November 15, 2022

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

Re: K220535
Trade/Device Name: Cardio10
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, BZG
Dated: October 12, 2022
Received: October 12, 2022

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 (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,

for Shruti N. Mistry -S

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

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)*
K220535

Device Name
Cardio10

Indications for Use *(Describe)*
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.
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.

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)]

February 18, 2022

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	Cardio10
Common Name	Electrocardiograph & Spirometer
Regulation Number	870.2340 / 868.1840
Regulation Name	Electrocardiograph / Diagnostic spirometer
Regulation Class	2
Product Code	DPS / BZG

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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: K113306
- Applicant: Bionet Co., Ltd.
- Trade/Device Name Cardio7
- Regulation Number 870.2340
- Regulation Name: Electrocardiograph
- Regulation Class: 2
- Product Code: DPS

Reference device

- 510(k) Number: K130322
- Applicant: Bionet Co., Ltd.
- Trade/Device Name SPM-300
- Regulation Number 868.1840
- Regulation Name: Diagnostic spirometer
- Regulation Class: 2
- Product Code: BZG

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

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

Cardio 10 is a device to measure and record ECG of a patient as an ECG recording machine with 12 channels.

It provides parameters required for the diagnosis, ECG records of a patient, and automatic diagnosis and prints ECG records and output report if entering patient or user information and efficiently use them for the chart management. At the same time, it is possible to transmit saved data to the PC connected to the network and manage digital files.

In addition, it is possible to measure ECG by pressing the button only once in consideration of the convenience of a user as much as possible and save, transmit, and print data all at once after completing the automatic diagnosis.

Parameter and automatic diagnosis required on the spirometer record and diagnosis of patients are provided to users while printing the A4 size and Letter size report along with the spirometer records by entering the information of patients or users for the efficient management of chart. At the same time, saved data are delivered to the PC connected to the network managing digital files.

In addition, the battery can be internally saved as an optional component making it feasible to carry and use for checkup while moving.

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

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.

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.

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 Subject Device to Predicate Device K113306

	Subject Device	Predicate Device
Product Name	Cardio10	Cardio7
510(k) Number	K220535	K113306
Manufacturer	Bionet Co., Ltd.	Bionet Co., Ltd.
Product Code	DPS	DPS
Device Class	2	2
Indications for Use	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	Cardio7 is intended for use as a diagnostic tool by trained operators in health facilities. It provides the following functions: • Acquire ECG waveform data from up to twelve (12) leads through surface electrodes adhered to the patient's body. • Input patient data. • View, store and print captured data.

	Subject Device	Predicate Device
	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. 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.	• Analyze captured data; display and print analysis results. • Retain captured data and analysis results for up to 120 patients. • Transfer retained data to a PC (via server IP) or directly to insertable USB memory.
Target Population	Adult and pediatric patients	Adult and pediatric patients
ECG Leads	Simultaneous 12 channel ECG and acquisition	Simultaneous 12 leads resting ECG connect directly to Cardio7 system unit
Gain	2.5, 5, 10, 20, Auto (I~aVF: 10, V1~V6: 5) mm/mV	2.5, 5, 10, 20, auto(I~aVF: 10, V1~V6: 5) mm/mV
Sampling Rate	Analysis Sampling Rate – 500Hz Digital Sampling Rate -8,000Hz	500 samples/sec/channel
Filters	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),	AC (50/60 Hz, -20dB or better), Muscle (25~35Hz, -3dB or better), Base line drift (0.1Hz, -3dB or better),

	Subject Device	Predicate Device
	Low pass filter(off, 40Hz, 100Hz, 150Hz)	Low pass filter(off, 40Hz, 100Hz, 150Hz)
Patient data	ID, Name, Birthday, Age, Gender, Height, Weight, Race, Smoke, Department, Room no., Study desc., Accession No.,Referring Physician	ID, Name, Age, Gender, Height, Weight, Race, Smoke
Basic Measurement	Heart rate(30~300bpm ±3), PR/RR int. , QRS dur., QT/QTc int., P-R-T axis, SV1/RV5/R+S amp.	Heart rate, PR int, QRS dur, QT/OTc, P-R-T axis
Battery	10 hours of normal use or print 350 ECG(12 channel format at 25mm/s and 10mm/mV) or Spiro pages. Battery recharge to full capacity in 3hours. (The device is turned off)	1 hours of normal use or print 100 ECG pages. Battery recharge to full capacity in 4hours. (The device is turned off)
Data storage	Internal Storage for 500 data : Built in memory	Internal Storage for up to 120 ECG Additional storage available using built in SD RAM slot
Dimension	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(Main Body)	296 x 305 x 92 mm Approx. 3.5kg

Comparison of Subject Device to Reference Device K130322

	Subject Device	Reference Device
Product Name	Cardio10	SPM-300
510(k) Number	K220535	K130322
Manufacturer	Bionet Co., Ltd.	Bionet Co., Ltd.
Product Code	DPS	BZG
Device Class	2	2
Indications for Use	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 0 and less than 16 years. Basic systems deliver 12 lead ECG's, interpretive analysis, and can be upgraded to provide software	The SPM-300 Spirometer is intended for prescription use only to conduct diagnostic spirometry testing of adults and pediatric patients in general practice, specialty physician. and hospital settings.

	Subject Device	Reference Device
	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. 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.	
Target Population	Adult and pediatric patients	Adult and pediatric patients
Measuring values	- FVC : FVC, FEV1, FEV1/FVC, FEF 0.2-1.2L, FEF 25-75%, FEF 75-85%, PEF, FEF 25%, FEF 50%, FEF 75%, FIVC, FEV6, PEFT, FET 100%, Error Code, Extrapolation volume -COPD : FEV1, FEV6, FEV1/FEV6, LFI - SVC : SVC, TV, ERV, IRV, EC - MVV : MVV, FB, TV	- FVC : FVC, FEV1, FEV1/FVC, FEF 0.2-1.2L, FEF 25-75%, FEF 75-85%, PEF, FEF 25%, FEF 50%, FEF 75%, - SVC : SVC, TV, ERV, IRV, EC, IC, RV - MVV : MVV, FB, TV
Presentation	Flow Volume loop Volume Time Graph Measurement values table	Volume/Time curve Flow/Volume curve Measurement Values Table

	Subject Device	Reference Device
Measuring range	Flow : 0 to 14 L/s Volume : 0 to 12 L	Flow : 0 to ± 14 L/s Volume : 0 to ± 11 L
Measuring method	Differential pressure method	Differential pressure method
Measuring accuracy	Complies with ISO26782 and ISO23747	Complies with ISO26782 and ISO23747

The Cardio 10 and predicate devices are similar in their target population, functions, technical characteristics includes ECG leads, Gain, Sampling rate, measurement, etc.

Differences between Cardio10 and the predicate device such as base line drift of filter, type of patient data, measuring range, and dimension do not raise any new concerns with respect to safety or effectiveness. The subject device and predicate device are designed to meet the IEC 60601-2-25, ISO 26782, ISO 23747.

Non-Clinical Test Summary

1) Electrical Safety, Electromagnetic Compatibility and Performance:

The Cardio 10 comply with the electrical safety and electromagnetic compatibility requirements established by the standards.

- 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
- Testing to confirm compliance with ISO 26782:2009
  Anaesthetic and respiratory equipment — Spirometers intended for the measurement of time forced expired volumes in humans
- Testing to confirm compliance with ISO 23747:2009
  Anaesthetic and respiratory equipment — Peak expiratory flow meters for the

assessment of pulmonary function in spontaneously breathing humans

- ANSI AAMI EC53

2) Software Validation

The Cardio10 contain Major level of concern software as 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 (Cardio10) is substantially equivalent in terms of technological characteristics to the predicate device (K113306) and reference device (K130322).

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

The Cardio10 has similar intended use and technical characteristics to the predicate device. Based on the information summarized above, the Cardio10 is substantially equivalent to the predicate device and does not raise any new questions regarding safety or effectiveness.