April 16, 2020

Philips Medical Systems
Suzanne Goodman
Head of Quality and Regulatory
2 Canal Park
Cambridge, Massachusetts 02141

Re: K192875
Trade/Device Name: Philips Biosensor BX100
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG, DRT, BZQ
Dated: March 17, 2020
Received: March 18, 2020

Dear Suzanne Goodman:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer Shih
Assistant Director (Acting)
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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)*
K192875

Device Name
Philips Biosensor BX100

Indications for Use *(Describe)*

The Philips Biosensor BX100 is a physiological measurement device for use by healthcare professionals to aid in the treatment and management of patient conditions in general care areas of a hospital.

The Philips Biosensor BX100 is intended for use by healthcare professionals on patients 18 years of age and older. This chest-worn biosensor collects, stores, and transmits physiological data and contextual parameters to a qualified backend system. Physiological data includes respiration rate and heart rate; contextual parameters include ambulation, activity level, and posture.

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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5. 510(K) SUMMARY

510(k) SUMMARY

This 510(k) summary was prepared in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER

DATE PREPARED	April 14, 2020
APPLICANT	Philips Medical Systems Connected Sensing Division 2 Canal Park, Cambridge, MA 02141 Tel.: 617-218-0802
OFFICIAL CORRESPONDENT	Suzanne Goodman Head of Quality and Regulatory 2 Canal Park, Cambridge, MA 02141 Tel.: (919) 608-6082 suzanne.goodman@philips.com

II. DEVICE INFORMATION

TRADE NAME	Philips Biosensor BX100
COMMON NAME	Wearable Biosensor
CLASSIFICATION	Class II 21 CFR 870.2910, Radiofrequency physiological signal transmitter and receiver. 21 CFR 870.2300, Cardiac monitor (including Cardiotachometer and Rate Alarm). 21 CFR 868.2375, Breathing frequency monitor.
PRODUCT CODE	DRG: Transmitters and Receivers, Physiological Signal, Radiofrequency DRT: Monitor, Cardiac (Incl. Cardiotachometer and Rate Alarm) BZQ: Monitor, Breathing Frequency

III. PREDICATE INFORMATION

PREDICATE DEVICE	Primary Predicate: Philips Wearable Biosensor-G5 Solution (K181165) Secondary Predicate: Zephyr Technology Corporation BioModule 3-M1 (K123658) The predicate devices have not been subject to a design related recall.
PRIOR SUBMISSION	This is an original submission. There has been no prior submission for the subject device.

Note that G10 was the internal Philips project name for the BX100; the G10 and the BX100 are the same device. Philips Biosensor BX100, BX100, BX100 Biosensor and G10 are used interchangeably throughout this 510(k).

IV. DEVICE DESCRIPTION

The Philips Biosensor BX100 is a single patient use, small, lightweight, chest-worn sensor, which collects, stores and transmits physiological data and contextual parameters to a qualified backend system. The Philips Biosensor BX100 includes Bluetooth communication capabilities. The Philips Biosensor BX100 has an LED indicator and a power button, and requires integration into a qualified system. The Philips Biosensor BX100 sends the collected patient data wirelessly to a qualified system directly or indirectly through IT equipment. Physiological data provided by the Philips Biosensor BX100 includes respiration rate and heart rate; contextual parameters include ambulation, activity level and posture. The Biosensor has a 115-hour wear life.

V. INTENDED USE AND INDICATIONS FOR USE

Intended Use

Biosensor BX100 is a physiological measurement device to aid in the treatment and management of patient conditions.

Indications for Use

The Philips Biosensor BX100 is a physiological measurement device for use by healthcare professionals to aid in the treatment and management of patient conditions in general care areas of a hospital.

The Philips Biosensor BX100 is intended for use by healthcare professionals on patients 18 years of age and older. This chest-worn biosensor collects, stores, and transmits physiological data and contextual parameters to a qualified backend system. Physiological data includes respiration rate and heart rate; contextual parameters include ambulation, activity level, and posture.

The Indications for Use statement for the Philips Biosensor BX100 is not identical to the predicate devices; however, the differences do not alter the intended therapeutic use of the subject device nor do they affect the substantial equivalence of the subject device relative to the predicate. Both the subject device and predicate devices have the same intended use of collecting and transmitting physiological measurements by acquiring electrical signals from the skin surface.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Philips Biosensor BX100 has the following similarities to the legally marketed primary predicate device (Philips Wearable Biosensor G5 Solution):

- Same intended use
- Same operating principle
- Same technology

See Table 5-1for a comparison of the Philips Biosensor BX100 to the primary predicate device, Philips Wearable Biosensor-G5 Solution (K181165). The secondary predicate (BioModule 3-MI) is used for comparison of the respiration rate features.

Table 5-1. Comparison of Technological Features with the Primary Predicate Device

Similarities	
Scientific Concept	The scientific concept is based upon deriving physiological signals by continuously acquiring surface electrical waveforms related to cardiac excitations through electrodes. The subject device includes also includes a tri-axial accelerometer. These signals are further processed by embedded firmware.
Reusable, Single-Use	Fully disposable single-use device with encapsulated electrode technology and puck.
Electrodes	Two fully encapsulated 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, disposable battery.
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.

Parameters Measured	The Philips Biosensor BX100 heart rate algorithm is the same algorithm previously cleared in the G5 biosensor. The algorithm has been enhanced to allow for accurate heart rate across a broader measurement range. The Philips Biosensor BX100 is substantially equivalent to the G5 Biosensor with respect to the heart rate measurement feature. The Philips Biosensor BX100 also measures activity level and posture. The Philips Biosensor BX100 subject device is substantially equivalent to the secondary predicate BioModule 3-MI as it relates to the function of providing respiration rate.
Heart Rate Resolution	±1bpm
Heart Rate Range	30 – 220 bpm
Heart Rate Accuracy	IEC 60601-2-47 and IEC 60601-2-27
Respiration Rate Resolution (As Compared to Secondary Predicate)	± 1 rpm static
Respiration Rate Accuracy (As Compared to Secondary Predicate	±3 rpm (excluding periods of undefined respiration rate due to patient talking, eating, or coughing, for example) for subject device. This is within the range listed for the secondary predicate device (±2 rpm to ±5 rpm).
Differences	
Respiration Rate Range (As Compared to Secondary Predicate)	Both the subject device and the secondary predicate measure respiration rate as high as 40 rpm. The Philips Biosensor BX100 measures respiration rate as low as 3 rpm compared to the BioModule's 6 rpm. This difference does not alter the substantial equivalence of the device.
Respiration Rate Range (As Compared to Secondary Predicate)	Both the subject device and the secondary predicate measure respiration rate as high as 40 rpm. The Philips Biosensor BX100 measures respiration rate as low as 3 rpm compared to the BioModule's 6 rpm. This difference does not alter the substantial equivalence of the device.
Wear Duration	The primary predicate device G5 Biosensor can be worn for 24 hours. The subject device can be worn for 115 hours. While the wear duration is longer in the subject device, there are no new questions raised with the longer wear duration. Both the subject and predicate device need to address the risk of insufficient adhesive performance via electrical contact with the skin over the duration of use. The standard defines long term monitoring as "a period of days". The electrodes for the predicate device and the subject device both support long term monitoring.

Shelf Life	The primary predicate device G5 has a shelf life of 3 months. The subject device has a shelf life of 12 months. While the shelf life is longer in the subject device compared to the G5, there are no new questions raised with the longer shelf-life duration. Both the subject and predicate device address the risk of degradation of the device during storage and out of pouch. Shelf-life testing of the subject device demonstrated substantially equivalent performance to the predicate device after the stated shelf-life.
Materials	The only difference in materials between the Philips Biosensor BX100 and the primary predicate G5 is a change in hydrocolloid adhesive. Biocompatibility testing in accordance with ISO 10993-1 and clinical study data demonstrate that the Philips Biosensor BX100 is safe for use on intact skin for the proposed wear duration.
Atmospheric Range	The primary predicate device has an atmospheric range of 50kPa to 106kPa, and the subject device has an atmospheric range of 70 kPa - 102kPa. While the subject and predicate device have a slight difference in labeled atmospheric use range, this does not affect the substantial equivalence of the device. Philips Biosensor BX100 functionality was successfully tested after exposure to extreme environmental use conditions.
Operational Temperature Range	The primary predicate device has an operational temperature range of 15º C to +35º C, and the subject device has an operational temperature range of 10º C to +40º C. While the subject and predicate device have a slight difference in labeled operational temperature range, this does not affect the substantial equivalence of the device. Philips Biosensor BX100 functionality was successfully tested after exposure to extreme environmental use conditions.
Operational Humidity Range	The primary predicate device has an operational humidity range of 15% to 95% non-condensing, and the subject device has an operational humidity range of 10% to 95% non-condensing. While the subject and predicate device have a slight difference in labeled operational humidity range, this does not affect the substantial equivalence of the device. Philips Biosensor BX100 functionality was successfully tested after exposure to extreme environmental use conditions.

VII. PERFORMANCE DATA

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

Bench Testing and Shelf life

Bench testing was performed to verify system level device specifications, mechanical and electrical specifications, and packaging integrity. Applicable bench testing was repeated after 12 months of aging to support the labeled shelf life claim for the Philips Biosensor BX100.

The Biosensor BX100 was integrated with a custom tool as a proxy for a qualified backend system. The tool mimicked the functionality of a backend system including bluetooth interface and a user interface capable of displaying the data output of the device (heart rate, respiration rate, activity type, activity level, posture and error messaging).

Biocompatibility

The Philips Biosensor BX100 is a chest-worn biosensor that has contact with intact skin for up to 120 hours (5 days). In accordance with ISO 10993-1 (2018), the Philips Biosensor BX100 is classified as a surface-contacting device with prolonged (> 24 hours to 30 days) contact with intact skin. Evaluation endpoints and detailed tests were selected in accordance with *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).* Table 5-2 below details the biocompatibility endpoints evaluated, along with the corresponding tests completed.

Cytotoxicity Testing/Evaluation Summary

The Biosensor BX100 uses a hydrocolloid adhesive that is incompatible with current ISO 10993-5 MEM elution methods for evaluating cytotoxicity due to cell lysis with high salt concentration in the extract medium. The pass results of a clinical study (25 subject), osmolarity evaluation, ISO 10993-10 irritation testing (3 animals tested, initial exposure for 5 days) and ISO 10993-10 sensitization testing (Buehler Method closed patched sensitization study, 15 animals, induction 3 times per week for 3 consecutive weeks, challenged at 14 days) demonstrate biocompatibility for use on intact skin per ISO 10993-1: 2018.

Table 5-2. Philips Biosensor BX100 Biocompatibility Testing

Evaluation Endpoint	Tests Performed	Applicable Standard
Sensitization	ISO Guinea Pig Maximization Sensitization Test	ISO 10993-10
Irritation	ISO Skin Irritation Study in Rabbits (24 hour and 120 hour)	ISO 10993-10
Cytotoxicity	Cytotoxicity- MEM Elution Method (72 hour extraction)	ISO 10993-5

Software Verification and Validation

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 (2005).* The Philips Biosensor BX100 Software Level of Concern was determined to be **Moderate**, since a failure or latent flaw in the software could directly result in minor injury to the patient or operator.

Electromagnetic Compatibility and Electrical Safety

Electrical safety and electromagnetic compatibility (EMC) testing was conducted on the Philips Biosensor BX100. The device complies with the applicable requirements within the ANSI AAMI ES60601-1, IEC 60601-2-27, and IEC 60601-2-47 standards for safety and the ANSI AAMI IEC 60601-1-2 standard for EMC. Additional wireless and co-existence testing per US FCC CFR 47 Part 15 and ANSI IEEE C63.27 was conducted to demonstrate substantial equivalence of the Philips Biosensor BX100 radio frequency wireless technology features.

Clinical Performance Testing

Philips conducted clinical studies in support of the Philips Biosensor BX100. The Philips G10 Biosensor Wear Study was conducted to evaluate design requirements for the Philips Biosensor BX100 (G10). This study enrolled 25 subjects, who wore the Philips Biosensor BX100 for a period of 7-10 days. The primary objective of the wear study was to establish the adhesive performance (duration of use) of the Philips Biosensor BX100. A second study, the G10 Algorithm Validation Study, was conducted to acquire physiological and contextual data using the Philips Biosensor BX100 and reference measurements to validate design specifications related to Biosensor software algorithms. This study enrolled 53 subjects, who wore the Philips Biosensor BX100 for approximately 2 hours.

In addition to the studies described above, usability and human factors testing was performed for the Philips Biosensor BX100 in accordance with IEC 62366-1, the 2016 *Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering to Medical Devices*, and ANSI/AAMI HE75.

Clinical Trials Summary

In a wear study of 25 subjects conducted with the Biosensor BX100 an average adhesive performance of 6.7 days (excluding electrical performance) and 4.8 days (including electrical performance) was demonstrated with no significant skin reactions. In an algorithm validation study of 53 subjects respiratory rate algorithm accuracy within ±3 breaths per minute was demonstrated as compared to capnography.

VIII. CONCLUSIONS

The results of the substantial equivalence assessment, taken together with non-clinical bench and shelf life testing, biocompatibility, electrical safety and electromagnetic compatibility, software testing, and clinical performance testing demonstrate that the Philips Biosensor BX100 does not raise different questions of safety and effectiveness when compared to the predicate, performs as intended, and has performance characteristics that are substantially equivalent to the Philips Wearable Biosensor-G5 Solution and Zephyr Technology Corporation BioModule 3- MI predicate devices.