March 26, 2019

Memtec Corporation
Dennis Garboski
President
68 Stiles Road Unit D
Salem, New Hampshire 03079

Re: K181658
Trade/Device Name: MobileECG 2 BT
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II
Product Code: DSI, MWJ
Dated: February 21, 2019
Received: February 26, 2019

Dear Dennis Garboski:

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,

for Jessica E. Paulsen -S

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)*
K181658

Device Name

MobileECG 2 BT

Indications for Use *(Describe)*
Indications for Use

Configuration 1) Holter Mode: The MobileECG 2 BT is intended to record continuous data for 30+ days for the detection of arrhythmias in ambulatory patients. Such monitoring is frequently used for patient symptoms such as: Palpitations, shortness of breath, chest pain, syncope, evaluating pacemakers, heart rate variability's, and clinical studies. The MobileECG 2 BT device transmits all collected data to a call center for interpretation using the TM eCloud ECG Analysis System at the end of the completed study.

Configuration 2) Mobile Cardiac Telemetry Mode: The MobileECG 2 BT is intended to continuously monitor, transmit, and record data for up to 30 days for patient transient symptoms that may suggest cardiac arrhythmia. The MobileECG 2 BT device continuously transmits data to a call center for interpretation of ECG data using the TM eCloud ECG Analysis System.

Configuration 3) Event Mode: The MobileECG 2 BT is intended to monitor and record patient activated data for up to 30 days for patient transient symptoms that may suggest cardiac arrhythmia. The MobileECG 2 BT device transmits all patient event activated data to a call center for interpretation of ECG data using the TM eCloud ECG Analysis System.

The MobileECG 2 BT is intended for use in adults and children of any age from birth upwards.

The MobileECG 2 BT and the TM eCloud ECG Analysis System interpretation software is not intended as sole means of diagnosis and is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG.

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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007_510(K) Summary

510(k) Summary

Date: 11/28/2018

1. General Information

Submitter's Name:	Dennis Garboski Memtec Corporation 68 Stiles Road Unit D Salem, NH 03079
Telephone:	603 893-8080 Ext. 204
Contact Person:	Dennis Garboski
Trade Name:	MobileECG 2 BT
Classification Name:	Detector and Alarm, Arrhythmia
Device Classification:	870.1025
Product Codes:	DSI, MWJ
Class:	Class II Device

2. Description of Device

The MEMTEC MobileECG 2 BT digital Monitor provides high resolution recording of patient ECG data and pacemaker spike detection for a period of up to 30 Days. The 3 in 1 Multi - Function BT monitor provides Holter, Event, and MCT ambulatory use. The data is stored on a removable Micro SD Card and no data compression is used. The data can be downloaded by a USB 3.0 cable, BT, or removable Micro SD Card. The BLE 4.1 (Bluetooth) sends patient data to cell phone continuous for 30 days for use as an Event or MCT Monitor. The patient ID/Date/Time is stamped on the recording every 2 minutes preventing the mixing of data with another patients data. The large LCD provides real time patient ECG signals and confirms lead hook-ups. In Holter Mode the unit has selectable sample rates of 250, 500, or 1000 samples per second with resolution of 12bits. The MobileECG 2 BT operates on a single "AAA" alkaline or "AAA" lithium battery.

Configuration 1 (Holter Mode): MobileECG 2 BT is used with the TM eCloud Analysis System (K142349) for Holter monitoring. In Holter usage, data is recorded for the prescribed duration and then uploaded and analyzed after the recording period has ended. The TM eCloud algorithm suite is used to analyze and interpret the ECG data.

Configuration 2 (MCT Mode): MobileECG 2 BT is combined with a special purpose cell phone and Android APP to store and transmit real-time ECG to the TM eCloud Analysis System (K142349) to

provide Mobile Cardiac Telemetry (MCT). The TM eCloud algorithm suite is used to analyze and interpret the ECG data.

Configuration 3 (Event Mode): MobileECG 2 BT is combined with a special purpose cell phone and Android APP to store and transmit real-time ECG on patient activated events to the TM eCloud Analysis System (K142349). The TM eCloud algorithm suite is used to analyze and interpret the ECG data.

3. Indications for Use

Configuration 1) Holter Mode: The MobileECG 2 BT is intended to record continuous data for 30+ days for the detection of arrhythmias in ambulatory patients. Such monitoring is frequently used for patient symptoms such as: Palpitations, shortness of breath, chest pain, syncope, evaluating pacemakers, heart rate variability's, and clinical studies. The MobileECG 2 BT device transmits all collected data to a call center for interpretation using the TM eCloud ECG Analysis System at the end of the completed study.

Configuration 2) Mobile Cardiac Telemetry Mode: The MobileECG 2 BT is intended to continuously monitor, transmit, and record data for up to 30 days for patient transient symptoms that may suggest cardiac arrhythmia. The MobileECG 2 BT device continuously transmits data to a call center for interpretation of ECG data using the TM eCloud ECG Analysis System.

Configuration 3) Event Mode: The MobileECG 2 BT is intended to monitor and record patient activated data for up to 30 days for patient transient symptoms that may suggest cardiac arrhythmia. The MobileECG 2 BT device transmits all patient event activated data to a call center for interpretation of ECG data using the TM eCloud ECG Analysis System.

The MobileECG 2 BT is intended for use in adults and children of any age from birth upwards.

The MobileECG 2 BT and the TM eCloud ECG Analysis System interpretation software is not intended as sole means of diagnosis and is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG.

4. Alarms

Alarms: Automatically processed by TM eCloud ECG Analysis System (K142349) after cellular transmission. All urgent events (Tier 1) and non urgent events (Tier 2) are verified by monitor center technicians within one hour maximum after being received.

5. Predicated Device

The legally marketed predicated devices to which equivalence is being claimed is:

Preventice	BodyGuardian	DSI	K151188
Memtec Corporation	Model 950-12L	MWJ	K102723

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6. Reference Device

TM eCloud ECG Analysis System (K142349)
Product Codes: DQK, KRE, MLO, DPS, DXH, OUG

7. Predicated Device Comparison

The following table compares the "Technical Specifications" and "Indications for Use" of the predicated devices to the MobileECG 2 BT.

	Memtec Corporation	Preventice	Memtec Corporation	
	MobileECG System	BodyGuardian	Model 950-12L	Comparison Discussion
Technical Specifications				
Number of ECG Channels	1, 2, 3, or 8 Ch	1 Ch	1, 2, 3, or 8 Ch	Different - MobileECG 2 BT is the same when used in the same configuration. There is no change to the safety or effectiveness of the device.
Resolution	12bit	12bit	12bit	Same: There is no change to the safety or effectiveness of the device.
Device Type	Digital	Digital	Digital	Same: There is no change to the safety or effectiveness of the device.
Power Source	1 "AAA" Alkaline	3.7v Li-ion	"AA" Alkaline	Different- Power source does not affect the operation of any of the devices. There is no change to the safety or effectiveness of the device.
Signal Verification	On Device, or Smartphone	Smartphone	On Device	Same: There is no change to the safety or effectiveness of the device.
Common Mode Rejection	100db	Not Specified	100db	Same: There is no change to the safety or effectiveness of the device.
Frequency Response	0.05 - 40Hz	Not Specified	0.05 - 40Hz	Same: There is no change to the safety or effectiveness of the device.

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Maximum Storage	64GB (30+ days)	Not Specified	16GB	Different- Storage Capacity does not affect the operation of any of the devices. There is no change to the safety or effectiveness of the device.
Maximum Days for Holter	30 days	30 days	7 days	Same: There is no change to the safety or effectiveness of the device.
Battery Life	7 days	24 Hrs.	3 Days	Different- MobileECG 2 BT battery life exceeds the BodyGuardian and the Model 950-12L. There is no change to the safety or effectiveness of the device.
Enclosure	Molded Plastic	Molded Plastic	Molded Plastic	Same: There is no change to the safety or effectiveness of the device.
Operating range	5 °C to +45 °C	5 °C to +45 °C	5 °C to +45 °C	Same: There is no change to the safety or effectiveness of the device.
Transport and Storage Range	0 °C to +60 °C	0 °C to +60 °C	0 °C to +60 °C	Same: There is no change to the safety or effectiveness of the device.
Relative Humidity	10% - 95% Non-Condensing	10% - 95% Non-Condensing	10% - 95% Non-Condensing	Same: There is no change to the safety or effectiveness of the device.
Dimensions	2.55"L X 2.0" W X .5 H	2.36"L X 2.25"W X .67"H	3.35"L X 2.4"W X .71"H	Different- Dimensions does not affect the operation of any of the devices. There is no change to the safety or effectiveness of the device.
Weight	1.45 oz.	1.23 oz.	3.4 oz	Different- Size does not affect the operation of any of the devices. There is no change to the safety or effectiveness of the device.
Wireless Transmission	Bluetooth BLE 4.1	Bluetooth	Not Applicable	Same: There is no change to the safety or effectiveness of the device.
Communication Monitoring	Continuous	Continuous	Not Applicable	Same: There is no change to the safety or effectiveness of the device.
Lead-Off Detection	Yes	Yes	Not Applicable	Same: There is no change to the safety or effectiveness of the device.

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Low Battery Indication	Yes	Yes	Yes	Same: There is no change to the safety or effectiveness of the device.
Retrieval of Data	30 days	30 days	30 days	Same: There is no change to the safety or effectiveness of the device.
Holter Mode	Yes	Yes	Yes	Same: There is no change to the safety or effectiveness of the device.
30 Day Long Term Holter Mode	Yes	Yes	Not Applicable	Same: There is no change to the safety or effectiveness of the device.
Patient Activated Event Mode	Yes	Yes	Yes	Same: There is no change to the safety or effectiveness of the device.
Mobile Cardiac Telemetry Mode	Yes	Yes	Not Applicable	Same: There is no change to the safety or effectiveness of the device.
Electrode Type Used	Snap	Snap	Snap	Same: There is no change to the safety or effectiveness of the device.
Indications For Use				
Environment of Use	Office,Clinic,or Outpatient (Home)	Office,Clinic,or Outpatient (Home)	Office,Clinic,or Outpatient (Home)	Same: There is no change to the safety or effectiveness of the device.
Detects and Stores Cardiac Arrhythmias in Ambulatory Patients	Yes	Yes	Yes	Same: There is no change to the safety or effectiveness of the device.
Provide Diagnostic Analysis	No	No	No	Same: There is no change to the safety or effectiveness of the device.
Use in Clinical and Non-Clinical Settings	Yes	Yes	Yes	Same: There is no change to the safety or effectiveness of the device.
In-Hospital Monitoring	No	No	No	Same: There is no change to the safety or effectiveness of the device.
Collects and Transmits Cardiac Arrhythmias in Ambulatory Patients	Yes	Yes	Not Applicable	Same: There is no change to the safety or effectiveness of the device.
Prescriptive Device	Yes	Yes	Yes	Same: There is no change to the safety or effectiveness of the device.

Use With Age Requirements	Infant to Adult	Adult	Infant to Adult	Different - This specification is different because of its use with an approved FDA Analysis System. There is no change to the safety or effectiveness of the device.
Pacemaker Detection	Yes	Yes	Yes	Same: There is no change to the safety or effectiveness of the device.

Conclusion: The MobileECG 2 BT performance testing results demonstrate that the differences in the above "Technological Specifications" between the devices do not raise any new issues of safety or effectiveness, demonstrating that the subject device is as safe and as effective as the predicated devices. And after comparing the "Indications For Use" between the predicated devices to the MobileECG 2 BT, Memtec concludes that the MobileECG 2 BT is substantially equivalent to the predicated devices.

8. Non-clinical Tests Used in Determination of Substantial Equivalence

The MobileECG 2 BT was tested and conforms to the predicated devices using the following FDA recognized standards:

MobileECG 2 BT

1. ANSI/AAMI ES60601-1-2005 (R)2012 AND A1-2012- C1-2009 (R)2012 AND A2:2010/(R)2012 (FDA 19-4)
2. ANSI/AAMI IEC 60601-1-2:2014 (FDA 19-12)
3. ANSI/AAMI-IEC 60601-2-47-2012(R)2016 (FDA 3-127)

Leadwires

1) ANSI/AAMI EC53:1995(R)2008 (FDA 3-129)

9. Conclusions from Nonclinical Testing

After comparing predicated devices to Memtec's MobileECG 2 BT results show that with the intended use, the MobileECG 2 BT with the TM eCloud ECG Analysis System® is equivalent in safety and effectiveness. Therefore, Memtec supports a claim of substantial equivalence for the MobileECG 2 BT to the Predicated Devices.