



September 29, 2026

QT Medical, Inc.
Irving Yu
Principle Engineer
1370 Valley Vista Dr. Suite 266
Diamond Bar, California 91765

Re: K260250

Trade/Device Name: QCA 10 Electrocardiograph (QCARD-10); QCA 10W Electrocardiograph (QCARD-10W)

Regulation Number: 21 CFR 870.2340

Regulation Name: Electrocardiograph

Regulatory Class: Class II

Product Code: DPS, DSA

Dated: August 30, 2026

Received: August 31, 2026

Dear Irving Yu:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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 Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K260250

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Please provide the device trade name(s).

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QCA 10 Electrocardiograph (QCARD-10);
QCA 10W Electrocardiograph (QCARD-10W)

Please provide your Indications for Use below.

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The QCA 10/10W ECG System is a non-invasive prescription medical device intended for use by trained healthcare professionals in clinical settings (e.g., hospitals, medical clinics, physician offices). The device is intended to acquire, record, display, analyze, store, and print 12-lead ECG signals from both adult and pediatric patients (pediatric: >1 month to 21 years of age). The analysis function provides basic automated ECG measurements.

The device is not intended for use as a vital signs physiological monitor.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	QT Medical Inc.
Applicant Address	1370 Valley Vista Dr Ste 266, Diamond Bar, CA 91765, USA Diamond Bar CA 91765 United States
Applicant Contact Telephone	+886-2-23957378
Applicant Contact	Dr. Irving Yu
Applicant Contact Email	lp.yu@qtmedical.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	QCA 10 Electrocardiograph (QCARD-10); QCA 10W Electrocardiograph (QCARD-10W)
Common Name	Electrocardiograph
Classification Name	Electrocardiograph
Regulation Number	870.2340
Product Code(s)	DPS, DSA (CLASS 2) - CABLE, TRANSDUCER AND ELECTRODE, PAT

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K120865	RScribe Electrocardiograph	DPS

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

Purpose and Use: Non-invasive, prescription 12-lead resting ECG for trained professionals, using 10 electrodes to capture and transmit cardiac signals to a Windows app in real time. # Signal Processing: Uses biopotential sensing and DSP algorithms for noise removal and automated ECG measurements based on Global Fiducial Points, with hardware pacemaker detection. # Design and Performance: Compact, IP66-rated, Class II, Type CF device with 1000 Hz sampling, 0.05–150 Hz bandwidth, and the ability to withstand 360 J defibrillator shocks and auto-recover within 5 seconds. # Clinical Use Conditions: For use in hospitals, clinics, and physician offices; not intended for home use or for use during patient transport. The patient lies supine with Ag/AgCl electrodes placed on the limbs and chest. The QCA 10 connects to a PC via USB, while the QCA 10W connects via Bluetooth with the aid of a USB dongle. # Safety and Interface: MR Unsafe and not for use near high-frequency surgical equipment; operated via a side button and Windows-based graphical interface for data entry and reporting.
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Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The QCA 10/10W ECG System is a non-invasive prescription medical device intended for use by trained healthcare professionals in clinical settings (e.g., hospitals, medical clinics, physician offices). The device is intended to acquire, record, display, analyze, store, and print 12-lead ECG signals from both adult and pediatric patients (pediatric: >1 month to 21 years of age). The analysis function provides basic automated ECG measurements.

The device is not intended for use as a vital signs physiological monitor.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The subject and predicate devices have the same medical purpose or function (the core of intended use): to acquire, record, display, analyze, and print 12-lead resting electrocardiograms (ECG) for adult and pediatric populations. Both devices are prescription-only, intended for use by trained healthcare professionals in professional healthcare facilities, and are not intended for vital signs monitoring. The differences in the indications for use do not constitute the intended diagnostic purpose of the device. Specifically:

- ECG Interpretation: The predicate device provides automated ECG interpretation for physician consideration. The subject device provides automated ECG measurements (e.g., intervals, amplitudes) but does not offer automated diagnostic interpretation text. The absence of the interpretation feature reduces the complexity of the software and relies on the physician's review of the waveforms and measurements, which remains the standard of care. This difference does not constitute a new intended use.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The subject device, QCA 10/10W, shares the same fundamental scientific technology and operating principles as the predicate device, the RSCRIBE (K120865). Both are PC-based diagnostic 12-lead electrocardiographs operating on a Windows platform, utilizing either a wired (USB) or wireless acquisition module to transmit patient signals.

Minor differences in technological characteristics exist but do not raise different questions of safety and effectiveness:

- Wireless Technology: The predicate uses a proprietary RF protocol, while the subject device (QCA 10W) utilizes standard Bluetooth 5.0 technology. The subject device has undergone wireless coexistence and performance testing (ANSI C63.27) to demonstrate reliable data transmission comparable to the predicate.

- Signal Processing (Pacemaker Detection): The predicate employs digital sampling for pacemaker detection, whereas the subject device utilizes a dedicated analog pulse detector. Both methods are verified to meet the performance requirements of IEC 60601-2-25.

- Filtering Algorithms: The subject device employs a digital baseline removal algorithm, whereas the predicate uses a traditional high-pass filter. Performance testing confirms that the subject device's algorithm meets the distortion and signal fidelity requirements of IEC 60601-2-25, ensuring equivalent diagnostic quality.

- System Integration: The subject device is designed for local storage and PDF export, whereas the predicate supports direct integration with Hospital Information Systems (HIS). This difference in connectivity features does not impact the device's ability to acquire or display accurate ECG data.

Verification and validation activities—including electrical safety (IEC 60601-1), EMC (IEC 60601-1-2, including IEC 60601-4-2), ANSI/AAMI C63.27 wireless coexistence, ANSI/AAMI EC53 ECG trunk cables and patient leadwires, particular performance (IEC 60601-2-25), and conformity with IEC 62304 and IEC 62366-1 — demonstrate that the subject device is as safe and effective as the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Non-Clinical Tests Summary

A summative usability validation study was conducted in accordance with IEC 62366-1. The results demonstrated that the device can be used safely and effectively by the intended users, for the intended uses, and in the intended use environments. The device was also tested and found to conform to the consensus standards identified in the submission, including IEC 60601-1, IEC 60601-1-2, IEC TS 60601-4-2, IEC 60601-1-12, IEC 60601-2-25, AAMI EC53, IEC 62133-2, ANSI C63.27, and ISO 10993-1. The device software was developed in accordance with IEC 62304.

Conclusions

The results of the non-clinical testing demonstrate that the QCA 10 Electrocardiograph (QCARD-10) and QCA 10W Electrocardiograph (QCARD-10W) are as safe, as effective, and perform as well as the predicate device, the RSCRIBE Electrocardiograph (K120865). The differences in technological characteristics do not raise different questions of safety and effectiveness. Therefore, the subject devices are substantially equivalent to the predicate device.