August 2, 2022

Quanta Computer Inc.
Vivian Yang
Regulatory Affairs Specialist
No. 188, Wenhua 2nd Road, Guishan District
Taoyuan City, 33377
Taiwan

Re: K210179
Trade/Device Name: QOCA Portable ECG Monitoring Device
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH
Dated: June 27, 2022
Received: July 1, 2022

Dear Vivian Yang:

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)*

Device Name
QOCA Portable ECG Monitoring Device

Indications for Use *(Describe)*
The QOCA Portable ECG Monitoring Device is intended to capture continuous electrocardiogram (ECG) information for long-term (up to 14 days). It is indicated for use on adult patients 21 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. ECG and heart rate data are stored in the device for later viewing 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

5.1 General Information

Applicant:	Quanta Computer Inc.
Address	No. 188, Wenhua 2nd Rd., Guishan Dist., Taoyuan City 33377, Taiwan (R.O.C)
Contact Person:	Vivian Yang
Contact Information:	vivian.yang@quantatw.com +886-3327-2345 ext. 12928
Date Prepared:	January 19, 2021

5.2 Device Information

Trade Name:	QOCA Portable ECG Monitoring Device
Common Name:	Ambulatory ECG Device
Classification Name:	Recorder, Magnetic Tape, Medical
Regulation Number:	870.2800
Product Code:	DSH, DXH

5.3 Predicate Device

Trade Name:	ZIO® SkyRunner (SR) Electrocardiogram (ECG) Monitoring Service
Premarket Notification:	K143513
Classification Name:	Recorder, Magnetic Tape, Medical
Regulation Number:	870.2800
Product Code:	DSH, DQK, DXH

5.4 Device Description

The QOCA Portable ECG Monitoring Device consists of 3 parts: a rechargeable and re-usable ECG sensor with Bluetooth technology, a single-use electrode and hydrogel patch, and an optional mobile platform app (QOCA ecg App).

The QOCA Portable ECG Monitoring Device provides a continuous, single-channel recording for up to 14 days. The QOCA Portable ECG Monitoring Device records ECG without patient interaction, and patients have the option of pressing the power button on the ECG sensor to trigger an event record. Patients can also choose to use the QOCA Portable ECG Monitoring Device along with a mobile platform app so that the event trigger

can be triggered with the App and the data can be transmitted via BLE from the ECG sensor to the mobile platform for display.

The subject device provides operational alarms such as lead off detection and battery monitoring. The operational alarms display on both the sensor and QOCA ecg App to inform the patient of the operation status of the sensor. The subject device does not provide any alarms based on physiological data setting.

After the recording period (up to 14 days) ends, the patient returns to his/her healthcare provider, and the data stored in the sensor can be transferred to the computer by connecting with a USB cable and viewed with QOCA ecg Reader, a non-device MDDS for displaying data.

The device is intended to be used on general care patients who are 21 years of age or older. This device is solely intended for manual interpretation of the recorded ECG and heart rate detection using the integrated software. The ECG signal recorded by this device is not intended for automated analysis. This device is not intended to be used for real-time and/or continuous patient monitoring.

5.5 Indications for Use

The QOCA Portable ECG Monitoring Device is intended to capture continuous electrocardiogram (ECG) information for long-term (up to 14 days). It is indicated for use on adult patients 21 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. ECG and heart rate data are stored in the device for later viewing by healthcare professionals.

5.6 Comparison of Physical and Technological Characteristics with the Predicate Device

	Predicate device	Subject device
Product Name	Zio SkyRunner(SR) Electrocardiogram (ECG) Monitoring Service	QOCA Portable ECG Monitoring Device
K number	K143513	
Indications for Use	The Zio SR ECG Monitoring Service is intended to capture, analyze, and report symptomatic and/or	The QOCA Portable ECG Monitoring Device is intended to capture continuous electrocardiogram (ECG)

	continuous electrocardiogram (ECG) information for long-term (up to 14 days). It is indicated for use on adult patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. The reported ECG metrics include single-lead analysis on a beat by beat basis, heart rate measurement and rhythm analysis. The report does not contain diagnostic interpretation; the reported analysis is provided for review by the intended user to render a diagnosis based on clinical judgement and experience.	information for long-term (up to 14 days). It is indicated for use on adult patients 21 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. ECG and heart rate data are stored in the device for later viewing by healthcare professionals.
Product Code	DSH, DQK, DXH	DSH, DXH
Intended Users	Healthcare Professionals	Identical
Patient Populations	General care, non-pediatric	General care adult patient (21 years of age or older)
Environment	Ambulatory	Identical
Placement	Left upper chest	Identical
Reuse or single use	Single-use	Reusable ECG device and Single-use body patch
Duration	14 days	Up to 14 days
Size	Device: 132*51*14 mm	Device: 35*35*8.85 mm

	Weight: 24.7g	Patch: 130*81.8*1.2 mm Weight: 19.5 g
Signal Transmission	BLE to gateway	BLE to mobile platform
Operating Temperature	5~40℃	5~45℃
IP rating	IPX4	IP26
Electrical Safety	Conformed to IEC 60601-1	Identical
EMC	Conformed to IEC 60601-1-2	Identical
Biocompatibility	Conformed to ISO 10993-1	Identical
Performance	Conformed to IEC 60601-2-47	Identical

5.7 Summary of Performance Data

Quanta Computer Inc. (Quanta Computer) follows the requirement in 21 CFR 820.30 Design Controls and completed bench testing, biocompatibility, packaging testing, shelf life, and electromagnetic compatibility testing were conducted to assure the performance and safety of the subject device. These tests were performed in accordance with the following FDA recognized standards:

- ISO 10993-1 5th Edition 2018-08, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-5 3rd Edition 2009-06-01, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 3rd Edition 2010-08-01, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- ANSI AAMI EC12: 2000/(R)2015, Disposable ECG electrodes
- ANSI AAMI 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)
- IEC 60601-1-2 Ed. 4.0 2014-02, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
- IEC 60601-1-11 Ed. 2.0 2015-01, 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

- IEC 60601-2-47 Ed. 2.0 2012-02, Medical electrical equipment – Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
- ANSI IEEE C63.27-2017 American National Standard for Evaluation of Wireless Coexistence
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION, Medical device software – Software life cycle processes

5.8 Conclusion

Based on the comparison of physical and technical characteristics and the performance data, the subject device is as safe and effective as the predicate device. While the subject device does not provide an analysis report, it presents the complete recorded data for the healthcare professional to review, and this difference does not affect the safety or effectiveness. In conclusion, the subject device, QOCA Portable ECG Monitoring Device, is substantially equivalent to the predicate device.