November 30, 2018

G-Medical Innovations Ltd.
Asher Kassel
RA, QA
5 Openheimer St.
Park Rabin
Rehovot 7670105, Israel

Re: K173589
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: October 8, 2018
Received: October 10, 2018

Dear Asher Kassel:

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,

Jessica E. Paulsen -S

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: 06/30/2020
See PRA Statement on last page

510(k) Number *(if known)*
K173589

Device Name
Prizma

Indications for Use *(Describe)*

The Prizma device is indicated for home users to measure, record, display and/or transmit ECG one-lead data, heart rate, peripheral oxygen saturation, pulse rate and body temperature data. The device utilizes a mobile platform to initiate user actions (test, display and data transfer by email) through the mobile application.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

G-Medical Innovations Ltd., Prizma Device

Submitter

Company:	G-Medical Innovations Ltd.
Address:	5 Openheimer St., Park Rabin, Rehovot, 7670105, Israel
Phone:	972-8-9584777
Facsimile:	972-8-9584783
Contact person:	Asher Kassel
Date prepared:	20 November 2017 (for original submission)
Date updated:	25 July 2018

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 880.2910 Clinical electronic thermometer
Regulatory Class:	2
Product Code:	DXH, DQA, FLL

PREDICATE DEVICES

Prizma (K170181) – Primary predicate

SpO Medical, PulseOx 5500 Finger Device, K040178 – for HR calculation in PPG signal

Reference Device

Card Guard Scientific Survival, Health-ePod, K083174 – for skin temperature conversion

DEVICE DESCRIPTION

The Prizma device described in this submission is based on the cleared Prizma device (K170181), and its physical design has not been modified.

The following algorithm functions have been added to the system, thereby extending the indications for use:

a) conversion of the previously cleared and reported skin temperature measurement into body temperature

b) Pulse rate calculation using the oximeter function.

The sensor capabilities of the new Prizma are as follows:

- One lead ECG sensor - ECG rhythm recording and heart rate measurement
- Photo-plethysmography - Peripheral capillary Oxygen Saturation ($SPO_{2)}$ measurement, pulse rate;
- IR thermometer – skin temperature converted into body temperature.

INDICATIONS FOR USE

The Prizma device is indicated for home users to measure, record, display and/or transmit ECG one-lead data, heart rate, peripheral oxygen saturation, pulse rate and body temperature data. The device utilizes a mobile platform to initiate user actions (test, display and data transfer by email) through the mobile application.

Intended population: adult patients.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Prizma device described in this submission are the same as in the cleared Prizma device (K170181). The main differences between the subject and previously cleared Prizma are modifications to the software that allow:

(1) calculation of body temperature from skin temperature measurements

(2) calculation of pulse rare via the pulse oximeter test

These features have been previously cleared in the Health-ePod, and the PulseOx 5500 finger device, respectively. The company performed the validation testing summarized below to show equivalent performance.

No safety and effectiveness questions are raised in comparing the subject Prizma to the predicates. Differences between the devices are supported by testing demonstrating at least equivalent performance; therefore we submit that the device is substantially equivalent to its predicate devices.

PERFORMANCE DATA

<u>The Prizma was tested according to the following standards:</u>

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, usability testing was conducted per IEC 62366-1:2015.

CLINICAL DATA

Clinical Validation Prizma IR measured skin temperature to body temperature

Temperature conversion by the subject Prizma was compared against the auxiliary temperature (under armpit) measured by mercury thermometer during 10 min as a reference temperature, in 167 patients (57 % percentage of which were febrile patients).

Statistical characteristics (clinical bias, limits of agreement and clinical repeatability) were calculated in accordance with requirements in ISO 80601-2-56: 1st edition 2009.

CONCLUSIONS

The Prizma device is not modified in physical design, materials and technology from the predicate Prizma, and is as safe and effective as the Health-ePod and PulseOx 5500 Finger medical devices. The Prizma has the same intended use 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 predicate devices. We therefore submit that the Prizma is substantially equivalent to the cleared predicate devices.