Code:** DQD<br>**Regulation No:** 21 CFR 870 1875<br>**Class:** II<br>**Panel:** Cardiovascular |

| **Predicate Device** | | |
|---|---|---|
| **Device Name** | **510(k) No.** | **Date of Clearance** |
| Tyto Stethoscope (OTC) | K181612 | December 17, 2018 |

### Intended Use/Indication for Use Statement

The Medaica M1 Telehealth Stethoscope is an electronic stethoscope that enables transmission of auscultation sound data, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient on site or at a different location on the IP network with the signal carried on an IP connection between the two locations.

The Medica M1 Telehealth Stethoscope is intended to be used by professional users in a clinical environment or by lay users in a nonclinical environment. The device is for medical diagnostics purposes only. The device is not intended for self-diagnosis.

### Device Description

The Medaica M1 Telehealth Stethoscope is designed for use by professional as well as lay users in clinical or non-clinical environments. It enables three types of stethoscope exams:

Heart, Lungs and Audio (Audio is for clinician only). The operation process of the Medaica M1 Telehealth Stethoscope uses four (4) primary functional elements:

(1) The Medaica M1 Telehealth Stethoscope.

(2) A patient's web-connected computer on which the Medaica Web Client software is running.

(3) The Medaica Server on which the Medaica server software is running.

(4) A clinician's web-connected computer on which the Medaica Web Client software is running.

The Medaica M1 Telehealth Stethoscope operates either in Patient Store and Forward mode or Live, online mode. Both modes are essentially similar and share the same fundamental steps: performing one or more exams using the Medaica M1 Telehealth Stethoscope, recording the data and sending to a clinician, review of the exams by the clinician, and the user receiving a summary from the clinician presenting his/her assessment and/or recommendations. While in the Patient Store and Forward mode, the Patient can send the recorded data to the clinician whenever convenient for him/her. A Live, online mode can only be executed when the clinician is available online at the same time as the patient.

**Substantial Equivalence to Predicate Device:**

The Medaica M1 Telehealth Stethoscope has the same intended use, same indications for use and similar fundamental technological characteristics as the predicate, the Tyto Stethoscope OTC (K181612).

The Medaica M1 Telehealth Stethoscope, like its predicate device, is an electronic stethoscope intended for transmitting recorded auscultation sounds to a remote location where a clinician can listen to them. In addition, both devices are indicated for use by lay users as well as by professional users.

The Medaica M1 Telehealth Stethoscope shares with its predicate similar structural design (i.e., device components and additional operational elements). In addition, similar principles and mode of operation are used:

- Both devices have the same intended use.
- Both the Medaica and Tyto Stethoscopes detect auscultation using a microphone sensor.
- The M1 and Tyto have the same frequency range of 20 - 3,500 Hz.
- Both devices have two operational modes: Patient Store and Forward and Live Clinician Guided Exams.
- Both devices support the same exam types: Heart, Lungs, and Audio (Clinician auscultation review).
- Both M1 and the predicate perform data transfer online.

Any minor differences in technology between the Medaica M1 Telehealth Stethoscope and Tyto Stethoscope OTC do not raise different questions of safety or effectiveness. Furthermore, testing demonstrates that the performance of the Medaica M1 Telehealth Stethoscope is comparable to its predicate device.

**Performance Testing:**

Performance testing was conducted to demonstrate the performance, safety, and usability of the Medaica M1 Telehealth Stethoscope. The testing plan included the following:

- Electrical safety and electromagnetic compatibility testing in accordance with:

  *ANSI AAMI ES 60601-1:2005 and A1:2012. Medical electrical equipment - Part 1 General requirements for safety and essential performance (IEC 60601-1 2005. MOD)*, FDA Recognition Number 19-4.

  *IEC 60601-1-2:2014 Medical Electrical Equipment, Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests.* FDA Recognition Number 19-8.

  *IEC 60601-1-11 Edition 2.1 2020-07 Consolidated Version. Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.* FDA Recognition Number 19-38.

- Biocompatibility in accordance with *ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.* Testing performed included Cytotoxicity per ISO 10993-5, Sensitization per ISO 10993-10 and Irritation per ISO 10993-10.
- Stethoscope performance testing was conducted to demonstrate that the device has the required sensitivity and signal to noise response over the desired frequency range of 20Hz to 3,500 Hz.
- Software validation testing in accordance *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 5,2011)* and *IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes* was successfully conducted.
- A usability study in accordance with Medaica's System Usability Test Protocol and in accordance with FDA guidance document *Applying Human Factors and Usability Engineering to Medical Devices, February 3, 2016*.

**Conclusion**

Performance data and test results support the substantial equivalence of the Medaica M1 Telehealth Stethoscope and its predicate device. The Medaica M1 Telehealth Stethoscope functions as expected and is as safe and effective as its predicate device for its intended use. It is, therefore, concluded that the Medaica M1 Telehealth Stethoscope is substantially equivalent to its predicate device without raising any new safety and/or effectiveness issues.