



June 7, 2024

Qompium nv
Jo Van der Auwera
Director of Compliance
Kempische Steenweg 303/27
Hasselt, 3500
Belgium

Re: K232804

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: September 12, 2023
Received: May 7, 2024

Dear Jo Van der Auwera:

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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,


Kimberly Crowley

For: 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

Indications for Use

Submission Number (if known)

K232804

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.

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Contact Details

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

Applicant Name	Qompium nv
Applicant Address	Kempische Steenweg 303/27 Hasselt 3500 Belgium
Applicant Contact Telephone	+32479393153
Applicant Contact	Mr. Jo Van der Auwera
Applicant Contact Email	jo.vanderauwera@fibrichk.com

Device Name

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

Device Trade Name	FibriCheck
Common Name	Telephone electrocardiograph transmitter and receiver
Classification Name	Transmitters And Receivers, Electrocardiograph, Telephone
Regulation Number	870.2920
Product Code	DXH

Legally Marketed Predicate Devices

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

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K173872	FibriCheck	DXH

Device Description Summary

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

FibriCheck is a medical device software that can be used to determine heart rhythm conditions, with a primary focus on the detection of atrial fibrillation.

The FibriCheck Mobile Application is a smartphone application for patients intended to record, display, store and transmit photoplethysmography (PPG) data. Heart rhythm measurements are performed by placing the fingertip on the camera of a smartphone device. This way, volumetric changes can be detected.

The FibriCheck Portal is a web application for healthcare providers intended to display data that was captured by the FibriCheck Mobile Application. Healthcare providers can use the FibriCheck Portal to issue FibriCheck prescriptions, to manage their patients and to consult measurement data.

Intended Use/Indications for Use

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

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.

Indications for Use Comparison

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

The subject device's indications for use are identical to the predicate and are provided below:

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.

Technological Comparison

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

The subject device and the predicate device have the same intended use, the same key technological characteristics, and the same signal-acquisition capabilities. In clinical testing, FibrCheck demonstrated that it can achieve heart rhythm detection in line with the predicate device. Therefore, FibrCheck is substantially equivalent to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

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

The following non-clinical testings were conducted to demonstrate safety and effectiveness of the subject device:

- Skin tone quality verification
- External aggressor verification
- Software verification

No concerns regarding new safety or effectiveness issues were raised during this testing.

Our clinical validation study NCT06282380 included 252 cardiology patients recruited in-clinic or consulting the cardiac outpatient clinic, with or without AF. The participants were instructed to record PPG measurements using the subject device which were compared against the gold-standard reference diagnosis. The performance metrics are in line with those reported for the predicate device, and did not raise concerns regarding the safety or effectiveness of the subject device.

The subject device and predicate device have the same intended use, the same key technological characteristics, and the same signal-acquisition capabilities. In clinical testing, the subject device demonstrated that it is capable of irregular rhythm detection accuracy in line with the predicate device. Therefore, the subject device can be considered as safe and as effective as the predicate device.