September 26, 2022

QT Medical, Inc.
Jackal Chen
Department Director
1360 Valley Vista Drive, Suite 203
Diamond Bar, California 91765

Re: K220795
Trade/Device Name: QT ECG
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter And Receiver
Regulatory Class: Class II
Product Code: DXH
Dated: August 25, 2022
Received: August 29, 2022

Dear Jackal Chen:

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

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)*
K220795

Device Name
QT ECG

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), 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

5.1 Type of Submission: Traditional

5.2 Date of Summary: 03/07/2022

5.3 Submitter:

QT MEDICAL, Inc.
Address: 1360 Valley Vista Drive, Suite 203, Diamond Bar, CA 91765, US
Phone: 1-909-323-0007
Fax: 1-310-755-3108
Representative: Ruey-Kang Chang, CEO
(rk.chang@qtmedical.com)

5.4 Identification of the Device:

Trade name:	QT ECG
Classification Product Code:	DXH
Regulation Number:	870.2920
Regulation Description:	Telephone electrocardiograph transmitter and receiver
Review Panel:	Cardiovascular
Device Class:	II

5.5 Identification of the Predicate Device:

Predicate Device Name:	QT ECG
Manufacturer:	QT MEDICAL, Inc.
Classification Product Code:	DXH
Regulation number:	870.2920
Device Class:	II
510(k) Number:	K180157

5.6 Indications for Use of the Device

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), 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.

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.

5.7 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 recoded 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 intended for use on infants, children and adults patients to acquire ECG signals to be transmitted wirelessly via Bluetooth to a mobile device, and then over the Internet to a web service. The ***QT ECG*** System is designed to be used by a patient to record and transmit ECG data to a physician's office, hospital or other medical receiving center for review.

5.8 Non-clinical Testing

A series of validation activities were conducted on the subject device, QT ECG.

- Biocompatibility
  - *in vitro* cytotoxicity test
  - white rabbit skin irritation test
  - skin sensitization study (maximization test)
- Software validation and cybersecurity evaluation
- Electromagnetic compatibility and electrical safety
  - electrical safety test
  - external defibrillation assessment
    The system is not defibrillation-proof. The defibrillation safety assessment manifests that the patient's safety is assured.
  - EMC test
  - cable performance test
  - electrical safety in home healthcare environment
  - battery safety test
- Performance
  - performance test of electrode and the recorder
  - durability and measurement test of the system
  - wireless interference test
- Human Factor (Usability)

All the test results demonstrate QT ECG meets the requirements of its pre-defined acceptance criteria and indication for use, and is substantially equivalent to the predicate device.

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.
		ANSI/AAMI/ISO 10993-5:2009/(R)2014, 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.
Human Factor	-	Guidance on Applying Human Factors and Usability Engineering to Medical Devices: 2016.

5.9 Substantial Equivalence Determination

The QT ECG submitted in this 510(k) file is compared with the cleared device, former QT ECG (K180157). Differences between the devices are cited as below, and other technological specifications are all the same as that of K180157. The patient population is extended,

so the risk management and verification & validation activities in our design and development control process are all completed.

Item	Subject device	Predicate device	Substantial equivalence determination
Brand Name	QT ECG	QT ECG	
Model Name	PCA 500	-	
510(k) No.	(to be assigned)	K180157	
Indications 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), 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.	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 adult patients and pediatric patients age 18 – 22 years. It is designed to be used by a patient or other layperson 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 enable review at a physician's office, hospital or other medical receiving centers.	***Equivalent*** Both devices are designed to acquire, record and process an electrocardiographic signal. The difference in patient population has been evaluated, verified & validated, and the difference in wording is to specify the user more clearly. Above all, it does not raise new issues of SE.

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.	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 a patient or another layperson 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.	***Equivalent*** The intended use for both devices is the same. The difference in wording is to specify the user more clearly, and it does not raise new issues of SE.
Type of protection against electrical shock	Type: CF; non-defibrillator proof	Type: CF; non-defibrillator proof	***Identical*** Both devices do not have the defibrillation-proof specification, and both devices have stated warning on labeling to control the relevant risk.
Recorder storage and transport temperature	-25℃~70℃	-20℃~40℃	***Equivalent*** The storage and transport condition has been tested and met its pre-defined criteria, and it does not raise new issues of SE.
Electrode Strip sizes	7 sizes: S, M, L, XL for adults, 1, 2 ,3 for pediatrics	4 sizes: S, M, L ,XL for adults	***Equivalent*** The performance of new strips for pediatrics has been tested and met

			its pre-defined criteria, and it does not raise new issues of SE.
Electrode Strip materials in contact with the human body	Hydrogel, and Medical grade tape	Hydrogel, and Medical grade tape	Identical Both devices use the same materials on the electrode strip in contact with the human body.
Electrode Strip shelf life	3 year	1 year	***Equivalent*** The extended shelf life has been tested and met its pre-defined criteria, and it does not raise new issues of SE.
Electrode Strip storage and transportation temperature	5℃~30℃	5℃~27℃	***Equivalent*** The storage condition has been tested and met its pre-defined criteria, and it does not raise new issues of SE.
Electrode Strip operation temperature	5℃~30℃	< 32℃	***Equivalent*** The operation condition has been tested and met its pre-defined criteria, and it does not raise new issues of SE.

Item	Subject device	Predicate device	Substantial equivalence determination
Brand Name	QT ECG	QT ECG	
Model Name	PCA 500	-	
510(k) No.	(to be assigned)	K180157	
App modules	add Configuration module	• Recorder control module • ECG data module • User/Patient identification module	***Equivalent*** The added or modified modules have been tested and met its pre-defined criteria, and it does not raise new issues of SE.
Web Service modules	• change User management module to Authentication module • add RBAC module, Organization module, and Configuration module	• User management module • ECG data storage module • Report module	
Analysis modules	add Pre-processing module and Noise detection module	Measurement module	
Mobile application	on Phone: iPhone 11 Pro Max (iOS 13.5)	iOS 10 or later; Android 5.0 or later.	***Equivalent*** The mobile device compatibility has been tested and met its pre-defined criteria, and it does not raise new issues of SE.
Mobile device	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)	on Phone: iPhone 6, 6 Plus, 6s, 6s Plus iPhone 7, 7 Plus Google Pixel Samsung Galaxy A7 LG G5 on Tablet:	

	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)	iPad Air (or later) iPad Air 2 iPad Mini 2 (or later) iPad Mini 3 iPad Mini 4 HTC nexus 9 Samsung Galaxy Tab S2	

	iPad mini 2 (iOS 12.4.7) iPad Air 2 (iOS 13.5) iPad Air 1 (iOS 12.4.7) Samsung Tab S4 (Android 9) Samsung Tab S3 (Android 9) Samsung Tab S2 (Android 7.0) Samsung Tab A 10.1" 2019 (Android 9) Lenovo Tab 4 8 Plus (Android 8.1.0) Asus Zenpad 3s 10 (Android 7.0) Asus Zenpad 3 8.0 (Android 7.0)		

5.10 Similarity and Difference

The QT ECG has been compared with former "QT ECG". The subject device has similar indications for use, same technology/mechanism of action, and similar safety and performance as the predicate device. The patient population is extended to infant and children in the subject device, which is operated through 3 new sizes Electrode Strip.

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

5.11 Conclusion

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