March 7, 2019

Connected Sensing-Division of Philips Medical Systems
Katie Pacheco
Regulatory Affairs Specialist 4
2 Canal Park
Cambridge, Massachusetts 02141

Re: K181165
Trade/Device Name: Philips wearable biosensor-G5 Solution
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: DRT
Dated: February 1, 2019
Received: February 4, 2019

Dear Katie Pacheco:

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 below.

510(k) Number *(if known)*
K181165

Device Name
Philips wearable biosensor-G5 Solution

Indications for Use *(Describe)*

The Philips wearable biosensor-G5 is indicated for single patient use whenever heart rate measurement is needed in non-critical hospital settings. The Philips wearable biosensor-G5 solution is used as a higher resolution heart rate log by nurses or physicians retrospectively as an aid in making non-critical or non-life threatening therapeutic decisions. The biosensor is intended for patients who are 18 years of age or older.

The G5 Biosensor is intended only for patients with a baseline narrow QRS complex (less than 100 ms).

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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510(K) SUMMARY

(per 21 CFR 807.92)

I. SUBMITTER

Connected Sensing-Division of Philips Medical Systems.
2 Canal Park
Cambridge, MA 02141
Phone: 617-218-0802
Fax: 617-218-0802
Contact Person: Katie Pacheco
Date Prepared: March 6, 2019

II. DEVICE

Name of Device: Philips wearable biosensor-G5 Solution
Common or Usual Name: Wearable Biosensor
Classification Name: Monitor, Cardiac (Incl. Cardiotachometer and rate alarm) (21 CFR 870.2300)
Regulatory Class: II
Product Code: DRT

III. PREDICATE DEVICE

BioModule 3-MI, K123658
This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Philips wearable biosensor-G5 Solution is a physiological sensing solution that gathers, displays and stores a patient's heart rate. Philips wearable biosensor-G5 Solution is comprised of the:

- Philips wearable biosensor-G5
- and data visualization application "G5application"

The Philips wearable biosensor-G5 is a battery operated, single-use device, measuring heart rate by continuously acquiring surface electrical waveforms related to cardiac excitations and measuring beat-to-beat intervals when a patient is stationary or ambulatory. The sensor functions by capturing and then sending physiological data wirelessly to the software application. The sensor's frequency of data collection and transmission is configurable. The G5 application receives and displays data from the Philips wearable biosensor-G5 providing a user interface and exportable file for retrospective review and analysis.The G5 Biosensor is intended only for patients with a baseline narrow QRS complex (less than 100 ms**).**

V. INDICATIONS FOR USE

The Philips wearable biosensor-G5 is indicated for single patient use whenever heart rate measurement is needed in non-critical hospital settings. The Philips wearable biosensor-G5 solution is used as a higher resolution heart rate log by nurses or physicians retrospectively as an aid in making non-critical or non-life threatening therapeutic decisions. The biosensor is intended for patients who are 18 years of age or older. The G5 Biosensor is intended only for patients with a baseline narrow QRS complex (less than 100 ms**).**

The Indications for Use statement for the Philips wearable biosensor-G5 Solution is not identical to the predicate device; however, the differences do not alter the intended therapeutic use of the subject device nor do they affect the safety and effectiveness of the subject device relative to the predicate. Both the subject and predicate devices have the same intended use of collecting and transmitting heart rate measurement, by acquiring electrical signals from the skin surface.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Acquiring surface electrical waveforms related to the contractile activity of the heart is the technological principle for both the subject and predicate devices. It is based on the use of electrode technology to capture electrical waveforms via the chest to derive physiological signals processed by the system firmware.

At a high level, the subject and predicate devices are based on the following same technological elements:

Similarities	
Scientific Concept	Single-Lead ECG used to derive heart rate measurements.
Electrodes	Two electrodes and biocompatible adhesive materials used for adhesion and electrical contact=
Device Placement Location	Devices are both placed on the chest
Analog or digital technology	Analog physiological signals converted to digital
Computer Processing	On sensor signal processing through firmware
Storage of recorded signals	Data storage and transfer capabilities
Radio frequency telemetry	Bluetooth® Transmitter/Receiver
Power	Battery operated
Alarm management	Not an alarming device
IEC 60601-1	Portable, Body-worn, CF-Applied Part Internally powered
IEC 60601-1-2	RF emission CISPR 11: Group 1, Class B
Heart Rate Resolution	±1bpm
Heart Rate Range	The predicate device has heart rate range of 30 – 240 bpm per IEC 60601-2-47, while the subject device has a heart rate range of 30 – 220 bpm per IEC 60601-2-27.
Heart Rate Accuracy	IEC 60601-2-47, subject device also meets IEC 60601-2-27
Operational Relative Humidity Range	15% to 95% non-condensing

Differences	
Reusable, Single-Use	The subject device is a fully disposable single- use device with encapsulated electrode technology and puck. The predicate device is comprised of single-use electrodes with a reusable puck.
Electrodes	Fully encapsulated electrode technology and puck. The predicate device is comprised of single-use electrodes with a reusable puck.
Parameters Measured	The subject device provides Heart Rate while the predicate device provides multiple parameters Heart Rate, ECG, Respiration Rate, Activity.
Wear Duration	The predicate electrodes can be worn up <72 hours, while the subject device can be worn for 48 hours. While the wear duration is shorter in the subject device, there are no new questions of safety and efficacy raised with the shorter wear duration. Adhesive performance of the subject device and predicate device demonstrated by compliance to recognized standard AAMI ANSI EC12:2000/(R) 2010.
Shelf Life	The predicate electrodes have a 24 month shelf life, while the subject device have a 3 month shelf life. While the shelf life is shorter in the subject device, there are no new questions of safety and efficacy raised with the shorter shelf-life duration. Both the subject and predicate device address the risk of degradation of the device during storage and out of pouch.
Atmospheric Range	The predicate electrodes have an atmospheric range of 12kPa to 107kPa, while the subject device have an atmospheric range of 50 kPa -106kPa. While the while the atmospheric lower range is higher in the subject device, there are no new questions of safety and efficacy for in hospital use.
Operational Temperature Range	The predicate electrodes have an operational temperature range of 0º C to +45º C, while the subject device have an operational temperature range of 15º C to +35º C. While the while the operational temperature range is different in the subject device, there are no new questions of safety and efficacy for in hospital use.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing
The biocompatibility evaluation for the Philips wearable biosensor-G5 Solution was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process"(2016), and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The Philips wearable biosensor-G5 Solution is considered skin contacting for a duration of more than 24 hours.

Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted on the Philips wearable biosensor-G5 Solution. The system complies with the applicable requirements within IEC 60601-1, and IEC 60601-2-27 standards for safety and the IEC 60601-1-2 standard for EMC.

Performance Testing
Performance testing bench testing was performed using voluntary standards IEC 60601-2-27, IEC 60601-2-47, EC57, and EC12. Testing to applicable requirements were conducted and the system was found to be compliant.

Software Verification and Validation Testing
Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could directly result in minor injury to the patient or operator.

Wear Duration Study
Testing of the Philips wearable biosensor-G5 Solution included a feasibility wear study of 28 normal healthy volunteers. Data collected from this study was used to determine the adhesive performance (duration of use) as calculated per the ANSI/AAMI EC12:2000/® 2010 Disposable ECG Electrodes. The study established a 48 hour maximum duration of use for the Philips wearable biosensor-G5 Solution.

VIII. CONCLUSIONS

The results of the verification and validation testing demonstrate that the Philips wearable biosensor-G5 Solution is safe and effective and should perform as intended in the specified use conditions. The non-clinical and clinical testing performed demonstrate that the Philips wearable biosensor-G5 Solution is substantially equivalent to the predicate device.