June 3, 2021

QT Medical, Inc.
Ruey-Kang Chang
CEO
1360 Valley Vista Dr., Suite 203
Diamond Bar, California 91765

Re: K200722
Trade/Device Name: PCA-C1 series Patient Cable
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer And Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: May 19, 2021
Received: June 1, 2021

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. 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,

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)*
K200722

Device Name
PCA-C100 Patient Cable

Indications for Use *(Describe)*
PCA-C100 Patient Cable is intended to be used with QT ECG device. The Patient Cable is used to connect electrodes placed at appropriate sites on the patient to an ECG device for general diagnostic evaluation by 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.

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510(k) Summary

510(k) SUMMARY

5.1 Type of Submission: Traditional 510(k)

5.2 Date of Summary: 02/20/2020

5.3 Submitter: QT Medical, Inc.

Address:	1360 Valley Vista Dr., Suite 203, Diamond Bar, CA 91765, USA
Phone:	+1 909 323 0007
Fax:	+1 310 755 3108
Contact:	Ruey-Kang Chang (rk.chang@qtmedical.com)

5.4 Identification of the Device:

Proprietary/Trade name:	PCA-C100 Patient Cable
Classification Product Code:	DSA
Regulation Number:	870.2900
Regulation Description:	Patient transducer and electrode cable (including connector).
Review Panel:	Cardiovascular
Device Class:	II

5.5 Identification of the Predicate Device:

Predicate Device Name:	Cable / lead-wire
Manufacturer:	Shenzhen Med-link Electronics Tech Co., Ltd.
Classification Product Code:	DSA
Regulation number:	870.2900
Device Class:	II
510(k) Number:	k120010

5.6 Indications for Use of the Device

Indication for Use:

PCA-C100 Patient Cable is intended to be used with QT ECG device. The Patient Cable is used to connect electrodes placed at appropriate sites on the patient to an ECG device for general diagnostic evaluation by healthcare professionals.

5.7 Device Description

The PCA-C100 Patient Cable is a reusable ECG patient cable that is used to transmit cardiac electrical signals (ECG) from electrodes, which are affixed to the patient's body for both diagnostic purposes.

The PCA-C100 Patient Cable is a crucial part of the system used diagnose the cardiac electrical signal (ECG). It allows a safe connection between the electrodes on the patient and QT ECG (K180157).

The PCA-C100 Patient Cable is composed of three components:

- Snap - Connected with Leadwire and commercial ECG electrode.
- Leadwire - fitted with Trunk, and connected with ten Snaps.
- Trunk - Fitted with two ends:
  - one of them connects the QT ECG (K180157); and
  - the other end connects the Leadwires.

5.8 Non-clinical Testing

A series of safety and performance tests were conducted on the subject device, PCA-C100 Patient Cable.

- **Biocompatibility**
  - In Vitro Cytotoxicity Test
  - White Rabbit Skin Irritation Test
  - Skin Sensitization Study (Maximization Test)
- **Electromagnetic compatibility and electrical safety tests**
  - Electrical Safty Test
    - ANSI AAMI EC53:2013
      ECG Trunk Cables And Patient Leadwires
    - ANSI AAMI 60601-1: ES60601-1:2005/(R)2012 And A1:2012
      C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)
  - Safety and Essential Performance of Electrocardiographs
- **Leadwires to trunk cable interconnection**
  - ANSI AAMI EC53:2013, ECG Trunk Cables And Patient Leadwires

- **Performance & Shelf life**

  - Shelf life testing is not applicable since the PCA-C100 Patient Cable is reusable.

  - Performance testing - Bench was conducted on the PCA-C100 Patient Cable according with established protocols and test results confirm that the final product met the requirements for the safety and performance standards and it's intended use.

  - Performance testing – Clinical is not required and was not performed to demonstrate safty and effectiveness of PCA-C100 Patient Cable.

  - Performance testing – Animal is not required and was not performed to demonstrate safty and effectiveness of PCA-C100 Patient Cable.

All the test results demonstrate PCA-C100 Patient Cable meets the requirements of its predefined acceptance criteria and intended use, and is substantially equivalent to the predicate device.

5.9 Substantial Equivalence Determination

The PCA-C100 Patient Cable submitted in this 510(k) file is substantially equivalent in intended use, technology/mechanism of action, safety and performance to the cleared device, Cable / lead-wire (K120010). Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

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Item	Subject device	Predicate device	Substantial equivalence determination
Manufacturer	QT Medical, Inc.	Shenzhen Med-link Electronics Tech Co., Ltd.	
Trade Name	QT ECG	Cable / lead-wire	
Common Name	Cable / lead-wire	Cable / lead-wire	
Device Model	PCA-C100	VA018BCA	
510(k) No.	(to be assigned)	K120010	
Product Code	DSA	DSA	***Identical***
Regulation Number	870.2900	870.2900	***Identical***

Item	Subject Device	Predicate device	Substantial equivalence determination
Indications for Use	PCA-C100 Patient Cable is intended to be used with QT ECG device. The Patient Cable is used to connect electrodes placed at appropriate sites on the patient to an ECG device for general diagnostic evaluation by healthcare professionals.	The **Shenzhen Med-link Cable / lead-wire** are intended to be used with ECG, EKG, Sp02 and Invasive Blood Pressure monitoring devices. The Cable / lead-wire are used to connect electrodes, catheters, and/or sensors placed at appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by healthcare professional.	***Equivalent*** PCA-C100 Patient Cable is used with a specified ECG device (QT ECG) and can not be used with a defibrillator. The predicate has various types connect to various devices, like ECG, EKG, and Spo2 and invasive blood pressure monitoring devices. The differences in indications for use do not change the device's intended use to connect electrodes placed at appropriate sites on the patient to a general diagnostic evaluation device by healthcare professionals.
Patent Usage	Reusable	Reusable	***Identical***
Anatomical Site	The ECG cable attached to sensors places at standard specified locations on the chest wall.	The ECG and EKG cable attached to sensors places at standard specified locations on the chest wall.	***Identical***
Design / Appearance	ECG and EKG Cable with connector (lead wire, electrode snapper)	ECG and EKG Cables with various connectors (monitor, truck / lead wire, electrode grabber & snapper)	***Equivalent*** PCA-C100 Patient Cable differs in that it has only one type to connect a specified device (QT ECG), and only one type (snapper) to connect with electrodes.

Item	Subject Device	Predicate device	Substantial equivalence determination
Cable Length	550mm (limb lead) 350mm (chest lead)	Various specified 3060mm (model:VA008BBA)	***Equivalent*** Since the main device (QT ECG) is closer to the patient, the cable length is shorter than the predicate device. Both devices provide adequate length to connect with the main device and electrode.
Wire Material	Shielded & Unshielded Copper with TPU Jacket	Shielded & Unshielded Copper with PVC or TPU Jacket	***Identical***
Sterility	Non sterile	Non sterile	***Identical***
Biocompatibility Evaluation	All the patient contracting materials are evaluated by the biocompatibility standard ISO 10993-5, ISO 10993-10	All the patient contracting materials are evaluated by the biocompatibility standard ISO 10993-5, ISO 10993-10	***Identical***
Connector Retention Force	ANSI/AAMI EC 53:2013	ANSI/AAMI EC 53:1995 / (R) 2001	***Identical***
Performance and Safety	ANSI/AAMI EC 53:2013 and IEC 60601-1:2005 + A1:2012	ANSI/AAMI EC 53:1995 / (R) 2001 and IEC 60601-1:1998; AM1; A2:1995	***Identical***

5.10 Similarity and Difference

The PCA-C100 Patient Cable has been compared with "Cable/Lead-Wire ". The subject device has the 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 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 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.

5.11 Conclusion

In conclusion, QT Medical, Inc. believes that PCA-C100 Patient Cable is as safe and as effective as the predicate, and thus, is substantially equivalent to the predicate device.