June 12, 2024

Mediblu Medical LLC
% Jorge Millan
Biomedical Director
Sigma Biomedical
490 Sawgrass Corporate Parkway Suite 130
Sunrise, Florida 33325

Re: K233266
Trade/Device Name: Mediblu ECG System Models ME3, ME6P, ME12P, ME15P
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: May 8, 2024
Received: May 13, 2024

Dear Jorge Millan:

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233266

Device Name
Mediblu ECG System Models ME3. ME6P, ME12P, ME15P

Indications for Use *(Describe)*

The Digital Electrocardiograph ME3 is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. The proposed device has analysis feature, however the ECG with measurements and interpretive statements is offered to clinician on an advisory basis only.

The ME6 is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiographs shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

Digital Electrocardiographs ME12P is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiographs shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

Digital Electrocardiograph ME15P is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiographs shall he used in healthcare facilities by doctors and/or trained healthcare professionals.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Submitter Information

Submitter	Mediblu Medical LLC 3016 NW 82 Ave Doral, FL-USA- 33122
Contact:	Jorge Millan, PhD
Telephone number	(786) 416-5587
E-mail	jmillan@sigmabiomedical.com
Date prepared:	June 11, 2024

Subject Device Name

Trade/Proprietary Name:	Mediblu ECG System Models ME3, ME6P, ME12P, ME15P
Regulation Number:	870.2340
Regulation Name:	Electrocardiograph
Product Code:	DPS
Class	II
Panel	Cardiovascular

Predicate Devices

Predicate Device:	iE 15
Sponsor	Biocare Bio-medical Equipment Co., Ltd.
510(K)	K123816
Regulation Number:	870.2340
Regulation Name:	Electrocardiograph
Product Code:	DPS
Class	II
Panel	Cardiovascular

Predicate Device:	iE 3, iE 6
Sponsor	Biocare Bio-medical Equipment Co., Ltd.
510(K)	K132758
Regulation Number:	870.2340
Regulation Name:	Electrocardiograph
Product Code:	DPS
Class	II
Panel	Cardiovascular

Predicate Device:	Digital Electrocardiograph, iE300
Sponsor	Biocare Bio-medical Equipment Co., Ltd.
510(K)	K160092
Regulation Number:	870.2340
Regulation Name:	Electrocardiograph
Product Code:	DPS
Class	II
Panel	Cardiovascular

Predicate Device:	iE 12
Sponsor	Shenzhen Biocare Electronics Co., Ltd.
510(K)	K122712
Regulation Number:	870.2340
Regulation Name:	Electrocardiograph
Product Code:	DPS
Class	II
Panel	Cardiovascular

Device Description

The Mediblu ME3 Digital Electrocardiograph is intended to acquire, display and record ECG signals from adult and pediatric patients through body surface ECG electrodes. ECG data result and patient information could be stored in the memory of the device. The obtained ECG records can help users to analyze and diagnose heart disease.

The Mediblu ME6P Digital Electrocardiograph is intended to acquire, display and record ECG signals from adult and pediatric patients through body surface ECG electrodes. ECG data result and patient information could be stored in the memory of the device. The obtained ECG records can help users to analyze and diagnose heart disease.

The Mediblu ME12P Digital Electrocardiograph is designed to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. After been amplified and filtered, the ECG signal waveforms are displayed in the LCD and recorded in the paper through thermal printer. ECG data result and patient information could be stored in the memory of the device.

The Mediblu ME15P Digital Electrocardiograph is designed to acquire, display and record ECG signals from adult and pediatric patients through body surface ECG electrodes. After been amplified and filtered, the ECG signal waveforms are displayed in the LCD and recorded in the paper through thermal printer. ECG data result and patient information could be stored in the memory of the device.

Indications for Use:

The Digital Electrocardiograph ME3 is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. The proposed device has analysis feature, however the ECG with measurements and interpretive statements is offered to clinician on an advisory basis only.

The ME6 is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiographs shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

Digital Electrocardiographs ME12P is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiographs shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

Digital Electrocardiograph ME15P is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiographs shall he used in healthcare facilities by doctors and/or trained healthcare professionals.

Predicate Device Comparison

ME3 Comparison

Name/510K # Owner	Subject Device ME3/K233266 Mediblu	Predicate Device E300/K160092 Biocare	Comparison
Indications forUse	The Digital Electrocardiograph ME3 is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. The proposed device has analysis feature, however the ECG with measurements and interpretive statements is offered to clinician on an advisory basis only.	The Digital Electrocardiograph iE300 is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. The proposed device has analysis feature, however the ECG with measurements and interpretive statements is offered to clinician on an advisory basis only.	Same
Dimensions	281mm x 191mm x 59mm	281mm x 191mm x 59mm	Same
Net Weight	1.3 kg	1.3 kg	Same
Lead	Standard 12-lead	Standard 12-lead	Same
AcquisitionMode	1 × 12, 1 × 12+1R, 3 × 4, 3 × 4+1R, 3/2	1 × 12, 1 × 12+1R, 3 × 4, 3 × 4+1R, 3/2	Same
Record Format	Auto, Manual, Upload	Auto, Manual, Upload	Same
Display Format	3 × 4, 3 × 4+1R, 6 × 2, 6 × 2+1R, 12 × 1	3 × 4, 3 × 4+1R, 6 × 2, 6 × 2+1R, 12 × 1	Same
Rhythm Time	30~300s waveforms acquisition for rhythm analysis	30~300s waveforms acquisition forrhythm analysis	Same
Measurement Parameters	Ventricular Rate, PR Interval, QRS Time Limit, QT/QTC Interval, P/QRS/TAxis, RV5/SV1 Amplitude and RV5+SV1 Amplitude	Ventricular Rate, PR Interval, QRS Time Limit, QT/QTC Interval, P/QRS/TAxis, RV5/SV1 Amplitude and Same RV5+SV1 Amplitude	Same
Filters	AC Filter Baseline Wander FilterEMG Filter	AC Filter Baseline Wander Filter EMG Filter	Same
Input CIR Current	≤0.1 μA	≤0.1 μA	Same

Input Impedance	≥30 MΩ (10Hz)	≥30 MΩ (10Hz)	Same
Time Constant	≥3.2 s	≥3.2 s	Same
Frequency Response	0.01 Hz～250 Hz	0.01 Hz～250 Hz	Same
Noise Level	≤12.5 μVp-v	≤12.5 μVp-v	Same
Sensitivity Threshold	20 μVp-v	20 μVp-v	Same
Sensitivity	Auto, 0.625 mm/mV, 1.25 mm/mV, 2.5 mm/mV, 5 mm/mV, 10/5 mm/mV, 10mm/mV, 20/10mm/mV, 20 mm/mV, and 40 mm/mV	Auto, 0.625 mm/mV, 1.25 mm/mV, 2.5 mm/mV, 5 mm/mV, 10/5mm/mV, 10 mm/mV, 20/10mm/mV, 20 mm/mV,and 40 mm/mV	Same
Sensitivity	10 mm/mV ± 2%	10 mm/mV ± 2%	Same
CalibrationVoltage	1 mV±3 %	1 mV±3 %	Same
Accuracy of inputsignal reproduction	Using the method described in 4.2.7.1 of AAMI EC11 to test the overall system error, which is within ±5%;Using method A and D described in 4.2.7.1 of AAMI EC11 to test frequency response. Because of sampling characteristics and the asynchronism between sample rate and signal rate of the ECG machine, digital systems may produce a noticeable modulating effect from one cycle to the next, particularly in pediatric recordings. This phenomenon, which is not physiologic, shall be clearly described in the operator's and service manuals.	Using the method described in 4.2.7.1 of AAMI EC11 to test the overall system error, which is within ±5%;Using method A and D described in 4.2.7.1 of AAMI EC11 to test frequency response. Because of sampling characteristics and the asynchronism between sample rate and signal rate of the ECG machine, digital systems may produce a noticeable modulating effect from one cycle to the next, particularly in pediatric recordings. This phenomenon, which is not physiologic, shall be clearly described in the operator's and service manuals.	Same

CMRR	＞115 dB	＞115 dB	Same
Patient Leak Current	＜10 μA	＜10 μA	Same
Sampling rate	8000Hz	8000Hz	Same
Display on LCD	5-inch TFT LCD screen	5-inch TFT LCD screen	Same
Safety Classification	IEC60601-1, Class I, TypeCF	IEC60601-1, Class I, Type CF	Same
AC Power Supply	100 V-240V, 50 Hz /60 Hz, 80 VA	100 V-240V, 50 Hz /60 Hz, 80 VA	Same
DC Power Supply	Rechargeable lithium battery, 11.1 V/ 2600mAh.In environment temperature 25 ℃± 5 ℃ and with the machine turning off, the charging time is not more than 2 hours to charge the battery to 90%. In environment temperature 25 ℃± 5 ℃, the continuous working time is not less than 3 hours while the ECG deviceis continuously printing.	Rechargeable lithium battery, 11.1 V/ 2600mAh. In environment temperature 25 ℃± 5 ℃ and with the machine turning off, the chargingtime is not more than 2 hours to charge the battery to 90%. In environment temperature 25 ℃± 5℃, the continuous working time is not less than 3 hours while the ECGdevice is continuously printing.	Same

ME6 Comparison

Name / 510K # Owner	Subject Device ME6 / K233266 Mediblu	Predicate Device iE6 / K132758 Biocare	Comparison
Indications forUse	The ME6 is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiographs shall be used in healthcare facilities by doctors and/or trained healthcare professionals.	The intended use of the iE6 electrocardiograph is to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiographs shall be used in healthcare facilities by doctors and/or trained healthcare professionals.	Same
Dimensions	257 mm × 291 mm × 106 mm	257 mm × 291 mm × 106 mm	Same
Net Weight	2.5 kg	2.5 kg	Same
Leads	Standard 12-lead	Standard 12-lead	Same
Acquisition Mode	Simultaneous 12-lead Acquisition	Simultaneous 12-lead Acquisition	Same
Record Format	1 × 12, 1 × 12+1R, 3 × 4, 3 × 4+1R (3-channel) 3 × 4,3 × 4+1R,3 × 4+3R,6 × 2,6 × 2+1R (6-channel, Standard leads) 6 × 1, 3 × 2	1 × 12, 1 × 12+1R, 3 × 4, 3 × 4+1R (3-channel) 3 × 4,3 × 4+1R,3 × 4+3R,6 × 2,6 × 2+1R (6-channel, Standardleads) 6 × 1, 3 × 2	Same
Record Mode	Auto, Manual, Upload (3-channel) Auto, Manual, Upload, Cycle,Trigger (6-channel)	Auto, Manual, Upload (3-channel) Auto, Manual, Upload, Cycle,Trigger (6-channel)	Same
Lead Format	Standard leads: 3 × 4, 3 × 4+1R,6 × 2, 6 × 2+1R, 12 × 1 6-channel, Nehb lead: 6 × 1, 3 × 2	Standard leads: 3 × 4, 3 × 4+1R,6 × 2, 6 × 2+1R, 12 × 1 6-channel, Nehb lead: 6 × 1, 3 × 2	Same
Rhythm Time	30~300s waveforms acquisitionfor rhythm analysis	30~300s waveforms acquisitionfor rhythm analysis	Same
Measurement Parameters	Standard leads:HR, PR Interval, QRS duration, QT/QTC Interval, P/QRS/T Axis, RV5/SV1 voltage and RV5+SV1 voltage Nehb lead: HR, PR interval, P duration, T duration, QRS duration, QT/QTC interval, P/QRS/T axis, P amplitude	Standard leads:HR, PR Interval, QRS duration, QT/QTC Interval, P/QRS/T Axis, RV5/SV1 voltageand RV5+SV1 voltage Nehb lead: HR, PR interval, Pduration, T duration, QRS duration, QT/QTC interval, P/QRS/T axis, P amplitude	Same
Filters	AC Filter Baseline Wander FilterEMG Filter	AC Filter Baseline Wander FilterEMG Filter	Same
Input CIR Current	≤0.1 μA	≤0.1 μA	Same

Input Impedance	≥2.5 MΩ	≥2.5 MΩ	Same
Time Constant	≥3.2 s	≥3.2 s	Same
Frequency Response	0.05 Hz～250 Hz	0.05 Hz～250 Hz	Same
Noise Level	≤15 μVp-v	≤15 μVp-v	Same
Sensitivity Threshold	20 μVp-v	20 μVp-v	Same
Sensitivity	Auto, 1.25 mm/mV, 2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV, 40 mm/mV, 10/5 mm/mV, 20/10 mm/mV	Auto, 1.25 mm/mV, 2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV, 40 mm/mV, 10/5 mm/mV, 20/10 mm/mV	Same
Standard Sensitivity	10 mm/mV ± 2%	10 mm/mV ± 2%	Same
Calibration Voltage	1 mV±5 %	1 mV±5 %	Same
Accuracy of input signal reproduction	Using the method described in 4.2.7.1 of AAMI EC11 to test theoverall system error, which is within ±5%; Using method A and D describedin 4.2.7.1 of AAMI EC11 to test frequency response. Because of sampling characteristics and the asynchronism between sample	Using the method described in 4.2.7.1 of AAMI EC11 to test the overall system error, which is within ±5%; Using method A and D described in 4.2.7.1 of AAMI EC11 to test frequency response. Because of sampling characteristics and the asynchronism between sample	Same
	rate and signal rate of the ECG machine, digital systems may produce a noticeable modulating effect from one cycleto the next, particularly in pediatric recordings. This phenomenon, which is notphysiologic, shall be clearly described in the operator's andservice manuals.	rate and signal rate of the ECG machine, digital systems may produce a noticeable modulatingeffect from one cycle to the next,particularly in pediatric recordings. This phenomenon, which is notphysiologic, shall be clearly described in the operator's andservice manuals.	
CMRR	>89 dB	>89 dB	Same
Patient LeakCurrent	<10 μA	<10 μA	Same
Sampling rate	8000 Hz	8000 Hz	Same
Display on LCD	8-inch TFT LCD screen (6-channel)	8-inch TFT LCD screen (6-channel)	Same
Safety Class	IEC60601-1, Class I, Type CF	IEC60601-1, Class I, Type CF	Same
AC PowerSupply	100 V～240 V, 50 Hz/60 Hz,80VA (6-channel)	100 V～240 V, 50 Hz/60 Hz,80VA (6-channel)	Same
DC PowerSupply	Rechargeable lithium battery, 14.8 V/ 2200mAh. In environment temperature ranging from 20 ℃ to 30 ℃ andwith the machine turning off, the charging time is not more than 2 hours to charge the	Rechargeable lithium battery, 14.8 V/ 2200mAh. In environment temperature ranging from 20 ℃ to 30 ℃ and with the machine turning off, thecharging time is not more than 2hours to charge the battery to 90%.	Same

	battery to 90%.				
Optional Wireless Networks Specifications					Same
Applicable Standard	IEEE 802.11b/g/ n(2.4G)	IEEE 802.11a/n(5G)	IEEE 802.11b/g /n(2.4G)	IEEE 802.11a/n(5G)	Same
Frequency Range	2.412 GHz～ 2.472 GHz	4.9 GHz～ 5.975 GHz	2.412 GHz～ 2.472 GHz	4.9 GHz～ 5.975 GHz	Same
Band Width	20~40MHz	20~40MHz	20~40MHz	20~40MHz	Same
Radiated Power	+18dBm	+13.5dBm	+18dBm	+13.5dBm	Same
Signal Path	1-13 (China)		1-13 (China)		Same
Type and Frequency Characteristicsof the Modulation	CCK/DSSS/OFDM/MCS7/MCS0		CCK/DSSS/OFDM/MCS7/MCS0		Same

ME12P Comparison

Name / 510K # Owner	**Subject Device ME12P Mediblu**	**Predicate Device iE 12 / K123816 Biocare**	**Comparison**
Indications forUse	Digital Electrocardiographs ME12P is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiographs shall be used in healthcare facilities by doctors and/or trained healthcare professionals.	Digital Electrocardiograph iEI12A is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiographs shall be used in healthcare facilities by doctors and/or trained healthcare professionals.	Same
Dimensions	345mm x 260mm x 86.7mm	345mm x 260mm x 86.7mm	Same
Net Weight	4 kg	4 kg	Same
Lead	Standard 12-lead	Standard 12-lead	Same
Acquisition Mode	Simultaneous 12-lead	Simultaneous 12-lead	Same
Record Format	Standard leads: 3×4, 3×4+1R, 3×4+3R, 6×2, 6×2+1R, 6×2+3R, 12×1 Nehb lead: 6×1, 3×2 VCG: 6×1+3, 3×2+3, 3×2+3+1R, 3×2+3+3R, Frank	Standard leads: 3×4, 3×4+1R, 3×4+3R, 6×2, 6×2+1R, 6×2+3R, 12×1 Nehb lead: 6×1, 3×2 VCG: 6×1+3, 3×2+3, 3×2+3+1R,3×2+3+3R, Frank	Same
Record Mode	Economic, Auto, Manual, Upload, Cycle, Trigger	Economic, Auto, Manual, Upload, Cycle, Trigger	Same

Lead Format	Standard leads: 3×4, 3×4+1R,6×2, 6×2+1R, 12×1 Nehb lead: 6×1, 3×2 VCG: 3×2+3, 6×1+3, Frank	Standard leads: 3×4, 3×4+1R,6×2, 6×2+1R, 12×1 Nehb lead: 6×1, 3×2 VCG: 3×2+3, 6×1+3, Frank	Same
Long-term Recording	Record for a long term (30 s～300 s) and rhythm analysis	Record for a long term (30 s～300 s) and rhythm analysis	Same
Measurement Parameters	Standard leads: HR, PR interval,QRS duration, QT/QTC interval, P/QRS/T axis, RV5/SV1 voltage andRV5+SV1 voltage Nehb lead: HR, PR interval, Pduration, T duration, QRS duration, QT/QTC interval, P/QRS/T axis, P amplitude	Standard leads: HR, PR interval,QRS duration, QT/QTC interval, P/QRS/T axis, RV5/SV1 voltage andRV5+SV1 voltage Nehb lead: HR, PR interval, Pduration, T duration, QRS duration, QT/QTC interval, P/QRS/T axis, P amplitude	Same
Filters	AC, low-pass and high-pass filters	AC, low-pass and high-pass filters	Same
CMRR	>89 dB >100 dB (with AC interferencefilter)	>89 dB >100 dB (with AC interferencefilter)	Same
Input CIR Current	≤0.1 μA	≤0.1 μA	Same
Patient Leak Current	<10 μA	<10 μA	Same
Time Constant	≥3.2 s	≥3.2 s	Same
Frequency Response	0.05 Hz～250 Hz	0.05 Hz～250 Hz	Same
Noise Level	≤15 μVp-v	≤15 μVp-v	Same
Sensitivity Threshold	20 μVp-v	20 μVp-v	Same
Signal Gain	1.25 mm/mV, 2.5 mm/mV, 5mm/mV, 10 mm/mV, 20 mm/mV, 40 mm/mV, 10/5 mm/mV, 20/10 mm/mV, Auto Gain (Auto Gain is just forthe Automatic mode)	1.25 mm/mV, 2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV, 40 mm/mV, 10/5 mm/mV, 20/10 mm/mV, Auto Gain (Auto Gain is just forthe Automatic mode)	Same
Calibration Voltage	1 mV±5 %	1 mV±5 %	Same
Accuracy of Input Signal Reproduction	Using the method described in 4.2.7.1 of AAMI EC11 to test theoverall system error, which is within ±5%; Using method A and D describedin 4.2.7.1 of AAMI EC11 to test frequency response. Because of sampling characteristics and the asynchronism between samplerate and signal rate of the ECGmachine, digital systems may produce a noticeable	Using the method described in 4.2.7.1 of AAMI EC11 to test the overall system error, which is within ±5%; Using method A and D described in 4.2.7.1 of AAMI EC11 to test frequency response. Because of sampling characteristics and the asynchronism between sample rate and signal rate of the ECG machine, digital systems may produce a noticeable modulating	Same

	modulating effect from one cycleto the next, particularly in pediatric recordings. This phenomenon, which is not physiologic, shall be clearly described in the operator's andservice manuals.		effect from one cycle to the next, particularly in pediatric recordings. This phenomenon, which is not physiologic, shall be clearly described in the operator's andservice manuals.		
Input Circuit	Floating circuit input		Floating circuit input		Same
Input Impedance	≥2.5MΩ (full-band)		≥2.5MΩ (full-band)		Same
Sampling Rate of Signals	8000 Hz		8000 Hz		Same
Display on LCD	1280×800, 9-inch LCD touch screen, the whole instrumentwork status, time, heart rate,and with the backlight		1280×800, 9-inch LCD touch screen, the whole instrumentwork status, time, heart rate,and with the backlight		Same
Safety Classification	IEC60601-1 Class I Type CF		IEC60601-1 Class I Type CF		Same
AC Power Supply	100 V~240 V, 50 Hz /60 Hz, 110VA		100 V~240 V, 50 Hz /60 Hz, 110VA		Same
DC Power Supply	Rechargeable lithium battery, 14.8 V/ 4400mAh. In environment temperature ranging from 20 ℃ to 30 ℃ andwith the machine turning off, the charging time is not more than 4 hours to charge the battery to 90%.		Rechargeable lithium battery, 14.8 V/ 4400mAh. In environment temperature ranging from 20 ℃ to 30 ℃ and with the machine turning off, the charging time is not more than 4hours to charge the battery to 90%.		Same
Optional Wireless Networks Specifications					
Applicable Standard	IEEE 802.11b/g/n (2.4G)	IEEE 802.11a/n(5G)	IEEE 802.11b/g /n(2.4G)	IEEE 802.11a/n(5G)	Same
Frequency Range	2.412 GHz～ 2.472 GHz	4.9 GHz～ 5.975 GHz	2.412 GHz～ 2.472 GHz	4.9 GHz～ 5.975 GHz	Same
Band Width	20~40MHz	20~40MHz	20~40MHz	20~40MHz	Same
Radiated Power	+18dBm	+13.5dBm	+18dBm	+13.5dBm	Same
Signal Path	1-13 (China)		1-13 (China)		Same
Type and Frequency Characteristicsof the Modulation	CCK/DSSS/OFDM/MCS7/MCS0		CCK/DSSS/OFDM/MCS7/MCS0		Same

ME15P Comparison

Common Name Owner	Candidate Device ME15P Mediblu	Predicate Device (K123816)iE 15 Biocare	Comparison
Indications forUse	Digital Electrocardiograph ME15P is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiographs shall he used in healthcare facilities by doctors and/or trained healthcare professionals.	Digital Electrocardiograph iE 15S is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiographs shall he used in healthcare facilities by doctors and/or trained healthcare professionals.	Same
Dimensions	460mm x 370mm x 250mm	460mm x 370mm x 250mm	Same
Net Weight	8.8 kg	8.8 kg	Same
Lead	Standard 15-lead	Standard 15-lead	Same
Acquisition Mode	Simultaneous 15-lead Acquisition	Simultaneous 15-lead Acquisition	Same
Record Format	12-lead: 3×4, 3×4+1R, 3×4+3R, 6×2, 6×2+1R, 6×2+3R,12×1 15-lead: 3×5, 3×5+1, 3×5+3R, 6×2+3, 6×2+3+1R, 6+9, 15×1, Extra 3 VCG: 3×4+3, 3×4+3+1R, 3×4+3+3R, 6×2+3, 6×2+3+1R, 15×1, Frank	12-lead: 3×4, 3×4+1R, 3×4+3R, 6×2, 6×2+1R, 6×2+3R,12×1 15-lead: 3×5, 3×5+1, 3×5+3R, 6×2+3, 6×2+3+1R, 6+9, 15×1, Extra 3 VCG: 3×4+3, 3×4+3+1R, 3×4+3+3R, 6×2+3, 6×2+3+1R, 15×1, Frank	Same
Record Mode	Economic, Auto, Manual,Upload, Cycle, Trigger	Economic, Auto, Manual,Upload, Cycle, Trigger	Same
Lead Format	12-lead: 3×4, 3×4+1R, 6×2, 6×2+1R, 12×1 15-lead: 3×5, 3×5+1R, 6×2+3, 6×2+3+1R, 6+9, 6+9+1R, Extra 3 VCG: 3×4+3, 6×2+3, Frank	12-lead: 3×4, 3×4+1R, 6×2, 6×2+1R, 12×1 15-lead: 3×5, 3×5+1R, 6×2+3, 6×2+3+1R, 6+9, 6+9+1R, Extra 3 VCG: 3×4+3, 6×2+3, Frank	Same
Rhythm Time:	30~300s waveforms acquisitionfor rhythm analysis	30~300s waveforms acquisitionfor rhythm analysis	Same
Measurement Parameters	Ventricular Rate, PR Interval, QRS Time Limit, QT/QTC Interval,P/QRS/T Axis, RV5/SV1 Amplitude andRV5+SV1 Amplitude	Ventricular Rate, PR Interval, QRS Time Limit, QT/QTC Interval,P/QRS/T Axis, RV5/SV1 Amplitude andRV5+SV1 Amplitude	Same
Filters	AC Filter Baseline Wander FilterEMG Filter	AC Filter Baseline Wander FilterEMG Filter	Same
CMRR	＞89 dB	＞89 dB	Same
Input CIR Current	≤0.1 μA	≤0.1 μA	Same

Patient Leak Current	<10 μA	<10 μA	Same
Time Constant	≥3.2 s	≥3.2 s	Same
Frequency Response	0.05 Hz～250 Hz	0.05 Hz～250 Hz	Same
Noise Level	≤15 μVp-v	≤15 μVp-v	Same
Sensitivity Threshold	20 μVp-v	20 μVp-v	Same
Standard Sensitivity	10 mm/mV ± 2%	10 mm/mV ± 2%	Same
Calibration Voltage	1 mV±5 %	1 mV±5 %	Same
Accuracy of Input Signal Reproduction	Using the method described in 4.2.7.1 of AAMI EC11 to test theoverall system error, which is within ±5%; Using method A and D describedin 4.2.7.1 of AAMI EC11 to test frequency response. Because of sampling characteristics and the asynchronism between samplerate and signal rate of the ECG machine,digital systems may produce a noticeable modulating effect from one cycle to the next	Using the method described in 4.2.7.1 of AAMI EC11 to test theoverall system error, which is within ±5%; Using method A and D describedin 4.2.7.1 of AAMI EC11 to test frequency response. Because of sampling characteristics and the asynchronism between samplerate and signal rate of the ECG machine,digital systems may produce a noticeable modulating effect from one cycle to the next	Same
	particularly in pediatric recordings. This phenomenon, which is not physiologic, shall beclearly described in the operator's and service manuals	particularly in pediatric recordings. This phenomenon, which is not physiologic, shall beclearly described in the operator's and service manuals	
Input Impedance	≥2.5 MΩ	≥2.5 MΩ	Same
Sampling Rate of Signals	8000 Hz	8000 Hz	Same
Display on LCD	12.1-inch TFT LCD screen	12.1-inch TFT LCD screen	Same
Safety Classification	IEC60601-1, Class I, Type CF	IEC60601-1, Class I, Type CF	Same
AC Power Supply	100 V～240 V, 50 Hz/60 Hz, 90VA	100 V～240 V, 50 Hz/60 Hz, 90VA	Same
DC Power Supply	Rechargeable lithium battery, 14.8 V/ 4400mAh. In environment temperature ranging from 20 ℃ to 30 ℃ andwith the machine turning off, the charging time is not more than 4 hours to charge the battery to 90%.	Rechargeable lithium battery, 14.8 V/ 4400mAh. In environment temperature ranging from 20 ℃ to 30 ℃ andwith the machine turning off, the charging time is not more than 4 hours to charge the battery to 90%.	Same

Optional Wireless Networks Specifications					
Applicable Standard	IEEE 802.11b/g/n (2.4G)	IEEE 802.11a/n(5G)	IEEE 802.11b/g /n(2.4G)	IEEE 802.11a/n(5G)	Same
Frequency Range	2.412 GHz～ 2.472 GHz	4.9 GHz～ 5.975 GHz	2.412 GHz～ 2.472 GHz	4.9 GHz～ 5.975 GHz	Same

Band Width	20~40MHz	20~40MHz	20~40MHz	20~40MHz	Same
Radiated Power	+18dBm	+13.5dBm	+18dBm	+13.5dBm	Same
Signal Path	1-13 (China)		1-13 (China)		Same
Type and Frequency Characteristicsof the Modulation	CCK/DSSS/OFDM/MCS7/MCS0		CCK/DSSS/OFDM/MCS7/MCS0		Same

Characteristics Comparison:

The basic and main technical features of the subject device are the same as the predicate devices. The intended use, design, materials, and fabrication technologies are the same. The Mediblu Digital Electrograph models ME3, ME6P, ME12P, and ME15P have passed all non-clinical testing. All Mediblu digital electrocardiograph models in this 510(k) submission have shown to be equivalent to their predicate devices and show no significant differences. There are no differences between the subject devices and the predicate devices.

Conclusion

The non-clinical test data demonstrates that the Mediblu ECG system models are substantially equivalent to digital electrocardiograph systems cleared for marketing in the US. The Mediblu model ME3 is equivalent to the iE300 Digital Electrocardiograph manufactured by Shenzhen Biocare Bio-medical Equipment Co., Ltd (K160092). The Mediblu model ME6P is equivalent to the iE6 Digital Electrocardiograph manufactured by Shenzhen Biocare Bio-medical Equipment Co., Ltd (K132758). The Mediblu model ME12P is equivalent to the iE12 Digital Electrocardiograph manufactured by Shenzhen Biocare Bio-medical Equipment Co., Ltd (K122712). The Mediblu model ME15P is equivalent to the iE15 Digital Electrocardiograph manufactured by Shenzhen Biocare Bio-medical Equipment Co., Ltd (K123816).