QT Medical Inc.
Jui-Hung Hung
Senior Quality Assurance Engineer
1370 Valley Vista Drive, Suite 266
Diamond Bar, California 91765

Re: K233521
Trade/Device Name: QT ECG (QTERD100)
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter And Receiver
Regulatory Class: Class II
Product Code: DXH, DRX
Dated: November 1, 2023
Received: November 1, 2023

Dear Jui-Hung Hung:

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,

Robert T. Kazmierski -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233521

Device Name

QT ECG (QTERD100)

Indications for Use *(Describe)*

The QT ECG System is intended to acquire, record and process an electrocardiographic signal so that it can be transmitted digitally via Bluetooth technology to a cell-phone or mobile device, then to a remote location. The QT ECG System is indicated for use on infants, children and adults. It is designed to be operated by adults in the home, or by healthcare workers in non-acute care clinical facilities (such as nursing homes, skilled nursing facilities), and in professional healthcare facilities (such as clinics, hospitals, and ambulances) to record and transmit a 12- lead ECG and rhythm strip in near real-time to enable review at a physician's office, hospital or other medical receiving centers.

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.

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510(k) Summary

12. Type of Submission: Special 510(k), 510(k) number: K233521

12.1. Date of Summary:10/31/2023

12.2. Submitter: QT MEDICAL. Inc.

12.2.1. Address: 1370 Valley Vista Dr., Suite 266, Diamond Bar, CA 91765, USA

12.2.2. Phone:1-(909) 323-0007

12.2.3. Fax:1-(310) 755-3108

12.2.4. Representative: Ruey-Kang Chang, CEO (rk.chang@qtmedical.com)

12.3. Identification of the Device

12.3.1. Proprietary/ Trade name: QT ECG

12.3.2. Classification Product Code: DXH

12.3.3. Regulation Number: 870.2920

12.3.4. Regulation Description:Telephone electrocardiograph transmitter and receiver

12.3.5. Review Panel: Cardiovascular

12.3.6. Device Class: II

12.4. Identification of the predicate Device

12.4.1. Original Device Name：QT ECG

12.4.2. Manufacturer: QT Medical, Inc.

12.4.3. Classification Product Code: DXH

12.4.4. Regulation number: 870.2920

12.4.5. Device Class: II

12.4.6. 510(k) Number: K220795

12.5. Indication for Use of the Device

12.5.1. Indication for Use:

The QT ECG System is intended to acquire, record and process an electrocardiographic signal so that it can be transmitted digitally via Bluetooth technology to a cell-phone or mobile device, then to a remote location. The QT ECG System is indicated for use on infants, children and adults. It is designed to be operated by adults in the home, or by healthcare workers in non-acute care clinical facilities (such as nursing homes, skilled nursing facilities), and in professional healthcare facilities (such as clinics, hospitals, and ambulances) to record and transmit a 12- lead ECG and rhythm strip in near real-time to enable review at a physician's office, hospital or other medical receiving centers.

12.5.2. Intended Use:

The QT ECG System is intended to condition an electrocardiographic signal so that it can be transmitted digitally via Bluetooth technology and cell-phone or communication device to a remote location. The QT ECG System is designed to be used by an adult or a healthcare worker to transmit a 12-lead ECG and rhythm strip in near real-time to enable review at a physician’s office, hospital or other medical receiving center.

12.6. Device Description

The QT ECG system is a non-defibrillator-proof, hand-held, cordless 12-lead

electrocardiograph (ECG) system with Bluetooth connectivity. The QT ECG system consists of 5 major components:

- The QT ECG Recorder-Compact device that records 12-lead, resting electrocardiograms, then transmits the recorded data to a mobile device (smartphone, tablet, etc.) paired via Bluetooth. A Bluetooth-enabled mobile device (not included) is needed to operate the QT ECG Recorder, and to send the recorded rhythm strip to a cardiologist or licensed physician for review.
- The QT ECG Electrode Strip-Disposable, patented electrodes that are prepositioned on a self-adhesive strip.
- The QT ECG App - Software that lets the user uses their mobile device to operate the QT ECG recorder, then send the recorded data via cloud to a certified medical professional for review.
- Analysis - The analysis module provides ECG measurement from the collected data. It does not make any interpretation of the intervals provided based on factors such as heart rate, QRS duration, etc.
- Web Service - The web service provides an interface for communication.

The recorded ECG data is saved temporarily on the mobile device until it is transferred via the Internet to the cloud server. The QT ECG System does not have monitoring capabilities and does not have diagnostic alarm function. The QT ECG System is indicated for use on infants, children and adults. It is designed to be operated by adults in the home, or by healthcare workers in non-acute care clinical facilities (such as nursing homes, skilled nursing facilities), and in professional healthcare facilities (such as clinics, hospitals, and ambulances) to record and transmit a 12- lead ECG and rhythm strip in near real-time to enable review at a physician's office, hospital or other medical receiving centers.

12.7. Non-clinical Testing

An validation activity was conducted on the subject device according to IEC 60601-1-12 (EMS, Emergency Medical Services), QT ECG.

The list of claimed standards and regulations for compliance:

Testing Item	FDA Recognition No.	Standards and Regulations Applied
Biocompatibility	-	Good Laboratory Practice for Nonclinical Laboratory Studies. Title 21 of the U.S. Code of Federal Regulations, Part 58 United States Food and Drug Administration.
	-	Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".
	2-222	ISO 10993-2:2006, Biological evaluation of medical devices -- Part 2: Animal welfare requirements.
	2-245	ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity.
	2-174	ISO 10993-10:2010, Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization.
	2-191	ISO 10993-12:2012, Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials.
		ANSI/AAMI/ISO 10993-12:2012, Biological Evaluation Of Medical Devices - Part 12: Sample Preparation And Reference Materials.
Software Validation and Cybersecurity Evaluation	-	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices: 2005.
	-	Guidance on Off-The-Shelf Software Use in Medical Devices: 2019.
	-	Guidance for content of Premarket Submissions for Management of Cybersecurity in Medical Devices: 2014.

	13-79	IEC 62304:2006+AMD1:2015, Medical device software - Software life cycle processes.
	5-125	ISO 14971:2019, Medical devices - Application of risk management to medical devices.
	3-105	ANSI/AAMI/IEC 60601-2-25:2011/(R)2016, Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs.
Electromagnetic Compatibility and Electrical Safety	-	Guidance on Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices: 2016.
	19-4	ANSI/AAMI ES60601-1: 2005 / A2:2010, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
	19-8	IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility.
	19-14	IEC 60601-1-11:2015, Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
	3-105	IEC 60601-2-25:2011, Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs.
	19-13	IEC 62133:2012, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications.

Performance	3-52	ANSI/AAMI EC12:2000/(R)2015, Disposable ECG electrodes.
	19-13	IEC 62133:2012, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications.
	19-39	**IEC 60601-1-12:2014, AMD1:2020 (excepted for clause 9)**
Human Factor	-	Guidance on Applying Human Factors and Usability Engineering to Medical Devices: 2016.

12.8. Description of the change(s) and unchange(s)

The QT ECG submitted in this 510(k) file is compared with the cleared device, former QT ECG (K220795). Differences between the devices are cited as below, and other technological specifications are all the same as that of K220795. The new use environment is EMS, so the risk management and verification & validation activities in our design and development control process are all completed.

All Differences between Subject Device and Original Device

Device Change	**Risk**	**Subject Device(K233521)**	**Original Device (K220795)**	**Verification/ Validation Method(s)**	**Acceptance Criteria**	**Summary of Results**
Indications for Use	The recorder may be used in EMS (Emergency Medical Services), it may malfunction.	The QT ECG System is intended to acquire, record and process an electrocardiographic signal so that it can be transmitted digitally via Bluetooth technology to a cell-phone or mobile device, then to a remote location. The QT ECG System is indicated for use on infants, children and adults. It is designed to be operated by adults in the home, or by healthcare workers in non-acute care clinical facilities (such as nursing homes, skilled nursing facilities), and in professional healthcare facilities (such	The QT ECG System is intended to acquire, record and process an electrocardiographic signal so that it can be transmitted digitally via Bluetooth technology to a cell-phone or mobile device, then to a remote location. The QT ECG System is indicated for use on infants, children and adults. It is designed to be operated by adults in the home, or by healthcare workers in non-acute care clinical facilities (such as nursing homes, skilled nursing facilities), to record and transmit a 12-lead ECG and rhythm strip in near real-time to	Undergo the test according to IEC 60601-1-12.	Pass the test according to IEC 60601-1-12.	Pass. The risk is controlled. The document: Risk_Management_Plan Risk_Control_Report Risk_Management_Summary Report of IEC 60601-1-12

		as clinics, hospitals, **and ambulances**) to record and transmit a 12- lead ECG and rhythm strip in near real-time to enable review at a physician's office, hospital or other medical receiving centers.	enable review at a physician's office, hospital or other medical receiving centers.			
Storage and transport temperature		**-40°C** ~ 70°C; **-40°F**~158°F	-25°C~70°C; -13°F~158°F			
Operating Temperature		**-40°C** ~ 70°C; **-40°F**~158°F	-25°C~70°C; -13°F~158°F			
Storage and Transport Atmospheric Pressure		**620 hPa** ~ 1060 hPa	700 hPa ~ 1060 hPa			
Operating Atmospheric Pressure		**620 hPa** ~ 1060 hPa	700 hPa ~ 1060 hPa			
Ingress Protection Rating		**IP33**	IP22			
Package	-	Package **(Remove Small White Box):** Small Blue Box, Industrial Package.	Package: **Small White Box,** Small Blue box, Industrial Package.	It's no need to conduct Verification/ Validation Method(s) because the small white box is no longer in use.	N/A	N/A
Quick guide	Simplify the quick guide for reducing risks and there is no other risk.	Update the quick guide to 02-C1-07-V3-R0-01 Quick Guide)	Quick guide (02-C1-07-V2-R4)	It's no need to conduct Verification/ Validation Method(s) because the quick guide is for reducing risks and there is no other risk.	N/A	N/A

Mobile device	New mobile system version is not supported.	On Phone: iPhone 13 Pro Max (iOS 15) iPhone 13 Pro (iOS 15) iPhone 13 (iOS 15) iPhone 13 mini (iOS 15) iPhone 12 Pro Max (iOS 15) iPhone 12 Pro (iOS 15) iPhone 12 (iOS 15) iPhone 12 mini (iOS 15) iPhone 11 Pro Max (iOS 15) iPhone 11 Pro (iOS 15) iPhone 11 (iOS 15) iPhone XS Max (iOS 15) iPhone XS (iOS 15) iPhone XR (iOS 15) iPhone X (iOS 15) iPhone 8/ 8 Plus (iOS 15) iPhone 7/ 7 Plus (iOS 15) iPhone 6S/ 6S Plus (iOS 15) iPhone SE 2 (iOS 15) Samsung Galaxy S10 (Android 11) Samsung Galaxy S9 (Android 10) Samsung Galaxy S9+ (Android 10) Samsung Galaxy S8 (Android 9) Samsung Galaxy S8+ (Android 9) Samsung Galaxy A21s (Android 11) Samsung Galaxy A20 (Android 11) LG G7 (Android 9) LG G6 (Android 9) Google Pixel 2 (Android 11) Google Pixel 2 XL (Android 11) Google Pixel (Android 10) Google Pixel XL (Android 10) On Tablet: iPad Pro 11 inch/2020 (iOS 15) iPad Pro 11 inch/2018 (iOS 15) iPad 9th/2021 (iOS 15) iPad 8th/2020 (iOS 15) iPad 7th/2019 (iOS 15) iPad 6th/2018 (iOS 15) iPad 5th/2017 (iOS 15) iPad mini 6 (iOS 15) iPad mini 5 (iOS 15) iPad mini 4 (iOS 15) iPad Air 2 (iOS 15)	on Phone: iPhone 11 Pro Max (iOS 13.5) iPhone 11 Pro (iOS 13.5) iPhone 11 (iOS 13.5) iPhone XS Max (iOS 13.5) iPhone XS (iOS 13.5) iPhone XR (iOS 13.5) iPhone X (iOS 13.5) iPhone 8/ 8 Plus (iOS 13.5) iPhone 7/ 7 Plus (iOS 13.5) iPhone 6S/ 6S Plus (iOS 13.5) iPhone 6/ 6 Plus (iOS 12.4.7) iPhone SE (iOS 13.5) iPhone SE 2 (iOS 13.5) iPod touch (6th) (iOS 12.4.7) Samsung Galaxy S9 (Android 9) Samsung Galaxy S9+ (Android 9) Samsung Galaxy S8 (Android 9) Samsung Galaxy S8+ (Android 9) LG G7 (Android 8.0.0) LG G6 (Android 8.0.0) LG G5 (Android 8.0.0) Google Pixel 2 (Android 10) Google Pixel 2 XL (Android 10) Google Pixel (Android 10) Google Pixel XL (Android 10) on Tablet: iPad 7th/2019 (iOS 13.5) iPad 6th/2018 (iOS 13.5) iPad 5th/2017 (iOS 13.5) iPad mini 5 (iOS 13.5) iPad mini 4 (iOS 13.5) iPad mini 3 (iOS 12.4.7)	Conduct the software system test.	Pass criteria according to test reports: Unit Test Integration Test System Test	Pass. The risk is controlled The document: Risk_Management_Plan Risk_Control_Report Risk_Management_Summary Software Test reports: Unit Test Integration Test System Test

		iPad Air 4 (iOS 15) Samsung Tab S4 (Android 10) Samsung Tab S3 (Android 10) Samsung Tab A 10.1" 2019 (Android 11) Samsung Tab A7 (Android 11) Lenovo Tab 4 8 Plus (Android 8.1.0) Asus Zenpad 3s 10 (Android 7.0) Asus Zenpad 3 8.0 (Android 7.0)				

12.9. Similarity and Difference

The QT ECG has been compared with the former “QT ECG” (K220795). The subject device has similar indications for use, same technology/mechanism of action, and similar safety and performance as the original device. The usage environment extends to Emergency Medical Services (EMS) in the objective device, which operates during emergency situations in compliance with IEC 60601-1-12.

Although there are some different specifications between two devices, the software validation, performance test and usability test have been completed to demonstrate that the differences between these parameters would not impact the safety and effectiveness of the subject device. The subject device has also undergone all safety and performance tests, and the results complied with the test requests.

Therefore, the difference between the subject device and the original device did not raise any problem of substantial equivalence. The subject device is substantially equivalent to the original device in intended use, safety and performance claims.

12.10. Conclusion

After analyzing all testing data and comparing with the original device, it can be concluded that the QT ECG is substantially equivalent to the original device.