



January 26, 2018

MiTAC International Corp.
Yihao Huang
Product Manager
No. 200, Wen Hua 2nd Rd.
Guishan Dist.
Taoyuan City, 33383 Taiwan

Re: K162665

Trade/Device Name: MiCor A100 Wearable ECG Recorder
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: December 26, 2017
Received: December 29, 2017

Dear Yihao Huang:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

A handwritten signature in black ink, appearing to read "M. D. Zuckerman".

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K162665

Device Name
MiCor A100 Wearable ECG Recorder

Indications for Use (Describe)

The device is intended for use by users who have transient symptoms that may suggest cardiac conduction abnormalities or by users who wants to monitor the cardiac function at home health care from Lead 1 ECG signal.

ECG acquisition and transmission is voluntary and mutually activated by the user. The intend users are adult.

The device is design to let user wear on wrist and record ECG signal while user feel transient cardiac abnormalities symptoms any time.

Users with implanted pacemaker are not recommended to use this device.

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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Appendix 8

510(k) Summary

510(k) Summary

- 5.1 Type of Submission:** Traditional
- 5.2 Date of Summary:** 01/17/2017
- 5.3 Submitter:** MiTAC International CORP.
Address: No. 200, Wen Hua 2nd Rd., Guishan Dist.,
Taoyuan City 33383, Taiwan (R.O.C.)
Phone: + 886-3-396-2888
Fax: + 886-3-396-1000
Contact: YiHao Huang (yihao.huang@mic.com.tw)
- 5.4 Identification of the Device:**
Proprietary/Trade name: MiCor A100 Wearable ECG Recorder
Regulation Description: Electrocardiograph
Review Panel: Cardiovascular
Regulation Number: 870.2340
Device Class: II
Product Code: DPS
- 5.5 Identification of the Predicate Device:**
Predicate Device Name: ReadMyHeart
Manufacturer: DailyCare BioMedical Inc.
Regulation Number: 870.2340
Device Class: II
Product Code: DPS
510(k) Number: K042814

5.6 Intended Use/ Indications for Use of the subject device

The device is intended for use by users who have transient symptoms that may suggest cardiac conduction abnormalities or by users who wants to monitor the cardiac function at home health care from Lead 1 ECG signal.

ECG acquisition and transmission is voluntary and mutually activated by the user. The intend users are adult.

The device is design to let user wear on wrist and record ECG signal while user feel transient cardiac abnormalities symptoms any time.

Users with implanted pacemaker are not recommended to use this device.

5.7 Device Description

MiCor A100 Wearable ECG Recorder is an easy-to-use electrocardiograph unit that can record and store electrocardiogram (ECG) measurements of users' heart rhythm. ECG acquisition and transmission is voluntary and mutually activated by the user. The intended users are adult. The device is designed to let user wear on wrist and record ECG signal while user feel transient cardiac abnormalities symptoms any time. Users with implanted pacemaker are not recommended to use this device.

The device is the wristband as wearable style. It is smaller and light weight, dry electrode and affordable ECG recording device. Its primary function is recording ECG signal of user/patient with one finger press on top of ECG plate of device. The device will record the user/patient ECG signal for 30 seconds and automatically store into build-in memory, meanwhile, the device also display the real time heart rate. The device can store 30 sets of ECG signal (30 seconds / set of data), then user can transfer ECG signal data from device to APP of the iPhone via BLE. The APP can display ECG of each recording ECG signal. And user can print the ECG and let his Cardiologist to refer and diagnose.

5.8 Non-clinical Testing

A series of safety and performance tests were conducted on the proposed device, MiCor A100 Wearable ECG Recorder.

- Reliability Test
- Biocompatibility Test
 - In Vitro Cytotoxicity Test
 - Skin Sensitization Study (Maximization Test)
 - White Rabbit Skin Irritation Test
- Software Validation
- Electrical Safety and EMC Tests
- Performance Test
 - IEC 60601-2-47: 2012
- Usability Test

All the test results demonstrate that MiCor A100 Wearable ECG Recorder meets the requirements of its pre-defined acceptance criteria, and is substantially equivalent to the predicate device.

5.9 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

5.10 Substantial Equivalence Determination

The MiCor A100 Wearable ECG Recorder has the same safety and performance claims, and similar technological characteristics to the predicate device, ReadMyHeart (K042814). A series of tests were performed and demonstrated substantial equivalence between the proposed and the predicate device. Differences between the devices cited in this section do not raise any new issues of substantial equivalence.

Item	Proposed device	Predicate device
Proprietary name	MiCor A100 Wearable ECG Recorder	ReadMyHeart
510(k) No.	-	K042814
Intended use	<p>The device is intended for use by users who have transient symptoms that may suggest cardiac conduction abnormalities or by users who wants to monitor the cardiac function at home health care from Lead I ECG signal.</p> <p>ECG acquisition and transmission is voluntary and mutually activated by the user. The intend users are adult.</p> <p>The device is design to let user wear on wrist and record ECG signal while user feel transient cardiac abnormalities symptoms any time.</p> <p>Users with implanted pacemaker are not recommended to use this device.</p>	<p>The device is a personal single lead Electrocardiograph monitor. The device is intended for self-testing by patients by recording 15 seconds of the first standard lead I of Electrocardiogram. The recording is activated by the patient when symptoms are experienced or whenever desired as routine recordings to be analyzed by a trained physician. The intended user are Users who are above 20 years old.</p> <p>The user is normally not required to apply electrode on the body. Two electrodes integrated within the device are provided. The user has to press his thumbs on the two electrodes in order record the ECG signal.</p> <p>The User may also record ECG signals optionally through auxiliary external electrode provided separately, if thumb pressings are inconvenient for any reason.</p> <p>The recorded data can be downloaded to Personal Computer via USB interface port. This device is not intended for use as precisely diagnostic</p>

		<p>tool. This device is also not intended for recording and transmission of user's ECG signal simultaneously. Users with implanted pacemaker are not recommended to use this device.</p>
Mechanism of action	<p>MiCor A100 Wearable ECG recorder is a non-invasive, wearable type ECG recorder. It allows user to measure and record electrical activities of the heart anywhere and anytime.</p> <p>Electrical signals of the heart can be obtained using one finger places on MiCor A100 wearable ECG recorder by dry conducting electrodes (Lead 1 ECG). It will record 30 seconds of the ECG signal (to measure cardiac activities), unlike traditional ECG device which requires at least 3 electrodes. The electrical signal goes filters then comes out the useful ECG data and recorder in the device.</p>	<p>ReadMyHeart (K042814) is a handheld, personalized use, dry electrode and affordable ECG recording device that records user's cardiac functions for daily health check.</p> <p>It takes ECG signals of user/patient with thumbs press on electrode at ReadMyHeart gently. The device will record user's ECG signal for 30 seconds, and automatically stores the last 15 seconds signals into the build-in memory, while three parameters measured, mainly, Heart Rate (HR), ST segment and QRS interval of cardiac ECG signal, displays on LCD of the device.</p> <p>Users may activate the device to acquire ECG Lead I information voluntarily and mutually.</p>
	Technology	
ECG type	Lead 1	Lead 1
Specification		
Input impedance	> 10 M - Ohm	> 10 Mohm

Input dynamic range	+/- 200 mV	+/-2 mV
Bandwidth	0.1 - 40Hz	0.15 –40 Hz
CMRR (Common Mode Rejection Ratio)	> 60 dB	> 60 dB
A/D conversion	16 bit	12 bit
Sampling rate	250 samples/sec	250 samples/sec
Measurement time	30 seconds	30 seconds
Storage ECG data	30 measurements	25 measurements
Feature		
Use type	Wearable	handheld
Display on device	72x32 Dot – OLED	LCD display
Other device connection & data display	Mobile application (APP) of smartphone	PC
Input	Dry conduction electrodes	Dry conduction electrodes and/or external auxiliary electrodes
Output / Data transfer	Bluetooth	USB interface
Power supply	Non-replaceable internal Lithium Ion battery / Rechargeable	1.5 V (AAA) ×2
Measurement range		
Average heart rate	30 to 240 bpm	45 to 180 bpm
ST segment	—	-3 to +3 mm
QRS interval	—	< 0.20 sec
Size		
Dimension	45.6 x 21.4 x 11.3 (mm)	12 x 8 x 2 cm
Weight	24.5g	116 g excluding batteries

Environmental conditions		
Storage temperature	-25 °C to 70 °C	-20 °C to 50 °C
Operating temperature	5 °C to 45 °C ECG plate: 46 °C (Max.)	10 °C to 40 °C
Humidity	10 % to 95 %	25 % to 95 %
Atmosphere pressure	800 - 1013 hPa	—
Compliance		
Test	IEC 60601-2-47	IEC 60601-2-47 IEC 60601-2-25

5.11 Similarity and Difference

Although the specification and features are different between the proposed and the predicate device, they have the same safety and performance claims, and similar technological characteristics. The proposed device has been conducted on safety and performance tests, and the results complied with the test requests. After comparison analysis considering test results, the difference of the proposed and the predicate device did not raise any problems of substantial equivalence. The proposed device is substantially equivalent to the predicate device in safety and performance claims.

5.12 Conclusion

After analyzing non-clinical studies and safety testing data, it can be concluded that MiCor A100 Wearable ECG Recorder is substantially equivalent to the predicate device.