May 4, 2018

QT Medical, Inc.
Ruey-Kang Chang
Chief Executive Offier
1001 W. Carson Street
Suite U
Torrance, California 90502

Re: K180157
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: March 31, 2018
Received: April 4, 2018

Dear Ruey-Kang Chang:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180157

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 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.

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: 04/27/2018

5.3 Submitter:

Address:	QT Medical, Inc. 1001 W Carson Street, Suite U, Torrance, CA, 90502, U.S.A.
Phone:	1-424-558-3500
Fax:	1-310-755-3108
Contact:	Ruey-Kang Chang (rk.chang@qtmedical.com)

5.4 Identification of the Device:

Proprietary/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:	Smartheart
Manufacturer:	SHL Telemedicine International Ltd.
Classification Product Code:	DXH
Regulation number:	870.2920
Device Class:	II
510(k) Number:	K113514

5.6 Identification of the Reference Device:

Predicate Device Name:	PageWriter TC70
Manufacturer:	Philips Medical Systems International BV
Classification Product Code:	DPS
Regulation number:	870.2340
Device Class:	II
510(k) Number:	K113144

5.7 Indications for Use / Intended 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 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.

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 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.

5.8 Device Description

The ***QT ECG*** system is a hand-held, cordless 12-lead electrocardiograph (ECG)

system with Bluetooth connectivity. The ***QT ECG*** system consists of 5 major components when using:

- 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. Once an ECG recording is done, the data is auto uploaded to the cloud for analysis.
- Analysis – The analysis module provides ECG measurement from the collected data.
- 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 adults and pediatric 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.

5.9 Non-clinical Testing

A series of safety and performance tests 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
- Electromagnetic compatibility and electrical safety
  - Electrical Safety Test
  - EMC Test
  - Electrical Safety in Home Healthcare Environment
  - Safety and Essential Performance of Electrocardiographs
  - Battery Safety Test
- Performance & Shelf life

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

The list of standards that claim compliance:

Testing Item	FDA recognition number	Standards and regulations applied
Bio-compatibility	2-220	ISO 10993-1: 2009, Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process [Including: Technical Corrigendum 1 (2010)]
	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.
	2-153	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.
	2-198	ANSI/AAMI/ISO 10993-12:2012, Biological Evaluation Of Medical Devices - Part 12: Sample Preparation And Reference

		Materials.
Software	13-79	IEC 62304:2006+AMD1:2015, Medical device software - Software life cycle processes.
	5-40	ISO 14971:2007, Medical devices - Application of risk management to medical devices.
	3-105	IEC 60601-2-25:2011, Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs.
Electromagnetic Compatibility and Electrical Safety	—	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
	—	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 & Shelf life	3-52	ANSI/AAMI EC12:2000/(R)2010, Disposable ECG electrodes.

5.10 Clinical and Usability Testing

Three Clinical and Usability Tests have been conducted on the subject device.

Study One is a clinical study that to present the equivalence of QT ECG to the reference device, Philips PageWriter ECG system. In conclusion, we achieved both objectives, reached the pre-determined acceptance criteria for electrode fit of 90% or more of the unselected population aged 18 to 75 years old, and 90% or higher rate of equivalence in clinical interpretation from patients aged 18 to 75 years old between Philips PageWriter and QT ECG in this study.

Study Two & Three are human factor and usability studies that conducted to test the Human Factor and Usability of QT ECG used by laypeople in home environments/ non-healthcare environment, and conducted with healthcare workers who have experience working at non-acute healthcare facilities to validate its use with nursing home staff respectively. In conclusion, we achieved the objectives in this study, and addressed all the human factor and usability issues identified.

5.11 Substantial Equivalence Determination

The QT ECG submitted in this 510(k) file is substantially equivalent in intended use, technology/mechanism of action, safety and performance to the cleared device, Smartheart (K113514). Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

Item	Subject device	Predicate device	Substantial equivalence determination
Manufacturer	QT Medical, Inc.	SHL Telemedicine International, Ltd.	
Trade Name	QT ECG	Smartheart	

510(k) No.	K180157	K113514	
Product Code	DXH	DXH	***Identical***
Regulation Number	870.2920	870.2920	***Identical***
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 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	The ***Smartheart*** device 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 ***Smartheart*** device is designed to be used by a patient to transmit a 12 lead EGG and rhythm strip in real-time to enable review at a physician's office, hospital or other medical receiving center.	***Equivalent*** The ***QT ECG*** System differs in that it specifies patient types as recommended in FDA Class II Special Controls Guidance Document: Electrocardiograph Electrodes (July 21, 2011). The intended patient population is similar to that of the predicate. QT ECG's intended users include patients themselves, and other laypersons with similar backgrounds as the adult patients that use the Smartheart. Other differences in wording are for clarification and convey the same meaning. The differences in indications for use do not change the intended use of the device to acquire and transmit 12-lead ECG signals from
Indications for Use	center. 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.		patients in the home.
	For the device features		
Mechanism of Action	The ECG signals are acquired via the QT ECG Electrode Strip attached to the patient. The Electrode Strip then transfers the ECG signals to the QT ECG Recorder that it is plugged into. Then, the Recorder sends the ECG data via Bluetooth to the App for display. The analysis module provides ECG measurement from the collected data. Using an algorithm to detect the positions of feature points such as P, Q, R, S, T. Then, calculate the eight measurements according to their definitions. And then, transmit the data to a physician's office, hospital or other medical receiving center	Electrode belt and recorder are applied to patient. ECG is acquired and transmitted to a mobile device using Bluetooth. Mobile application running on the device displays the ECG signal and transmits it to a remote location for subsequent clinician assessment.	***Equivalent*** There are no significant differences in the mechanism of action for both devices.

	for review.		
Technology Overview	• The QT ECG Electrode Strip with 10 electrode contacts (chest/right and left arm/left lower belly), 4 sizes available • Handheld, battery powered recorder • Records 12-lead ECG • Bluetooth data transmission • Mobile Application running on mobile device	• Electrode belt with 16 electrode contacts (belt chest/housing chest), 1 belt size with small - extra-large sizing • Waist (square) and right arm (round) electrodes with leadwire • Handheld, battery powered recorder • Records 12-lead ECG • Bluetooth data transmission • Mobile Application running on mobile device	***Equivalent*** Both devices use electrode components with pre-placed electrodes, Bluetooth transmission and a mobile device. They have similar technology to acquire, record and transmit the ECG signal.
User Interface	• Recorder – on/off button, status LEDs • Electrode Strip (4 sizes available: S, M, L, XL) • Right arm (RA), left arm (LA) and left lower belly (LL) • Mobile Device running the QT ECG App	• Recorder – on/off button, heart shaped indicator light • Electrode Belt (adjustable to 4 chest sizes: S, M, L, XL) • Right arm (RA), left arm (LA) and waist electrodes (LL) • Mobile Device running Smartheart mobile application	***Equivalent*** Both devices include a recorder with attached electrode. Both devices interface with a mobile device running a mobile application. QT ECG includes RA, LA and LL electrodes as part of the electrode strip whereas the Smartheart has separate wires that connect these electrodes to the recorder. It does not affect the safety and performance.
Anatomical Location	Chest, arm and lower belly	Chest, armpit and waist	***Equivalent*** Both devices align

			electrodes over standard ECG acquisition sites RA, LA, LL, V1 – V6
For the specifications			
Sterile	No	No	***Identical***
Single-Use	No (recorder) Yes (electrode)	No (recorder and electrode)	***Equivalent*** Both recorders can be used multiple times per patient or with multiple patients, with cleaning between each use. The Smartheart electrode belt can also be cleaned and used multiple times and by multiple users. The QT ECG System uses a single-use disposable electrode that is not cleaned between uses.
Record Time	10 seconds	30 seconds	***Equivalent*** Both devices have sufficient record time. In general, 10 seconds is sufficient for ECG diagnosis, and the subject device meets the performance requirements.
Recorder Input Impedance	6.875MΩ	Meets IEC 60601-2-25: 2011 which means at least 2.5MΩ	***Equivalent*** Both devices meet standards for input impedance. The QT ECG has a higher input impedance; thus it may

			have better ability to drive the whole circuit and to resist environmental interference.
Recorder Amplifier	CMRR: 97db min	CMRR: 80db min	***Equivalent*** Both devices sufficiently reject common mode signal.
	Frequency response: 0.05~150Hz	Frequency response: 0.05~150Hz	***Identical***
Recorder ECG Data Transmission	10 seconds of continuous rhythm strip (lead II); 2.5 seconds of leads: I, II, V1, V2, V3, V4, V5, V6. III, AVR, AVL and AVF are calculated at the receiver	12 seconds of continuous rhythm strip (lead II); 2.5 seconds of leads: I, II, V1, V2, V3, V4, V5, V6.III, AVR, AVL and AVF are calculated at the receiver	***Equivalent*** Both devices acquire sufficient amount of rhythm strip and diagnostic leads.
Recorder Calibration	Automatic – on power on, 2mVp-p 2Hz Square wave	Automatic – on power on, 2mVp-p 2Hz Square wave	***Identical***
Recorder Current Drain	Transmission: 180 mA max. Shutdown mode: < 1μA. Idle mode: 40mA typical	Transmission: 180 mA max. Shutdown mode: < 1μA. Idle mode: 40mA typical	***Identical***
Recorder Bluetooth (for ECG data transmit)	Class II	Class II	***Identical***
Recorder Battery	Rechargeable lithium battery (3.7 V)	AAA lithium (1.5 V) batteries	***Equivalent*** Both devices run on battery during operation. QT ECG' battery meets the requirement of IEC 62133.
Recorder	17 hours of continuous	6 hours of continuous	***Equivalent***

Battery Operating Time	recording and transmission 24 hours of normal use (use: standby = 1:5) with new battery	recording and transmission	Both devices have more battery time than needed to record an ECG.
Recorder AC Power	Battery charger can be connected (not during recording) Output: 5V, 1A Input 90 - 264 Vrms, 47~63 Hz	Not used	***Equivalent*** QT ECG passed the test of electrical safety; therefore, the difference would not affect the safety and performance.
Recorder Battery charging time (typical)	1.5 hour	Not applicable	***Equivalent*** QT ECG meets the requirements of IEC 60601-1 & IEC 62133; therefore, the difference would not affect the safety and performance.
Type of protection against electrical shock	Type: CF, non-defibrillator proof	Type: CF, non-defibrillator proof	***Identical***
Recorder Storage temperature	-20ºC~40ºC	-25ºC~70ºC	***Equivalent*** Narrowed storage temperature range eliminates the risk to the device integrity from lithium-ion battery. Thus, the subject device is safe as the predicate.
Electrode Strip Storage temperature	5 ºC ~27 ºC	-25ºC~70ºC	***Equivalent*** The storage range of QT ECG electrode strip is

			smaller, but the difference would not affect the safety and performance.
Storage relative humidity	10% – 93% Non-condensing	10% – 93% Non-condensing	***Identical***
Storage atmospheric pressure	700 hPa – 1060 hPa	700 hPa – 1060 hPa	***Identical***
Operating temperature	5~40°C	5~40°C	***Identical***
Operating relative humidity	15% – 93% Non-condensing	15% – 93% Non-condensing	***Identical***
Operating atmospheric pressure	700 hPa – 1060 hPa	700 hPa – 1060 hPa	***Identical***
Recorder Physical Dimension	72.00 x 68.02 x 18.60 (mm)	110 x 85 x 15 (mm)	***Equivalent*** Both devices are small, hand-held sizes. The difference would not affect the safety and performance.
Recorder Weight	67g (with battery)	110g (without batteries)	***Equivalent*** Both devices are small and light weight; the difference would not affect the safety and performance.
Electrical Safety Testing Passed	IEC 60601-1:2005+ CORR.1:2006+ CORR. 2:2007 + A1:2012 ANSI/AAMI ES60601-1: 2005 / A2:2010	EN 60601-1:2006 EN 60601-1-2:2007 EN 60601-1-11:2010 IEC 60601-2-25:2011	***Equivalent*** The QT ECG meets current versions of standards.

	IEC 60601-1-2:2014 IEC 60601-1-11:2015 IEC 60601-2-25:2011		
Mobile application	Compatibility: iOS 10 or later; Android 5.0 or later.	Compatibility: iOS 6.0 or later; Android	***Equivalent*** Both devices work on commonly available mobile technology.
Mobile device	The app works on Phone: iPhone 6 iPhone 6 Plus iPhone 6s iPhone 6s Plus iPhone 7 iPhone 7 Plus Google Pixel Samsung Galaxy A7 LG G5 on Tablet: 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	The app works on both iOS and Android devices: iPhone 3Gs, iPhone 4, iPhone 4s, iPhone 5, iPhone 5s, iPhone 6, Samsung Galaxy S II, Samsung Galaxy S, Samsung Galaxy S III, Samsung Galaxy S4, Samsung Galaxy S5, Samsung Galaxy Ace, Samsung Galaxy Ace 2, Samsung Galaxy Note, Samsung Galaxy Note II, Samsung Galaxy Note III, Samsung Galaxy Nexus, S.Galaxy S III Mini, Samsung Galaxy W, LG Optimus 4X HD, LG Optimus L7, LG Optimus Black, LG Optimus Sol, LG Optimus Sol , LG Prada 3.0 , LG Optimus 2X ,	***Equivalent*** Both devices work on commonly available mobile technology.

		LG Google Nexus 4 , LG Optimus 2X , Motorola Defy Plus , Motorola Defy , Motorola RAZR XT910 , Motorola Atrix 2 , Motorola Atrix 4G , Motorola MILESTONE , HTC ONE X , HTC One S , HTC One V , HTC Desire C , HTC Sensation XL , HTC Sensation XE, HTC Desire, HTC Incredible S , HTC Sensation , HTC Desire V , HTC EVO 3D , HTC Desire S , HTC Desire HD , Sony Xperia Sola , Sony Xperia P , Sony Xperia U , Sony Xperia S , Sony Xperia Go , Sony Xperia PLAY , Sony Xperia Neo L , Sony XPERIA X10 , Sony Xperia Neo V , Sony Xperia Neo , Sony XPERIA ARC	

5.12 Similarity and Difference

The QT ECG has been compared with "Smartheart". The subject device has same intended use, technology/mechanism of action, safety and performance as the predicate device. Although there are some specifications that are different between two devices, the software validation, performance test and clinical/usability studies 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 undergone 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.

5.13 Conclusion

After analyzing non-clinical laboratory studies, clinical trials and safety testing data, it can be concluded that the QT ECG is substantially equivalent to the predicate device.