November 9, 2023

Bionet Co., Ltd.
Kyungeun Park – Assistant Manager
5F, 61 Digital-ro 31 gil, Guro-gu
Seoul, South Korea 08375

Re: K231150
Trade/Device Name: Cardio P1
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: October 13, 2023
Received: October 13, 2023

Dear Kyungeun Park:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Stephen C. Browning -S

for

Jennifer Shih Kozen
Assistant Director
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)*
K231150

Device Name
Cardio P1

Indications for Use *(Describe)*
The Cardio P1 Analysis System is intended to acquire, analyze, display, and record ECG information from adult and pediatric populations. Pediatric population is defined as patients between the ages from 3 and less than 16 years. The system provides 12-lead ECG and interpretive analysis. The 12-Lead ECG interpretation algorithm provides analytical information about the patient's heart condition, which must be confirmed by a qualified medical professional along with other relevant clinical information. Sending and receiving ECG data to and from the Hospital Information System is optional. The Cardio P1 is intended to be used by personnel trained in hospitals or medical professional facilities under the direct supervision of a licensed healthcare practitioner.

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

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

April 14, 2023

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Manufacturer: Bionet Co., Ltd.
- Address: 5F, 61 Digital-ro 31 gil, Guro-gu, Seoul, Republic of Korea 08375
- Contact Name: Kyungeun Park / Assistant Manager
- Telephone No.: +82-2-6292-6410
- Fax No.: +82-2-6499-7788
- Email Address: kepark@ebionet.com
- Registration No.: 3003681187

3. Trade Name, Regulation Name, Classification [21 CFR 807.92(a)(2)]

Trade/Device Name	Cardio P1
K Number	K231150
Common Name	Electrocardiograph
Regulation Number	870.2340
Regulation Name	Electrocardiograph
Regulation Class	2
Product Code	DPS

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4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follow;

Predicate device

- 510(k) Number: K220535
- Applicant: Bionet Co., Ltd.
- Trade/Device Name Cardio10
- Regulation Number 870.2340 / 868.1840
- Regulation Name: Electrocardiograph / Diagnostic spirometer
- Regulation Class: 2
- Product Code: DPS / BZG

The predicate device has not been subject to a design-related recall.

5. Description of the Device [21 CFR 807.92(a)(4)]

Cardio P1 is a 12-channel ECG (Electrocardiogram) recording equipment that measures and records the patient's ECG. It not only provides parameters necessary for diagnosis, patient's ECG record and automatic diagnosis, but also increases chart management efficiency by providing ECG records and printing reports when patient or user information is entered. At the same time, it can transmit the saved data to a PC for file management. Its user-oriented design enables ECG examination with a single push of a button.

The Cardio P1 is installed on a standalone PC. For all configurations, an independent PC is used that can be positioned for patient convenience.

6. Indications for use [21 CFR 807.92(a)(5)]

The Cardio P1 Analysis System is intended to acquire, analyze, display, and record ECG information from adult and pediatric populations. Pediatric population is defined as patients between the ages from 3 and less than 16 years.

The system provides 12-lead ECG and interpretive analysis. The 12-Lead ECG interpretation algorithm provides analytical information about the patient's heart condition, which must be confirmed by a qualified medical professional along with other relevant clinical information. Sending and receiving ECG data to and from the Hospital Information System is optional. The Cardio P1 is intended to be used by personnel trained in hospitals or medical professional facilities under the direct supervision of a licensed healthcare practitioner.

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7. Determination of Substantial Equivalence

The Cardio10 is substantially equivalent to legally marketed predicate devices with respect to indications for use and technology characteristics.

Comparison of Proposed Device to Predicate Device K220535

	Proposed Device	Predicate Device
Product Name	Cardio P1	Cardio10
510(k) Number	K231150	K220535
Manufacturer	Bionet Co., Ltd.	Bionet Co., Ltd.
Product Code	DPS	DPS / BZG
Device Class	2	2
Indications for Use	The Cardio P1 Analysis System is intended to acquire, analyze, display, and record ECG information from adult and pediatric populations. Pediatric population is defined as patients between the ages from 3 and less than 16 years. The system provides 12-lead ECG and interpretive analysis. The 12-Lead ECG interpretation algorithm provides analytical information about the patient's heart condition, which must be confirmed by a qualified medical professional along with other relevant clinical information. Sending and receiving ECG data to and from the Hospital Information System is optional. The Cardio P1 is intended to be used by personnel trained in hospitals or medical professional facilities under the direct supervision of a licensed healthcare practitioner.	The Cardio10 ECG Analysis System is intended to acquire, analyze, display, and record electrocardiographic information from adult and pediatric populations. Pediatric population is defined as patients between the ages from 3 and less than 16 years. Basic systems deliver 12 lead ECG's, interpretive analysis, and can be upgraded to provide software analysis options such as a high resolution signal averaging of QRS and P wave portions of the electrocardiogram. The 12-lead ECG interpretive algorithm provides a computer-generated analysis of potential patient cardiac abnormalities, which must be confirmed by a physician with other relevant clinical information. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is optional.

	Proposed Device	Predicate Device
		The Cardio10 is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or medical professional's facility. Cardio10 is intended for prescription use only to conduct diagnostic spirometry testing of adults and pediatric patients, 5 years and older, in general practice, specialty physician, and hospital settings. The device is intended to be used as a spirometer which measures patient respiratory parameters including FVC, COPD, SVC, MVV.
Data storage	According to connected PC specifications	Internal Storage for 500 data : Built in memory
Dimension	- 90.75(W) x 103.5(D) x 24.93(H)mm - Approx. 110g	1) Main Body - 300(W) x 299(H) x 123(D) mm (monitor tilt down) - 300(W) x 299(H) x 237(D)mm (monitor tilt up)296 - Approx.4kg 2) Spiro Handle - 48(W) x 39(D) x 201(H) mm - Approx. 250g
Target Population	Adult and pediatric patients	Adult and pediatric patients
ECG		
ECG Leads	Simultaneous 12 channel ECG and acquisition	Simultaneous 12 channel ECG and acquisition
Gain	2.5, 5, 10, 20, Auto (I~aVF: 10, V1~V6:	2.5, 5, 10, 20, Auto (I~aVF: 10, V1~V6:

	Proposed Device	Predicate Device
	5) mm/mV	5) mm/mV
Sampling Rate	Analysis Sampling Rate – 500Hz Digital Sampling Rate -8,000Hz	Analysis Sampling Rate – 500Hz Digital Sampling Rate -8,000Hz
Filters	AC (50/60 Hz, -20dB or better), Muscle (25~35Hz, -3dB or better), Baseline Drift (0.05Hz, 0.1Hz, 0.2Hz, -3dB or better), Low Pass Filter(off, 40Hz, 100Hz, 150Hz)	AC (50/60 Hz, -20dB or better), Muscle (25~35Hz, -3dB or better), Base line drift (0.05Hz, 0.1Hz, 0.2Hz, -3dB or better), Low pass filter(off, 40Hz, 100Hz, 150Hz)
Patient data	ID, Name, Date of Birth, Age, Gender, Height, Weight, Race, Smoke, Department, Room No., Study Desc., Accession No., Referring Physician	ID, Name, Birthday, Age, Gender, Height, Weight, Race, Smoke, Department, Room no., Study desc., Accession No., Referring Physician
Basic Measurement	Heart Rate (30~300bpm, ±3bpm), PR/RR Int, QRS Dur, QT/QTc Int, P-R-T axis, SV1/RV5/R+S Amp Bionet ECG analysis algorithm(V 3.26)	Heart rate(30~300bpm ±3), PR/RR int. , QRS dur., QT/QTc int., P-R-T axis, SV1/RV5/R+S amp. Bionet ECG analysis algorithm(V 3.26)

The Cardio P1 and predicate devices are same in intended use, their target population and technical characteristics includes ECG leads, Gain, Sampling rate, filters, patient data, measurement, etc.

Differences between Cardio P1 and the predicate device such as Data storage, dimension do not raise any new concerns with respect to safety or effectiveness. The spirometer function of the predicate device is an optional function that does not affect its main function, ECG. The proposed device and predicate device are both designed to meet the IEC 60601-2-25.

Non-Clinical Test Summary

1) Electrical Safety, Electromagnetic Compatibility and Performance:

The Cardio P1 comply with the electrical safety and electromagnetic compatibility requirements established by the standards.

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- Testing to confirm compliance with IEC 60601-1:2005/AMD1:2012
  Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- Testing to confirm compliance with IEC 60601-1-2:2014

  Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- Testing to confirm compliance with IEC 60601-1-6:2010
  Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- Testing to confirm compliance with IEC 60601-2-25: 2011
  Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs
- ANSI AAMI EC53

2) Software Validation

The Cardio P1 contain moderate level of concern software and firmware. The software was designed and developed according to a software development process and was verified and validated.

Software information is provided in accordance with FDA guidance:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices: Guidance for Industry and FDA Staff
- Postmarket Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff

3) Biocompatibility

Most of the contents are prepared by being referenced the following standards:

- Cytotoxicity test by EN ISO 10993-5
- Sensitization test by EN ISO 10993-10
- Intracutaneous reactivity test by ISO 10993-10

#95-1 Biocompatibility Flow Chart for Selection of Toxicity tests for 510(k)s, FDA.

Clinical Test Summary

Clinical testing is not required

8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

The non-clinical testing demonstrates the subject device (Cardio P1) is substantially equivalent in terms of technological characteristics to the predicate device (K220535).

9. Conclusion [21 CFR 807.92(b)(3)]

The Cardio P1 has same intended use and technical characteristics to the predicate device. Based on the information summarized above, the Cardio P1 is substantially equivalent to the predicate device and does not raise any new questions regarding safety or effectiveness.