DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

December 10, 2015

Viatom Technology Co., Ltd.
% Donna-Bea Tillman
Senior Consultant
Biologics Consulting Group, Inc.
400 N. Washington St. Suite 100
Alexandria, Virginia 22314

Re: K150869
Trade/Device Name: CheckMe Pro Health Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: November 6, 2015
Received: November 10, 2015

Dear Donna-Bea Tillman:

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.

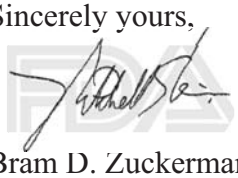
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K150869

Device Name
Checkme Pro Health Monitor

Indications for Use *(Describe)*
The Checkme Pro Health Monitor is intended to be used for measuring, displaying, reviewing and storing of ECG (adults only), oxygen saturation and pulse rate (adults only for continuous data collection and recording, adults and pediatrics for spot checking) and temperature in the home or in healthcare facilities.
This device is not intended to substitute for a hospital diagnostic ECG device and also not to be used on patients with implanted cardiac devices, such as pacemakers and/or implanted cardio-defibrillators (ICDs).

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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*"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

| | |
|---|---|
| **Device Common Name:** | Multiparameter Monitor |
| **Device Trade Name:** | Checkme Pro Health Monitor |
| **Applicant:** | Viatom Technology Co., Ltd.<br>C607,Languang Park, No. 7 Xinxi Road, Hi-Tech Park(north) Nanshan, Shenzhen, 518057, P.R.China<br>www.viatomtech.com |
| **Contact:** | Zhou Saixin<br>General Manager<br>Viatom Technology Co., Ltd.<br>C607,Languang Park, No. 7 Xinxi Road, Hi-Tech Park(north) Nanshan, Shenzhen, 518057, P.R.China<br>Phone: +86 755 86638929<br>Fax: +86 755 22649904<br>Email: zhousaixin@viatomtech.com |
| **Prepared by:** | Donna-Bea Tillman, Ph.D.<br>Senior Consultant, Devices<br>Biologics Consulting Group, Inc.<br>Phone: 410-531-6542<br>Email: dtillman@bcg-usa.com |
| **Date Prepared:** | November 6, 2015 |
| **Classification Regulation:** | 21 CFR 870.2300 – Cardiac Monitor |
| **Panel:** | Cardiovascular |
| **Product Code:** | MWI, Physiological Patient Monitor |
| **Secondary Product Codes:** | DQA (21 CFR 870.2700)<br>DPS (21 CFR 870.2340)<br>FLL (21 CFR 880.2910)<br>DRT (21 CFR 870.2300) |
| **Predicate Device:** | K131762, M800 Handheld Monitor |
| **Secondary Predicates:** | K062894, InstantCheck RTD-ECG Monitor<br>K100953, Microlife Non-Contact Infrared Forehead Thermometer |

**Indications for Use:**

The Checkme Pro Health Monitor is intended to be used for measuring, displaying, reviewing and storing of ECG (adults only), oxygen saturation and pulse rate (adults only for continuous data collection and recording, adults and pediatrics for spot checking) and temperature in the home or in healthcare facilities.

This device is not intended to substitute for a hospital diagnostic ECG device and also not to be used on patients with implanted cardiac devices, such as pacemakers and/or implanted cardio-defibrillators (ICDs).

**Device Description:**

The Checkme Pro Health Monitor is a lightweight, portable health monitor for use in the home or health care facility. The Checkme Pro Health Monitor is used for measuring, displaying, reviewing and storing of multiple physiological parameters including ECG, pulse oxygen saturation ($SpO_2$), pulse rate and temperature. This device is not intended to substitute for a hospital diagnostic ECG device. The device is capable of measuring and storing data for up to twelve users.

**Measurements Provided by Checkme Pro**

| **Functions** | **Measured parameters** | **Features** |
|---|---|---|
| ECG | ECG waveform<br>Heart Rate (HR) | Cable or cable-free, four modes, 30s waveform replay, voice memo, 100 measurements storage |
| Pulse Oximeter:<br>Spot-check | Pleth waveform<br>$SpO_2$, Pulse Rate (PR) | Cable or cable-free, 20 second measurement, 100 measurements storage |
| Pulse Oximeter:<br>Continuous Recording<br>(adult only) | Total duration, <90% STAT, Average saturation, Lowest saturation | Recording for up to 10 hrs |
| Thermometer | Temperature | Integrated infrared sensor, 3 second measurement, or °F configurable |
| Pedometer | Steps, distance, calories, fat burned, speed | Built-in high accuracy 3D smart sensor, algorithm to calculate distance |

**Performance Testing:**

The performance testing provided for the Checkme Pro Health Monitor consists of the following:

**ECG Testing**

The ECG algorithm used in the Checkme Pro Health Monitor has been tested according to the requirements of IEC 60601-2-47. Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.

**SpO2 Testing**

The Checkme Pro Health Monitor has been tested and shown to comply with the requirements of ISO 80601-2-61. Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

**Thermometer Testing**

The Checkme Pro has been tested and shown to comply with the requirements of the FDA-recognized standard ISO 80601-2-56:2009: Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.

**Home Healthcare Testing**

The Checkme Pro has been tested and shown to comply with the following FDA-recognized standard: IEC 60601-1-11 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.

**System Level Testing**

Viatom conducted system level performance testing to demonstrate that the device meets its specifications.

The device passed all tests and performed according to specifications.

**Biocompatibility Testing:**

It is a surface contacting device with less than 24 hours contact duration. The patient contacting materials were testing in accordance with ISO 10993-1: 2009/AC 2010.

**Software Verification and Validation:**

Similar to the predicate device, the software level of concern for the Checkme Pro Health Monitor is MODERATE. Per FDA Guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff", the required software documentation for a MODERATE Level of Concern device has been provided.

**EMC and Electrical Safety:**

The following EMC and Electrical Safety tests were performed on the device:

- IEC 60601-1: 2005 + Corrigendum 1 + Corrigendum 2 + AM1 (2012) IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- EN 60601-1-2: 2007 + AC: 2010 medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests. (General II (ES/EMC))

The results of these tests demonstrate the electrical safety and electromagnetic compatibility of the Checkme Pro device.

The Checkme Pro Health Monitor is provided with a rechargeable lithium ion polymer battery. Therefore, Viatom has also conducted battery safety testing in accordance with the FDA-recognized standard IEC 62133:2012 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications. The battery passed all required tests, and therefore has been shown to be safe for the proposed intended use.

The device comparison table below compares the primary features of the proposed Checkme device and the predicate M800 device.

**Device Comparison Table**

| | **Subject Device** | **Predicate Device** |
|---|---|---|
| **510(k) Number** | K150869 | K131762 |
| **Applicant** | Viatom Technology Co. Ltd. | GUANGDONG BIOLIGHT MEDITECH CO., LTD |
| **Device Name** | Checkme Pro Health Monitor | M800 Handheld Monitor |
| **Classification Regulation** | 870.2300 – Physiological Patient Monitor | 870.2300 – Physiological Patient Monitor |
| **Product Code (Primary)** | MWI | MWI |
| **Indications for Use** | The Checkme Pro Health Monitor is intended to be used for measuring, displaying, reviewing and storing of ECG (adults only), oxygen saturation and pulse rate (adults only for continuous data collection and recording, adults and pediatrics for spot checking) and temperature in the home or in healthcare facilities.<br>This device is not intended to substitute for a hospital diagnostic ECG device and also not to be used on patients with implanted cardiac devices, such as pacemakers and/or implanted cardio-defibrillators (ICDs). | M800 handheld monitor is intended for continuously monitoring or spot checking of $SpO_2$, PR, ECG and HR of adult, pediatric and neonatal patients in hospital, hospital type facilities as well as in the home care environment. |
| **Physiological Parameters Monitored** | ECG, HR, $SpO_2$, Temperature | ECG, HR, $SpO_2$ |
| **Location** | Home and Hospital | Home and Hospital |
| **Rx or OTC** | Rx | Rx |
| **Power Supply** | 560mAh rechargeable lithium-ion polymer battery | Rechargeable Lithium Battery or AA alkaline or lithium batteries |

The comparison of ECG Measurements table below provides a more detailed comparison of the Checkme device with the additional predicate for ECG monitoring, the DailyCare InstantCheck RTD-ECG Monitor (K062894)

**Comparison of ECG Measurements**

| | **Subject Device** | | **Predicate Device (Additional)** |
|---|---|---|---|
| **510(k) Number** | K150869 | | K062894 |
| **Applicant** | Viatom Technology Co. Ltd. | | Daily Care BioMedical, Inc. |
| **Device Name** | Checkme Pro Health Monitor | | InstantCheck RTD-ECG Monitor |
| **Classification Regulation** | 870.2300 – Physiological Patient Monitor | | 870.2340 – Electrocardiograph |
| Measured ECG Parameter | ECG waveform, Heart Rate (HR) | | ECG waveform, Heart Rate (HR), ST segment and QRS interval |
| ECG Rhythm Classification | Not included | | Regular Heart Rate<br>Fast Heart Rate<br>Slow Heart Rate<br>High ST Value<br>Low ST Value<br>High QRS Value<br>Irregular Heart Rate<br>Impossible to Analyze |
| ECG Lead Type | External ECG Cable and Electrodes | Integrated ECG Electrodes | External and Integrated ECG Electrodes |
| Input impedance | > 10 M Ohm | > 10 M Ohm | > 20 M Ohm |
| Input dynamic range | +/- 3 mV | +/- 3 mV | +/- 3 mV |
| Bandwidth | 0.05 – 40 Hz | 0.67 – 40 Hz | 0.1 – 40 Hz |
| A/D conversion | 16 bit | | 12 bit |
| Sampling Rate | 500 samples/sec | | 250 samples/sec |
| Measurement Time | 30 seconds | | 30 seconds |
| Display | 400*240 Dot-matrix LCD display | | 240 X 128 Dot-matrix LCD display |
| Input | Dry conduction electrodes and/or external auxiliary electrodes | | Dry conduction electrodes and/or external auxiliary electrodes |
| Heart rate Range | 30～250 bpm, ±2 bpm or ±2% whichever is larger | | 45 to 180 bpm |

The Comparison of Pulse Oximeter Measurement and Analysis table below provides a more detailed comparison of the pulse oximetry feature of the Checkme device with the primary predicate, theM800 Handheld Monitor.

**Comparison of Pulse Oximeter Measurement and Analysis**

| | **Subject Device** | | **Predicate Device** |
|---|---|---|---|
| **510(k) Number** | K150869 | | K131762 |
| **Device Name** | Checkme Pro Health Monitor | | M800 Handheld Monitor |
| **Classification Regulation** | 870.2300 – Physiological Patient Monitor | | 870.2300 – Physiological Patient Monitor |
| **Display Data** | $SpO_2$, Pulse Rate (PR) | | $SpO_2$, Pulse Rate (PR) |
| **Mode** | Continuous Recording and Spot-Check | | Continuous Recording and Spot-Check |
| **Sensor Types** | Integrated and external | | External |
| **Population** | Adult and Pediatric (continuous recording only for adult) | | Adult, Pediatric and Neonate |
| **$SpO_2$ Display Range** | 0 - 100% | | 0 - 100% |
| **Accuracy** | **Integrated Sensor**<br>70%-100%: ±3% (Arms:2.11)<br>70-80%: ±3%<br>80-90%: ±3%<br>90-100%: ±2%<br>0% - 69% not defined | **External Sensor**<br>70%-100%: ±2% (Arms:1.88)<br>70-80%: ±3%<br>80-90%: ±2%<br>90-100%: ±2%<br>0% - 69% not defined | 70% - 100%: ±2%<br><br>0% - 69% not defined |
| **Resolution** | 1% | | 1% |
| **PR range** | 30-250 BPM | | 25-250 BPM |
| **PR Accuracy** | 30-250 BPM, ±2 bpm or ±2% whichever is larger | | 25-250 BPM, ±1 bpm or ±2% whichever is larger |
| **Resolution** | 1bpm | | 1bpm |

The Comparison of Temperature Measurement and Analysis table below provides a more detailed comparison of the Checkme and the additional predicate for temperature measurement, the Microlife Non-Contact Infrared Forehead Thermometer (K100953).

**Comparison of Temperature Measurement and Analysis**

| | **Subject Device** | **Predicate Device (Additional)** |
|---|---|---|
| **510(k) Number** | K150869 | K100953 |
| **Applicant** | Viatom Technology Co. Ltd. | Microlife Intellectual Property, GMBH |
| **Device Name** | Checkme Pro Health Monitor | Microlife Non-Contact Infrared Forehead Thermometer |
| **Classification Regulation** | 870.2300 – Physiological Patient Monitor | 880.2910 – Thermometer, Electronic, Clinical |
| **Measurement technique** | infrared sensor (thermopile) | infrared sensor (thermopile) |
| **Measurement site** | Forehead | Forehead |
| **Unit** | °F | °C/°F |
| **Body mode measuring range** | 93.2°F to 108.0°F | 34°C to 42.2°C (93.2°F to 108.0°F) |
| **Body mode Accuracy** | ±0.4°F | 36°C to 39°C (96.8°F to 102.2°F): +/- 0.2°C /0.4°F<br>34.0°C to 35.9°C (93.2°C to 96.6°F), 39.1 °C to 42.2°C (102.4°F to 108.0°F): +/-0.3°C /0.6°F |

**Substantial Equivalence Conclusion:**

The primary predicate device for the Checkme Pro Health Monitor is M800 Handheld Monitor cleared in K131762. The M800 is also a handheld device for monitoring physiological parameters in the home or health care environment.

The Checkme Pro Health Monitor has three primary medical device functions, and each of these has been compared to a predicate device. While there are some minor differences in technological characteristics, this do not raise different questions of safety and effectiveness. Each function has been tested in accordance with the appropriate standards, and the results of testing demonstrate that the Checkme Pro Health Monitor complies with the standards and has equivalent performance to the reference predicate devices.

Therefore, the Checkme Pro Health Monitor has been shown to be substantially equivalent to the M800 Handheld Monitor.