September 23, 2020

Ken Persen
Chief Executive Officer
LIVMOR, Inc.
16470 Bake Pkwy., Ste. 200
Irvine, California 92618

Re: K201208
Trade/Device Name: LIVMOR HALO AF Detection System™
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter And Receiver
Regulatory Class: Class II
Product Code: DXH
Dated: August 21, 2020
Received: August 24, 2020

Dear Ken Persen:

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,

for

Jennifer 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)*
K201208

Device Name
LIVMOR Halo AF Detection SystemTM

Indications for Use *(Describe)*
The LIVMOR Halo AF Detection SystemTM is indicated for use by patients who have been diagnosed with or are susceptible to developing atrial fibrillation and who would like to monitor and record their pulse rhythms on an intermittent basis so that their physician can be alerted of detected irregular heart rhythms.

The LIVMOR Halo AF Detection System is intended for use in conjunction with the LIVMOR Halo+ Home Monitoring SystemTM, and is not validated for use with other pulse monitoring systems.

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.

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510(K) SUMMARY

SUBMITTER

Submitter Name:	LIVMOR, Inc.
Submitter Address:	16470 Bake Parkway, Suite 200 Irvine, CA 92618
Phone Number:	(612) 747-9595
Contact Person:	Ken Persen, CEO
Date Prepared:	May 2, 2020

DEVICE

Device Trade Name:	LIVMOR Halo AF Detection System™
Common Name:	Irregular Heart Rhythm Monitor
Classification Name:	Telephone electrocardiograph transmitter and receiver
Number:	21 CFR 870.2920
Product Code:	DXH
Class:	II
Classification Panel:	Cardiovascular

PREDICATE DEVICE

Primary Predicate:	FibriCheck (K173872)
Intended 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 pulse rhythms on an intermittent basis.

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

DEVICE DESCRIPTION

The LIVMOR Halo AF Detection System™ consists of an algorithm to filter and detect irregular pulse rhythm that may be suggestive of atrial fibrillation (AF) from photoplethysmograph (PPG) data, a patient user interface to notify the patient of data collection, and a physician user interface to alert the physician when irregular pulse rhythm suggestive of AF is detected. This medical device software interfaces with the LIVMOR Halo+ Home Monitoring System™ and compatible smartwatch to capture PPG data and sync to servers.

The LIVMOR Halo AF Detection System is designed to intermittently monitor for irregular heart rhythm using the LIVMOR Halo+ Home Monitoring System while the user is at rest at night. Photoplethysmograph (PPG) signals recorded by the Halo Watch are then analyzed by the Halo AF Detection System when WiFi connectivity is available. The signal is first analyzed for quality before performing the analysis. The complete set of data from the recording session is analyzed. When a signal is suggestive of AF, the rhythm is flagged for physician review through the LIVMOR HeartView physician portal.

INDICATIONS FOR USE

The LIVMOR Halo AF Detection System™ is indicated for use by patients who have been diagnosed with or are susceptible to developing atrial fibrillation and who would like to monitor and record their pulse rhythms on an intermittent basis so that their physician can be alerted of detected irregular heart rhythms.

The LIVMOR Halo AF Detection System is intended for use in conjunction with the LIVMOR Halo+ Home Monitoring System™, and is not validated for use with other pulse monitoring systems.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The LIVMOR Halo AF Detection System has the same intended use, technological characteristics, and principles of operation as its predicate device, FibriCheck. The minor differences between the LIVMOR device and its predicate device do not raise new questions of safety or effectiveness.

The LIVMOR Halo AF Detection was evaluated for sensitivity and specificity in the intended use subjects.

The **primary differences** between the LIVMOR Halo AF Detection System and predicate are:

- **Duration of recording** LIVMOR Halo AF Detection System analyses data recorded for a duration of hours automatically each night, and for periods of 10 minutes on patient initiation, with patient at rest, whilst Predicate records for 1 minute on patient initiation with patient at rest.
- **Delivery of result** - The LIVMOR AF Detection System results are delivered to the overseeing physician through the LIVMOR HeartView Physician Web Portal, whilst the Predicate delivers AF detection results direct to the patient

Device Name	**LIVMOR Halo AF Detection System**	**FibriCheck**
510(k) Number	K201208	K173872
Manufacturer	LIVMOR	Qompium
Regulation	870.2920	870.2920
Device Classification Name	Telephone electrocardiograph transmitter and receiver	Telephone electrocardiograph transmitter and receiver
Product Code	DXH	DXH
Indication Statement	The LIVMOR Halo AF Detection System™ is indicated for use by patients who have been diagnosed with or are susceptible to developing atrial fibrillation and who would like to monitor and record their pulse rhythms on an intermittent basis so that their physician can be alerted of detected irregular heart rhythms. The LIVMOR Halo AF Detection System is intended for use in conjunction with the LIVMOR Halo+ Home Monitoring SystemTM, and is not validated for use with other pulse monitoring systems.	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.
Intended User	Adult	Adult
Prescription device for home use	Yes	Yes
Single patient use	Yes	Yes
Monitors regularity of heartbeat	Yes	Yes

Device Name	LIVMOR Halo AF Detection System	FibriCheck
Alerts user to irregular rhythm	Physician would consult with the patient if AF is suggested.	User is notified when AF is detected and prompted to follow up with a physician.
Device design	LIVMOR Halo AF Detection System obtains PPG waveform via a smart watch and transmits to HeartView portal when connected to Wifi	FibriCheck obtains PPG waveform via mobile phone camera and displays signal in real time on the mobile phone with an arrhythmia index.
User Interface	Web portal	Web portal
AF Detection Functionality & Performance	Per Subject (n=92) Sensitivity: 100% Specificity: 93.0% Per Measurement (n=1834) Sensitivity: 93.3% Specificity: 99.1%	Per Subject (n=223) Sensitivity: 95.6% Specificity: 96.6% Per Measurement (n=547) Sensitivity: 95.3% Specificity: 96.2%

PERFORMANCE DATA

Non-Clinical Testing

Validation and Verification Testing carried out on the Halo AF Detection System indicates that it meets its predefined product's requirements and requirements from the following product standards:

- AAMI/ANSI/IEC 62304:2006, Medical Device Software - Software Life Cycle Processes

Clinical Performance Testing

The company performed a clinical study demonstrating sensitivity and specificity of the device in detecting atrial fibrillation when compared to ground truth as established by physician review of simultaneously collected ECG data with a Holter monitor. Mean values are presented below and are statistically significant. Device confirmed to meet performance goals.

	LIVMOR (n=92)	FibriCheck (n=223)
Sensitivity	100.0%	95.6%
Specificity	93.0%	96.55%
Positive Predictive Value	89.7%	95.60%
Negative Predictive Value	100.0%	96.55%
Accuracy	95.7%	96.14%

Software V&V Testing

Validation testing involved algorithm testing which validated the accuracy of Halo AF Detection System. The product was deemed fit for clinical use. Usability validation is part of the Clinical Performance data and Halo AF Detection System was tested and meets the requirements of the following standard:

- IEC 62366-1:2015, Medical devices - Application of usability engineering to medical devices.
- Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration

Staff; FEBRUARY 2016

Halo AF Detection System was designed and developed as recommended by FDA's Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Device". Halo AF Detection System was considered to represent "moderate" level of concern as it is not intended to provide recommendations for treatment. According to AAMI/ANSI/IEC 62304 Standard, Halo AF Detection System safety classification has been set to Class B.

Conclusion

The information discussed above and provided in the 510(k) submission demonstrate that the LIVMOR Halo AF Detection System (a SaMD device) is substantially equivalent to the predicate.