September 28, 2018

Qompium NV
% Patsy Trisler
Consultant
Qserve Group US Inc.
5600 Wisconsin Avenue
Chevy Chase, Maryland 20815

Re: K173872
Trade/Device Name: FibriCheck
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II
Product Code: DXH
Dated: August 19, 2018
Received: August 20, 2018

Dear Patsy Trisler:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Arielle Drummond -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173872

Device Name
FibriCheck

Indications for Use *(Describe)*
FibriCheck is indicated for self-testing by patients who have been diagnosed with, or are susceptible to developing, atrial fibrillation and who would like to monitor and record their heart rhythms on an intermittent basis.

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."

510(k) Summary

1. SUBMITTER

Submitter Name:	Qompium NV
Submitter Address:	Kempische Steenweg 311/27 3500 Hasselt, Belgium
Phone Number:	+32479393153
Contact Person:	Jo Van der Auwera
Date Prepared:	28 September 2018

2. DEVICE

Device Trade Name:	FibriCheck
Common Name:	Atrial Fibrillation Monitor
Classification Name, Number & Product Code: Class: Classification Panel:	Telephone electrocardiograph transmitter and receiver 21 CFR 870.2920 DXH II Cardiovascular

3. PREDICATE DEVICE

Primary Predicate Device:	K132206, Melys Atrial Fibrillation Monitor
Intended use:	The Melys Atrial Fibrillation Monitor is indicated for self-testing by patients, who have been diagnosed with, or are susceptible to developing, atrial fibrillation and who would like to monitor and record their heart rhythms on an intermittent basis.

The primary predicate device has not been subject to a design-related recall.

4. REFERENCE DEVICE

Reference Device:	K142743, AliveCor Heart Monitor
Intended use:	The AliveCor Heart Monitor is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The AliveCor Heart Monitor also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). The AliveCor Heart Monitor is intended for use by healthcare professionals, patients with known or suspected

heart conditions and health conscious individuals. The device has not been tested and it is not intended for pediatric use.

The reference device has not been subject to a design-related recall.

5. DEVICE DESCRIPTION

FibriCheck is medical device software that determines heart rhythm conditions, with a primarily focus on the detection of Atrial Fibrillation. It makes use of optical sensing from a mobile device to collect photoplethysmogram data (PPG data). The recordings can be shared optionally with a physician or monitoring service.

The FibriCheck web application, an online tool, has the sole intention to display data. Professional users can use the web application for managing patients and reviewing FibriCheck data.

6. INDICATIONS FOR USE

FibriCheck is indicated for self-testing by patients, who have been diagnosed with, or are susceptible to developing, atrial fibrillation and who would like to monitor and record their heart rhythms on an intermittent basis.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

	New Device	Primary Predicate Device	Reference Device
Device name	FibriCheck	Melys Atrial Fibrillation Monitor	Alivecor Heart Monitor
510(k) Number	K#	K132206	K142743
Manufacturer	Qompium	Advanced Fluidics, LLC	AliveCor, Inc.
Regulation Number	870.2920	870.2920	870.2920
Device Classification Name	Telephone electrocardiograph transmitter and receiver	Telephone electrocardiograph transmitter and receiver	Telephone electrocardiograph transmitter and receiver
Product Code	DXH	DXH	DXH, DPS
Intended Use/ Indications for use	FibriCheck is indicated for self-testing by patients, who have been diagnosed with, or are susceptible to developing, atrial fibrillation and who would like to monitor and record their heart rhythms on an intermittent basis.	The Melys Atrial Fibrillation Monitor is indicated for self-testing by patients, who have been diagnosed with, or are susceptible to developing, atrial fibrillation and who would like to monitor and record their heart rhythms on an intermittent basis.	The AliveCor Heart Monitor is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The AliveCor Heart Monitor also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). The AliveCor Heart Monitor is intended for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals. The device has not been tested and it is not intended for pediatric use.
Intended User	Adult	Adult	Adults
Prescription device for home Use	Yes	Yes	Yes
Single Patient Use	Yes	Yes	Yes
Monitors regularity of heartbeat	Yes	Yes	Yes

Alerts user to an irregularity in their pulse through a light indicator.	No, text indicator	Yes	No, text indicator
Principle of Operation	FibriCheck receives data from the Mobile Platform device, from which the waveform is directly created. The irregularity is indicated with a text indicator.	The monitor passes light through the fingertip sensor and receives data from which the waveform is directly created. Displays regularity or irregularity with a light indicator.	The device attaches to compatible smartphone or tablet and has electrodes to transmit ECG rhythms to the smartphone or tablet. Furthermore, the mobile app is used to collect, view, save, and wirelessly transmit recordings to the AliveCor server.
Device Design	FibriCheck obtains waveform via Mobile Platform camera and displays signal in real time on the Mobile Platform device with an arrhythmia index. Text display (green, amber, or blue) indicates heart regularity or irregularity. All tests are stored.	Monitor obtains waveform via finger sensor and displays waveform in real time on the monitor with an arrhythmia index. Light display (green, amber, or red) indicates heart regularity or irregularity. Last 8 tests are stored on the display by light indicator not Arrhythmia Index number.	The device utilizes the processing power of a mobile computing platform (MCP) while reducing the complexity of the electronics hardware associated with data acquisition and transmission. The AliveCor Heart Monitor can also analyze ECG signals and indicate the presence of noise, normal sinus rhythm and atrial fibrillation for each ECG recording.
Functional Features			
User programmable	No	No	No
Recording length	60 seconds	10 seconds (Recommended four (4) consecutive measurement should show same indication (red, amber or green) before a conclusion is drawn)	30 seconds to 5 minutes
Differences			
Data acquisition	PPG signal from the mobile computing platform (MCP)	Finger Sensor (K101692)	ECG signal from the mobile computing platform (MCP)

Table 5.1: Comparison of new device to predicate device

.

Equivalences:

The intended use is the same, and the technological characteristics are essentially the same, as those of the predicate, K132206, Melys Atrial Fibrillation Monitor. Both devices use Photoplethysmography (PPG) technique to detect blood volume changes and to determine heart rhythm.

Differences that are demonstrated to be substantially equivalent:

The most important difference with FibriCheck and Melys Atrial Fibrillation Monitor is that Melys Atrial Fibrillation Monitor uses Finger Sensor (K101692) for PPG signal acquisition and FibriCheck receives the PPG signal from the mobile computing platform (MCP). Furthermore, the predicate device is not a "mobile computing platform" device. However, recently FDA cleared several "mobile computing platform" devices which determine heart rhythm by using ECG technique (e.g. K142743 - reference device in this submission).

Performance testing was carried out to evaluate the diagnostic capability of FibriCheck compared to the reference device Kardia to assess the diagnostic accuracy of PPG versus single-lead ECG monitoring techniques to detection possible atrial fibrillation. The test results are available in the relevant sections of this 510(k) application. It is summarized below.

8. PERFORMANCE DATA

Non-Clinical testing	Validation and Verification Testing carried out on the FibriCheck indicates that it meets its predefined product's requirements and requirements from the following product standard: • AAMI/ANSI/IEC 62304:2006, Medical Device Software – Software Life Cycle Processes • ANSI/AAMI/IEC 60601-1-8:2006 and A1:2012 Medical Electrical Equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
Clinical Performance Testing	The clinical performance of FibriCheck was compared to the reference device Kardia (AliveCor) in a study where 223 subjects participated. In total 100/223 subjects suffered from atrial fibrillation. Both technologies were compared towards a gold-standard 12-lead ECG device. The diagnostic results yielded in a sensitivity/specificity/positive predictive value/negative predictive value and accuracy for FibriCheck of 95.60%/96.55%/95.60%/96.55%/96.14% and for Kardia 94.09%/97.47%/91.59%/89.53%/98%/95.09% This means that both methods have comparable diagnostic results.

Software Verification and Validation Testing	Validation testing involved algorithm testing which validated the accuracy of FibriCheck. The product was deemed fit for clinical use. Usability validation is part of the Clinical Performance data and FibriCheck was tested and meets the requirements of following standard: • IEC 62366-1:2015, Medical devices – Application of usability engineering to medical devices. FibriCheck was designed and developed as recommended by FDA's Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Device". FibriCheck was considered to represent "moderate" level of concern as it is not intended to provide recommendations for treatment nor to provide decisive information. According to AAMI/ANSI/IEC 62304 Standard, FibriCheck safety classification has been set to **Class B**.

9. CONCLUSION

The information discussed above and provided in the 510(k) submission demonstrate that the FibriCheck device is substantially equivalent to the predicate.