DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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September 1, 2017

G-Medical Innovations Ltd.
% Jonathan Kahan
Partner
Hogan Lovells US LLP
Columbia Square, 555 Thirteenth Street, NW
Washington, District of Columbia 20004

Re: K170181
Trade/Device Name: Prizma
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II
Product Code: DXH, DQA, FLL
Dated: August 1, 2017
Received: August 1, 2017

Dear Jonathan Kahan:

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 (DICE) 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 (DICE) 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,

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 on last page

510(k) Number *(if known)*

K170181

Device Name

Prizma

Indications for Use *(Describe)*

The Prizma device is indicated to measure, record and transmit ECG one-lead data, and to measure, record, display and transmit heart rate, peripheral oxygen saturation and skin temperature data. The device utilizes a mobile platform to initiate user actions (test, display and data transfer by email) through the mobile application. The device does not perform diagnostic functions.

Intended population: adult patients.

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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K170181

510(k) SUMMARY

G-Medical Innovations Ltd., Prizma Device

Submitter

Company:	G-Medical Innovations Ltd.
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Phone:	972-8-9584777
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Contact Person:	N. Epstein
Date Prepared:	September 1, 2017

Name of Device: Prizma

Common or Usual Name:	Transmitters and Receivers, Electrocardiograph, Telephone Oximeter
Classification Name:	870.2920 Telephone electrocardiograph transmitter and receiver 870.2700 Oximeter
Regulatory Class:	2
Product Code:	DXH, DQA, FLL

PREDICATE DEVICES

Card Guard Scientific Survival, Health-ePod, K083174

SpO Medical, PulseOx 5500 Finger Device, K040178

Radiometer, OSM-3 Hemoximeter, K853990 (reference device in oximeter trial)

DEVICE DESCRIPTION

The Prizma is designed in the form of a Mobile Device jacket. The device consists of:

- A sensor unit (Prizma device) embedded with electronics and physiological sensors, in polycarbonate housing.
- A silicone cover to mechanically receive the sensor unit and form a “Jacket” that is attached to the back of the smartphone. Cover design can be modified from one smartphone to another to fit the different dimensions.
- Prizma mobile App, installed on a smartphone, for operating the Prizma device.
- A medical power adapter

<u>The physiological sensors housed in the Medical Capsule</u> are as follows

- One lead ECG sensor, recording + heart rate measurement, derived out of ECG data;
- Photo-plethysmography, Peripheral capillary Oxygen Saturation ($SPO_{2)}$ measurement;

- Skin temperature - thermometer using IR;

INDICATIONS FOR USE

The Prizma device is indicated to measure, record and transmit ECG one-lead data, and to measure, record, display and transmit heart rate, peripheral oxygen saturation and skin temperature data. The device utilizes a mobile platform to initiate user actions (test, display and data transfer by email) through the mobile application. The device does not perform diagnostic functions.

Intended population: adult patients.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The following technological differences exist between the subject and predicate devices:

The main difference is the addition of the mobile application that controls the device.

The user downloads the application, and pairs the Prizma BLE with smartphone. To run tests, the Prizma application is touched, whereby main screen open with large test icons. Upon touching a test icon, the test screen opens with instructions how to make contact with sensor. Upon test end, the user can add comments to tests and send results via email.

In addition, at end of the tests, the data is automatically transferred over secured BLE protocol from the Prizma to the smartphone where they are stored. Browsing test results history (last five tests) can be performed by touching the Browse icon.

The performance of the sensors against their predicate is summarized below.

ECG

From technology perspective and parameters defined by the standards, both devices are essentially identical. There are some small differences between the devices, such as the dynamic range, which is better in the Prizma due to the fact that the Prizma was designed to comply with IEC-60601-2-47 which is a newer standard that requires better performance, compare to the EC-38 (1998) that the Health-ePod was designed to comply with.

In addition, for some parameters, the Prizma performed even better than the Health-ePod (e.g. sampling rate, resolution, heart rate range), which is due to technology and chip improvements over time.

The largest difference between the Prizma and the Health-ePod is the use of the mobile application which the Prizma which is expected to simplify device use as cell phones have larger screens than that used in the Health-ePod. Another difference is that the Prizma is intended solely for adults while the Health-ePod is intended also for pediatric use.

SpO_2

The SpO_2 sensor in the Prizma and the PulseOx 5500 finger device are similar. From a technology point of view, both devices use the finger to measure the oxygen saturation level. Both devices use reflective technology with similar ranges of wavelength. Both devices report 40% to 100% saturation.

The difference between the devices are minor and are primarily related to the fact that the PulseOx 5500 can be used continuously while the Prizma can be used for spot measurement. In addition, like in

the case of the ECG, the use of mobile app is expected to simplify the test by using a larger screen, animation that explain how to do the test, and an indication when the test is over.

Temperature

From technology point of view, the Health-ePod and the Prizma are identical. Both use the Melexis IR sensor. Both devices measure the skin temperature from the same position on the body (behind the Earlobe). The Health-ePod uses the MLX-90614 and the Prizma uses the MLX-90615 which is the newer generation of the MLX 90614 sensor. The relevant differences between the sensors are the thermal stability which is better in the MLX-90614. This is mostly due to the housing size of the 90614, which is bigger but can be easily resolved by using a metal cap on the 90615 as we did in our design to improve the stability.

The resolution, although better in the 90614, doesn't have clinical significance when measuring skin / body temperature. The measurement range is bigger in the 90614 due to its larger size, but in case of human skin and body temperature, the clinically relevant range can be measured by both devices.

Both devices can measure skin temperature accurately. The Health-ePod uses a look-up table which was developed based on a clinical trial to convert the skin temperature to body temperature.

Finally, the Prizma, like in the ECG and SpO_2, uses the Mobile App to initiate the test in a convenient manner.

Conclusion:

The differences between the device and its predicates do not raise different types of safety and effectiveness questions. Differences between the devices are supported by testing demonstrating at least equivalent performance. Therefore, the device is substantially equivalent to its predicate devices.

PERFORMANCE DATA

The Prizma was tested according to the following standards:

1. IEC60601-2-47 Ed. 2.0 Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems.
2. ISO 80601-2-56 Ed. 1.0 Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.
3. ISO 80601-2-61 Ed. 1.0 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.

In addition, the following testing was conducted:

1. QRS detection and HR measurement test (according to ANSI/AAMI EC57:2012)
2. Prizma QRS Detection Validation by means of a Signal Simulator
3. Usability testing per IEC 62366-1:2015

CLINICAL DATA

Clinical Validation Prizma Finger Oximeter

The SpO_2 function was validated in a clinical study at the Bickler Ye Hypoxia Research Laboratory, Shenzhen Medical University, China (report # BYL20160415).

The study protocol was established based on the pulse oximetry guidelines of ISO 80601-2-61 and consisted of blood gas analysis to determine oxyhemoglobin saturation in 12 subjects (including dark skin) subjected to hypoxia conditions followed by measurements from the finger.
The reference device was OSM-3R multi-wavelength oximeter (Hemoximeter, Radiometer, Copenhagen).

Conclusion of the study

ISO 80601-2-61 specifies that the SpO_2 accuracy of pulse oximeter shall be the root-mean-square difference of less than or equal to 3.5 % SpO_2 over the range of 70 % to 100 % SpO_2. Accuracy of the tested device shall be stated in terms of the rms difference between its measured values and the reference values of the reference device.

In the range of the Prizma device SpO_2 function, 70 – 100%, the a-rms was 2.33.
Based on the clinical performance, the Prizma has a safety and effectiveness profile that is similar to the predicate device.

CONCLUSIONS

The Prizma device is as safe and effective as the Health-ePod and PulseOx 5500 Finger Devices. The Prizma has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. In addition, the minor technological differences between the Prizma and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Prizma is as safe and effective as the Health-ePod and PulseOx 5500 Finger Device. Thus, the Prizma is substantially equivalent.