December 15, 2023

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

Re: K231160
Trade/Device Name: Cardio Q50, Cardio Q70
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, BZG
Dated: November 17, 2023
Received: November 17, 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,

Jennifer W. Shih -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)*
K231160

Device Name
Cardio Q50, Cardio Q70

Indications for Use *(Describe)*
The Cardio Q50 / Cardio Q70 ECG Analysis System is intended to acquire, analyze, display and record ECG information from adult and pediatric populations.
* Bionet Algorithm - 3 years or older / Glasgow Algorithm - 0 years or older
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 Q50 / Cardio Q70 is intended to be used by personnel trained in hospitals or medical professional facilities under the direct supervision of a licensed healthcare practitioner.
In addition, the Cardio Q50 / Cardio Q70 is intended for prescription use only to perform spirometry diagnostic tests in adults and pediatric patients aged 5 and older in general practice, specialist and hospital settings. The device is intended to be used what measures patient respiratory parameters including FVC, FEV1/FEV6, 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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Bionet Co., Ltd.
5F, 61 Digital-ro 31 gil, Guro-gu, Seoul, Republic of Korea 08375
Tel: 82-2-6292-6410, Fax: 82-2-6499-7788

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 Q50, Cardio Q70
K Number	K231160
Common Name	Electrocardiograph & Spirometer
Regulation Number	870.2340 / 868.1840
Regulation Name	Electrocardiograph / Diagnostic spirometer
Regulation Class	2
Product Code	DPS / BZG

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

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

Primary 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

Reference device

- 510(k) Number: K160840
- Applicant: Cardioline S.p.A
- Trade/Device Name ECG100+, ECG200+
- Regulation Number 870.2340
- Regulation Name: Electrocardiograph
- Regulation Class: 2
- Product Code: DPS

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

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

Cardio Q50 / Cardio Q70 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. It saves, transfers and prints the data that has been acquired by automatic diagnosis.

It provides the user with the necessary parameters, which are necessary for patient diagnosis, along with the spirometry record. After spirometry tests, you can print out a report on A4/letter paper together with the spirometer record to efficiently manage the patient's or user's chart. The stored data is forwarded to a PC that is in charge of managing digital files. In addition, the battery pack, which can be stored inside as an optional component, ensures high portability and makes it possible to inspect or use the equipment in an emergency.

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

The Cardio Q50 / Cardio Q70 ECG Analysis System is intended to acquire, analyze, display and record ECG information from adult and pediatric populations.

* Bionet Algorithm - 3 years or older / Glasgow Algorithm - 0 years or older

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 Q50 / Cardio Q70 is intended to be used by personnel trained in hospitals or medical professional facilities under the direct supervision of a licensed healthcare practitioner.

In addition, the Cardio Q50 / Cardio Q70 is intended for prescription use only to perform spirometry diagnostic tests in adults and pediatric patients aged 5 and older in general practice, specialist and hospital settings. The device is intended to be used what measures patient respiratory parameters including FVC, FEV1/FEV6, SVC, MVV.

7. Determination of Substantial Equivalence

The Cardio Q50, Cardio Q70 is substantially equivalent to legally marketed predicate device and reference device with respect to indications for use and technology characteristics.

Comparison of Proposed Device to Predicate Device K220535 and Reference device K160840

	Proposed Device	**Predicate Device**	**Reference device**
Product Name	Cardio Q50, Cardio Q70	Cardio10	ECG100+, ECG200+
510(k) Number	K231160	K220535	K160840
Manufacturer	Bionet Co., Ltd.	Bionet Co., Ltd.	Cardioline S.p.A
Product Code	DPS / BZG	DPS / BZG	DPS
Device Class	2	2	2
Common specification			
Indications for Use	The Cardio Q50 / Cardio Q70 ECG Analysis System is intended to acquire, analyze, display and record ECG information from adult and pediatric populations. * Bionet Algorithm - 3 years or older / Glasgow Algorithm - 0 years or older The system provides 12-lead ECG and interpretive analysis.	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,	ECGxxx(z)(+) is a high-performance, multi-channel, interpretative resting electrocardiograph. The ECG signal is acquired with a 10-wires patient cable and is displayed in real time on a LCD screen integrated in the device. The electrocardiograph can analyse and store the ECG traces, send them to an external peripheral via

	Proposed Device	Predicate Device	Reference device
	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 Q50 / Cardio Q70 is intended to be used by personnel trained in hospitals or medical professional facilities under the direct supervision of a licensed healthcare practitioner. In addition, the Cardio Q50 / Cardio Q70 is intended for prescription use only to perform spirometry diagnostic tests in adults and pediatric patients aged 5 and older in general practice, specialist and hospital settings. The device is intended to be used what measures patient respiratory parameters including FVC, FEV1/FEV6, SVC, MVV	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.	network or via USB, print the 12 lead ECG in automatic or manual mode by means of a thermal printer. ECGxxx(z)(+) is intended for assessment and diagnosis of cardiac functions. In any case the results of analysis performed by the electrocardiograph must be validated by a Physician. ECGxxx(z)(+) is intended for use in hospitals, in medical clinics and doctor's offices of any size. - The device is indicated for use to acquire, analyse, display and print electrocardiograms. - The device is intended to provide the physician with an automatic interpretation of the ECG to be reviewed by a physician. - The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis. - The interpretations of ECG offered by the device are only significant when used in conjunction with a physician overread as well as consideration of all other relevant patient data. - The device is indicated for use on adult and pediatric populations. - The device is not intended to be used as a vital signs physiological monitor.

	Proposed Device	Predicate Device	Reference device
Battery	Replaceable and Rechargeable Lithium Ion, 10.8V, 6500mA 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 3 hours. (The device is turned off)	Replaceable and Rechargeable Lithium Ion, 10.8V, 6500mA 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)	Internal rechargeable battery (NiMH), 12Vdc 2200 mAh
Data storage	Internal Storage for 500 Data : Built- in Memory	Internal Storage for 500 data : Built in memory	Up to 100 ECGs
Dimension	1) Main Body - 286(W) x 350(D) x 140(H) mm (Cardio Q50) - 286(W) x 350(D) x 144(H) mm (Cardio Q70) - Approx. 4.5kg (Max) 2) Spiro Handle - 48(W) x 39(D) x 201(H) mm - Approx. 250g	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	285 x 204 x 65 mm 1.8kg
Target Population	Adult and pediatric patients	Adult and pediatric patients	Adults and pediatric patients
ECG Leads	Simultaneous 12 channel ECG and acquisition	Simultaneous 12 channel ECG and acquisition	12 Leads Standard / Cabrera
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	5, 10, 20 mm/mV
Sampling Rate	Analysis Sampling Rate – 500Hz Digital Sampling Rate - 8,000Hz	Analysis Sampling Rate – 500Hz Digital Sampling Rate - 8,000Hz	500 samples/second/channel
Filters	AC (50/60 Hz, -20dB or better), Muscle (25~35Hz, -3dB or better),	AC (50/60 Hz, -20dB or better), Muscle (25~35Hz, -3dB or better),	AC (50/60 Hz) diagnostic fully digital high pass filter; adaptive digital AC interference filter (50/

	Proposed Device	Predicate Device	Reference device
	Bionet Baseline Drift (0.05Hz, 0.1Hz, 0.2Hz, -3dB or better) Low Pass Filter(off, 40Hz, 100Hz, 150Hz)	Base line drift (0.05Hz, 0.1Hz, 0.2Hz, -3dB or better), Low pass filter(off, 40Hz, 100Hz, 150Hz)	60 Hz); digital low pass filter muscular filter 25 and 40 Hz (only for display and printing)
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	Not known
Basic Measurement & Interpretation	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), the University of Glasgow ECG analysis algorithm(V 30.4)	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)	Heart rate(30~300bpm), Average RR, PR interval, QRS duration, QT/QTc int, P-R-T axis, Skolow-Lyon index, max R[V5]or[V6] and S[V1], J-Tp and Tp-Te intervals Glasgow resting ECG interpretation algorithm (V 28.6)
Spirometer (Option)			
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 - FEV1/FEV6 : 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%, 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	Not Applicable
Presentation	Flow Volume loop Volume Time Graph Measurement values table	Flow Volume loop Volume Time Graph Measurement values table	
Measuring range	Flow : 0 to 14 L/s Volume : 0 to 12 L	Flow : 0 to 14 L/s Volume : 0 to 12 L	
Measuring method	Differential pressure method	Differential pressure method	

	Proposed Device	Predicate Device	Reference device
Prediction Equation	Morris-Polgar, Knudson-ITS, ECCS-Quanjer, Korea CJK, Pereira, GLI-2012	Morris-Polgar, Knudson-ITS, ECCS-Quanjer, Korea CJK, Pereira, GLI-2012	
Sample Rate	200 samples/sec	200 samples/sec	
Flow Impedance	< 0.2 mbar s/L at 12 L/s	< 0.2 mbar s/L at 12 L/s	
Measuring accuracy	Complies with ATS2019, ISO26782 and ISO23747	Complies with ISO26782 and ISO23747	

The proposed device and primary predicate device (including reference device) are same in Intended use, Patient population, ECG Leads, Gain, Sampling Rate, Filters, Patient data, Basic Measurement, Target population, interpretation and Spirometer functions.

The only differences between the Cardio Q50, Cardio Q70 and the predicate device are Glasgow ECG analysis algorithm version and the dimension of the main body, which 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 Q50, Cardio Q70 comply with the electrical safety and electromagnetic compatibility requirements established by the standards.

- Testing to confirm compliance with IEC 60601-1 Edition 3.2 2020-08
  Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- Testing to confirm compliance with 60601-1-2 Edition 4.1 2020-09
  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 60601-1-6 Edition 3.1 2013-10
  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 Cardio Q50, Cardio Q70 contain Moderate 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 (Cardio Q50, Cardio Q70) is substantially equivalent in terms of technological characteristics to the predicate device (K220535) and Reference device(K160840).

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

The Cardio Q50, Cardio Q70 has similar intended use and technical characteristics to the predicate device and reference device. Based on the information summarized above, the Cardio Q50, Cardio Q70 is substantially equivalent to the predicate device and reference device and does not raise any new questions regarding safety or effectiveness as compared to the predicate.