June 28, 2022

Medicalgorithmics S.A.
% Agnieszka Romowicz
Product Compliance Manager
Medicalgorithmics US Holding Corporation
Corporation Service Company
251 Little Falls Drive
Wilmington, Delaware 19808

Re: K210758
Trade/Device Name: Q Patch
Regulation Number: 21 CFR 870.2800
Regulation Name: Electrocardiograph, Ambulatory (Without Analysis)
Regulatory Class: Class II
Product Code: MWJ

Dear Agnieszka Romowicz:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 2, 2022. Specifically, FDA is updating the SE Letter correspondent contact information as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jennifer Shih Kozen, OHT2: Office of Cardiovascular Devices, (301) 796-5813, Jennifer.Shih@fda.hhs.gov.

Sincerely,

Jennifer W. Shih -S

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

June 2, 2022

Medicalgorithmics S.A.
% Przemyslaw Tadla
Operations & Product Compliance Director
Medicalgorithmics US Holding Corporation
Corporation Service Company
251 Little Falls Drive
Wilmington, Delaware 19808

Re: K210758
Trade/Device Name: Q Patch
Regulation Number: 21 CFR 870.2800
Regulation Name: Electrocardiograph, Ambulatory (Without Analysis)
Regulatory Class: Class II
Product Code: MWJ
Dated: April 29, 2022
Received: May 2, 2022

Dear Przemyslaw Tadla:

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 W. Shih -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210758

Device Name
Q Patch

Indications for Use *(Describe)*
The Medicalgorithmics' Q Patch is intended to be used by patients who have a demonstrated need for extended cardiac monitoring and patients with symptoms that may be due to cardiac arrhythmias such as, dizziness, lightheadedness, shortness of breath, palpitations, dyspnea (shortness of breath), anxiety, syncope of unknown etiology in which arrhythmias are suspected or need to be excluded. It is indicated for use on adult patients. The sensor records single ECG channel for up to 15 days and can be used on patients with implanted pacemakers but is not intended to record pacemaker activity.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

June 2, 2022

510(k) Summary

I. Submitter's name and address:

Medicalgorithmics S.A.	Aleje Jerozolimskie 81, 02-001 Warsaw, Poland
Contact Person:	Agnieszka Romowicz
Phone:	(+1) 302 2615184
Email:	a.romowicz@medicalgorithmics.com
Date Prepared:	2022-06-02

II. Device

Trade/Device name:	Q Patch
Type:	P5HP-AA-ADS
Regulation number:	21 CFR 870.2800
Regulation name:	Electrocardiograph, Ambulatory (Without Analysis)
Regulatory Class:	Class II
Product codes:	MWJ
Classification:	Electrocardiograph, Ambulatory (Without Analysis) - MWJ

III. Predicate Device

The selected predicate device is:

myPatch®sl, K163535

IV. Device description

The Q Patch is a single channel ECG recorder. The device is intended to be placed on the sternum (in the middle of the chest). The Q Patch ECG recorder snaps onto the two off-the-shelf electrodes (Solid gel, Ag/AgCl) and records patient's ECG for up to 15 days powered from single disposable, non-rechargeable battery. The Q Patch Mobile Application is used to initiate recording session, for checking Q Patch status and to finish/stop the session if needed. When the recording is finished, the ECG data stored in Q Patch's memory can be downloaded through a USB port using the Q Patch Downloader (PC application).

The product and it's accessories are intended to be used by:

- Patients: adults which may require long-term, continuous heart activity monitoring to possible cardiac arrhythmias. Patients use the Q Patch recorder and Q Patch Mobile Application operating in patient mode
- Professional users:
    - Healthcare professionals: physician or other qualified healthcare professionals (Nurses/RNs and Certified Medical Assistants (CMA/AAMA))
    - Technicians: electronic device maintenance staff

Professionals use the Q Patch recorder, Q Patch Mobile Application operating in professional mode and Q Patch Downloader.

Use environment includes Healthcare facilities, Home, Office, Car, Outside under proper clothing.

The Q Patch recorder is accompanied with following accessories:

- Q Patch Mobile Application (Mobile application) – The Q Patch Mobile Application is intended to be used for interacting with the Q Patch recorder for transmission patient data to set up ECG recording session and displaying the Q Patch's status. The application is obligatory for healthcare professionals and optional for patients.
- Q Patch Downloader (PC application) – The intended use of the Q Patch Downloader application is to download the ECG data stored in the Q Patch memory after recording session is completed and then to upload files containing ECG data to the predefined remote storage.

The device is powered from a lithium coin non-rechargeable battery type CR2032, rated 3V, 230mAh. Battery capacity is sufficient to provide power throughout entire ECG monitoring period (15-days). The battery should be replaced by technicians of monitoring center. The Q Patch is designed to be defibrillation safe device, meaning that the Q Patch does not impact the defibrillation procedure performance and does not introduce additional risk. However, the Q Patch is not defibrillation proof device

thus it may not function or recovery after patient defibrillation. The Q Patch defibrillation safe performance has been proved via laboratory testing.

Although ECG analysis and visualization software are not included in this product, Q Patch, Q Patch Mobile Application and Q Patch Downloader are designed to be integrated with third-party data analysis and visualization software.

The ECG recording can be transferred in an available file format and can be reviewed using software being a part of Unified Arrhythmia Diagnostic System PocketECG IV (K193104). The ECG data can be reviewed by healthcare professionals or ECG technicians trained in the identification and treatment of arrhythmia events. However, the subject device is not intended for automated analysis and then arrhythmia classification algorithm being a part of Unified Arrhythmia Diagnostic System PocketECG IV (K193104) system should not be used to produce beat annotations to be considered during patient diagnosis.

Potential patient cardiac abnormalities, must be confirmed by a qualified ECG technician or by a physician with other relevant clinical information. The Q Patch does not provide interpretive statements.

The performance and integration tests were carried out to prove performance of Q Patch operation with Unified Arrhythmia Diagnostic System PocketECG IV (K193104).

The Q Patch is not intended for patients who should be hospitalized, patients with potentially life-threatening arrhythmias who require inpatient monitoring such as primary ventricular fibrillation or sustained ventricular tachycardia and for individuals where asystole represents the terminal rhythm of a cardiac arrest.

V. Indications for use

The Medicalgorithmics' Q Patch is intended to be used by patients who have a demonstrated need for extended cardiac monitoring and patients with symptoms that may be due to cardiac arrhythmias such as, dizziness, lightheadedness, shortness of breath, palpitations, dyspnea (shortness of breath), anxiety, syncope of unknown etiology in which arrhythmias are suspected or need to be excluded. It is indicated for use on adult patients. The sensor records single ECG channel for up to 15 days and can be used on patients with implanted pacemakers but is not intended to record pacemaker activity.

The Indications for Use statement for the Q Patch device is not identical to the predicate device; however, the differences do not alter the intended use nor do they affect the safety and effectiveness of the device relative to the predicate.

VI. Technological comparison to predicate device

The intended use and technological features of the proposed Q Patch do not substantially differ from the legally marketed predicate device. Both devices are comprised of essentially identical configuration where the main component is a recorder. The operational characteristics are identical for the proposed and predicate device as they are both a small Holter recorders operated by professionals to acquire ECG data from a patient at a patient setting or wherever the patient may go. Both sensors are placed on the patient's sternum and record ECG signal continuously. The patient's ECG signal is managed similarly for both devices as it is recorded by the ECG recorder and at the end of recording can be downloaded through a USB port.

There are some differences between these two devices:

- The patient population indicated for the predicate device includes adults and all pediatric subgroups, whereas the pediatric use is restricted for the Q Patch. The subject device can be used in adults in the same way as the predicate device.
- The predicate device records ECG in 1 or 2 channel mode for up to 14 days or in 3 channel mode for up to 9 days. The subject device records ECG in one of these modes – single channel mode; for up to 15 days. Longer monitoring time is a minor difference and does not pose any additional risks and has no impact on the substantial equivalence of the product.
- The predicate sensor uses a rechargeable Li-Ion battery versus off the shelf, disposable, non-rechargeable lithium coin battery used in the subject device.
- When the recording is finished the ECG data stored in Q Patch's memory can be downloaded through a USB port using the Q Patch Downloader (PC application). While in the predicate device the patient's ECG is recorded to the device and then transferred via the USB data transfer cable to Holter analysis system (*which is not a part of predicate's 510(k)*)
- The subject device is also equipped with an additional application the Q Patch Mobile Application for interacting with the Q Patch recorder for transmission patient data to set up ECG recording session and displaying the Q Patch's status.

Differences between the predicate device and Q Patch are minor and have no impact on the substantial equivalence of the product. Descriptive characteristics and performance testing are used to demonstrate substantial equivalence. The 510(k) Premarket Notification demonstrates that the proposed Q Patch is substantially equivalent to the predicate device.

VII. Performance data

The following performance data were provided in support of the substantial equivalence determination.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Q Patch device. The Q Patch was designed and tested for compliance with the applicable clauses of the following standards:

- 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);
- ANSI AAMI HA60601-1-11:2015, Medical Electrical Equipment -- Part 1-11: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment (IEC 60601-1-11:2015 Mod);
- IEC 62304:2006/A1:2015, Medical Device Software — Software life cycle processes [Including Amendment 1 (2016)];
- ANSI AAMI IEC 60601-2-47:2012 /(R)2016, Medical Electrical Equipment -- Part 2-47: Particular Requirements For The Basic Safety And Essential Performance Of Ambulatory Electrocardiographic Systems;
- ANSI AAMI IEC 60601-1-2:2014, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests (Edition 4);

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005). The software for Q Patch device was considered a Moderate Level of Concern as a design flaw or failure could directly result in minor injury to the patient or operator. Both, Q Patch Mobile Application and The Q Patch Downloader (MDDS), are classified as Minor

Level of Concern, which means that potential failures or latent design flaws are unlikely to cause any injury to the patient or operator.

Usability Engineering

The following recommendations and requirements related to the Human Factors and Usability Engineering to Medical Devices were applied:

- The FDA Guidance for Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016)
- IEC 60601-1-6 Edition 3.1 2013-10, Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability;
- ANSI AAMI IEC 62366-1:2015, Medical devices - Part 1: Application of usability engineering to medical devices;

There was a total of 60 participants involved in the summative usability testing of the Q Patch recorder and accessories. The usability testing covers all aspects of the product including the Q Patch recorder, Q Patch Mobile Application, and Q Patch Downloader.

Biocompatibility

The biocompatibility evaluation for the Q Patch device was conducted in accordance with the FDA Guidance for Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (September 4, 2020), and International Standard ISO 10993-1 Fifth edition 2018-08 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. The Q Patch device is intended to direct skin contact up to 15 days, according to ISO 10993-1 is category B- prolonged time contact therefore the following requirements were found applicable:

- Cytotoxicity
- Sensitization
- Irritation

Performance tests

Tests which confirmed that the subject device, when used in conjunction with compatible electrodes, adequately adheres to the patient's skin throughout the wearing period were carried out. Study involving 18 participants, proved that the standard off-the-shelf Ag/AgCl electrodes when replaced regularly can be used with the Q Patch device to record ECG for up to 15 days.

Clinical study where ECG signals were recorded by the subject device and reference device simultaneously have been performed. The results of this analysis confirmed that there were no clinically significant differences in performance of the Q Patch against reference device. It has been demonstrated that non-standard ECG lead recorded by the Q Patch device is appropriate for ECG evaluation performed by the trained human interpreter. There were 30 participants involved in this study.

The subject device acquires ECG data and does not perform automatic arrhythmia analysis.

Summary

Based on the performance study results the Q Patch system was found to have a safety and effectiveness profile that is similar to the predicate device and reference devices.

VIII. Conclusion

The Q Patch, type P5HP-AA-ADS is substantially equivalent to the predicate device as supported by the descriptive information and the performance testing. The verification and validation of hardware and software demonstrate that the Q Patch devices perform as intended in the specified use conditions. The performance data demonstrate that the Q Patch device performs comparably to the predicate device that is currently marketed for the same intended use.