May 4, 2022

LiveMetric (Medical) S.A.
Chen Botvin
Senior Regulatory and Clinical Manager
40 Rue Glesener
Luxembourg, L-1630
Luxembourg

Re: K201302
Trade/Device Name: LiveOne LM1P
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: April 22, 2022
Received: April 22, 2022

Dear Chen Botvin:

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,

LCDR Stephen Browning
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)*
K201302

Device Name
LiveOne LM1P

Indications for Use *(Describe)*
The LiveOne is intended to be used in patients who have a need for a noninvasive blood pressure and hemodynamic monitor.
The LiveOne is intended to be used on subjects ≥ 27 years old and who have a palpable radial pulse. Software is used to provide data to qualified medical professionals for the purpose of assessing the patient's cardiac health via blood pressure readings in clinic setting by health care professional. LiveOne is intended only for measurement and display; it makes no diagnosis.

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
LiveMetric's LiveOne LM1P

Submitter Information:

Submitter: LiveMetric (Medical) S.A.
40 Rue Glesener,
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Luxembourg

Contact Person: Tomer Bentzion
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Date Prepared: May 13, 2020

Device Information:

Trade Name: LiveOne LM1P
Common or Usual Name: Noninvasive Blood Pressure Monitor
Classification Name: Noninvasive Blood Pressure Monitor Measurement System
Regulatory Class: Class II
Product Code: 21CFR870.1130 DXN

Predicate Devices:

The LiveOne LM1P is substantially equivalent in indications for use to the devices shown in table below, that have been cleared for marketing:

Device Name	Manufacturer	510(K)
TL300 Tensymeter Noninvasive Blood Pressure Monitor	Tensys Medical, Inc.	K123446
TL10 Tensymeter Non-invasive Blood Pressure Monitor	Tensys Medical, Inc.	K020537

Device Description

The LiveOne is a non-invasive blood pressure monitor that utilizes a single patient use non-invasive pressure sensor placed on the wrist over the radial artery, and an electronic interface module. The device uses proprietary algorithms to analyze the radial artery pressure and display diastolic, systolic, and pulse rate and a pressure waveform. The device allows the healthcare provider to monitor blood pressure (based on visual waveform) in a clinical setting.

Intended Use

LiveOne is a non-invasive blood pressure monitor, intended to capture the arterial waveform on the wrist and use it to as the basis of measurement of the systolic and diastolic blood pressure and pulse rate in the adult patient population. The blood pressure is thereby measured on the patient's wrist.

The LiveOne provides intermittent blood pressure values to a medical professional. The LiveOne displays continuous radial arterial pressure waveform prior measurement to a medical professional.

The Interpretation of the numerical values will be made by medical professionals only. The device does not report any diagnosis but provides numerical values. It is the physician's responsibility to make proper judgments based on these numbers and the tracing.

The LiveOne is intended to be used for patients who have a need for a noninvasive blood pressure monitor and is intended for use in clinical settings only. It does not provide any alarms and is not intended to clinically monitor patients in operating rooms, intensive care units (ICU) and electrophysiology laboratories.

Indications for Use

The LiveOne is intended to be used in patients who have a need for a non-invasive blood pressure and hemodynamic monitor.

The LiveOne is intended to be used on subjects ≥ 27 years old and who have a palpable radial pulse. Software is used to provide data to qualified medical professionals for the purpose of assessing the patient’s cardiac health via blood pressure readings taken in a clinical setting by health care professional . LiveOne is intended only for measurement and display; it makes no diagnosis.

Summary of Technological Characteristics

The intended use of LiveOne LM1P has the same intended use as its predicate device(s) TL300 (K123446**)** and its predicate TL10 (K020537**)**. The technological characteristics of LiveOne LM1P are substantially similar to the technological characteristics of the predicate device(s), TL300 (K123446**)** and TL10 (K020537). Subject device and predicate device(s) are considered NIBP monitors; both subject device and predicate device(s) are based on applanation tonometry; they both apply the physical principle of applanation tonometry on the radial artery with the use of pressure sensor data. The reading from the sensor are transformed to a pressure waveform, from which, the values of systolic and diastolic pressure are calculated. Both subject device and predicate device(s) are auto-calibrating; do not require any external calibration using a cuff. Both devices use the radial artery site as the primary pressure source for the system, whereas, TL300 utilizes a single sensor on its wrist-worn bracelet, LiveOne LM1P also operates under this same underlying principle, but it reads and processes the pressure waveform using a high-resolution, MEMS-based sensor array. The predicate device(s) utilizes an algorithm to define an optimum pressure sensing position over the radial artery. The subject device uses a placement signal score module that ensures high fidelity, pressure waveform signal, sampled at a frequency of 100Hz, and extracts the systole, diastole and heart rate to be displayed on the device's dedicated monitor. Any differences in the technological characteristics between the LiveOne LM1P and the predicate device do not raise any new issues of safety or effectiveness. Therefore, the LiveOne LM1P is substantially equivalent to the predicate device(s).

Functionality	**LiveOne LM1P**	**TL10 Tensymeter Non-invasive Blood Pressure Monitor K020537**	**TL300 Tensymeter Noninvasive Blood Pressure Monitor K123446**
Regulatory compliance	ISO 81060-2:2016 (The successor of AAMI SP10:1992; AAMI SP10:2002; IEC 81060-2:2009 standard; ISO 81060-2:2013)	AAMI Standard SP-10 - 2002	IEC 81060-2:2009 The accuracy of the device will be compared to the standard radial artery catheter, as well as to the non-invasive blood pressure cuff.
Product Code Intended Use	DXN LiveOne is a non-invasive blood pressure monitor. The blood	DXN This device is intended for use by medically trained personnel in a	DXN TL-300 is a non-invasive hemodynamic monitor.

	pressure waveform is measured on the patient's wrist.	clinical setting to continuously monitor and display diastolic, systolic, and mean blood pressures.	
	Provides intermittent blood pressure values to a medical professional. The LiveOne displays continuous radial arterial pressure waveform prior measurement to a medical professional.		TL-300 does continuous beat-to-beat waveform and blood pressure monitoring.
	Software is used to provide data to qualified medical professionals for the purpose of assessing the patient's cardiac health via blood pressure readings in a clinical setting. The LiveOne is intended to be used on subjects ≥ 27 years old and who have a palpable radial pulse.	This device is intended for use by medically trained personnel in a clinical setting to continuously monitor and display diastolic, systolic, and mean blood pressures. The device is intended for use on adult patients with a palpable pulse. This device is intended for use by medically trained personnel in a clinical setting to continually monitor and display diastolic, systolic, and mean blood pressures and pulse rate.	
	The Interpretation of the numerical values will be made by medical professionals only. The device does not report any diagnosis but provides numerical values. It is the physician's responsibility to make proper judgments based on these numbers. LiveOne is intended only for measurement and display; it makes no diagnosis.		
Technological Characteristics	LiveOne is placed on the wrist over the area of the radial artery pulse while the sensor interface acts as a pressure transducer.	The design of the TL10 Tensymeter utilizes a semiconductor pressure-sensing element applied to the wrist, over the radial artery, to obtain a	The T-line device will be placed over the radial artery at the distal wrist.

		pressure waveform.	
	LiveOne LM1P also operates under this same underlying principle (Tonometry), but it reads and processes the pressure waveform at the radial artery by the use of a high-resolution, MEMS-based sensor array	The TL10 Tensymeter is a non-invasive blood pressure monitor that utilizes a single patient use non-invasive pressure sensor placed on the wrist, over the radial artery, and an electronic interface module.	To attach the device, a single-use sterile sensor is placed over the radial artery and the device then gently clamped around the wrist to incorporate the sensor.
	The LiveOne wristband is similar in size and weight to a sports wristwatch.	The monitor has a size and weight similar to a sports type wrist watch.	
	LiveOne is monitoring at the wrist using arterial tonometry	Blood pressure monitoring at the wrist using arterial tonometry.	
	An embedded microcontroller supervises the actions of the monitor	An embedded microcontroller supervises the actions of the monitor.	
	Utilizes a semiconductor pressure-sensing element / array of elements applied to the wrist, over the radial artery, to obtain a pressure waveform	The monitor is applied to the wrist with a pressure transducer placed over the radial artery.	
	The LiveOne LM1P uses weight, height, age and sex in its signal processing and pressure measurement algorithms.		The T-Line uses Body Mass Index (BMI, computed using height and weight) in its signal processing and pressure measurement algorithms.
	LiveOne LM1P is comprised of a wristband and an off-the-shelf tablet as a companion device.		The TL-300 T-Line system comprises a sensor, bracelet, wrist positioner, and a tablet monitor to form an integrated system.
Non-Clinical Tests Submitted	ANSI/AAMI ES60601-1:2005 / A2:2010 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	ANSI/AAMI ES60601-1:2005 / A2:2010	
	IEC 60601 – 1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	IEC 60601 – 1	
	IEC 60601-1-2	IEC 60601-1-2	

	Medical electrical equipment – Part 1-2: General requirements for safety – Electromagnetic compatibility – Requirements and tests IS0 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing	IS0 10993-1
Target Population	The LiveOne targets patients, over 27 years of age, who have a need for non-invasive blood pressure monitoring	The device is intended for use on adult patients with a palpable pulse.
Anatomical Site	LiveOne is placed on the wrist over the area of the radial artery pulse	The monitor is placed on the wrist over the area of the radial artery pulse
End User	The LiveOne is intended to be used for patients who have a need for a noninvasive blood pressure monitor and is intended for use in clinical settings only.	This device is intended for use by medically trained personnel in a clinical setting to continuously monitor and display diastolic, systolic, and mean blood pressures.

Performance data

Non-clinical testing

Biocompatibility testing

The biocompatibility evaluation for the LiveOne device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity

The LiveOne device is considered tissue contacting for a duration of more than 24 hours.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the LiveOne device, consisting of the LiveOne wristband and the Microsoft Surface tablet. The system complies with the IEC 60601-1 standard for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Clinical testing

Multi-center ICU accuracy study:

This was a multi-center, non-randomized, single arm study of 26 subjects. The study was conducted in accordance with ISO 81060-2:2018 standard. This LiveOne device accuracy was compared to arterial line in ICU patients.

Primary endpoint

The results of the Subject Device compared to the A-line measurement in the ICU accuracy validation data set were as follows: (1) mean bias of systolic BP: 0.7±6.6, (2) mean diastolic bias: 2.0 ±5.5 mmHg, and (3) HR relative distance: 2.9.

Those results are within the acceptance criteria for the accuracy of blood pressure monitors. The study demonstrated that the Subject Device is accurate, and the study population and results comply with the ISO standard requirements.

General population accuracy study:

This was a single-center, non-randomized, single arm study of 8 subjects. The study was conducted in accordance with ISO 81060-2:2018 standard. This LiveOne device accuracy was compared to arterial line in healthy subjects.

Primary endpoint

The results of the Subject Device compared to the A-line measurement in the general population validation data set were as follows: (1) mean bias for systolic BP: -1.3 ± 7.2 mmHg (2) mean bias of diastolic BP: -0.4 ± 5.7 mmHg (3) HR relative distance 1.36. Those results are within the acceptance criteria for the accuracy of blood pressure monitors. The study demonstrated that the Subject Device is accurate, and the study population and results comply with the ISO standard requirements.

Conclusion

The LiveOne LM1P is as safe and as effective as the TL300 and its predicate TL10. The LiveOne LM1P has the same intended uses and similar indications, as its predicate device. The minor differences in indications do not alter the intended use.

The LiveOne LM1P is as safe and effective as the Tensymeter's TL300 and the TL10. The LiveOne LM1P has the same technological characteristics, and principles of operation as its predicate device(s). In addition, the minor technological differences between the LiveOne LM1P and its predicate device(s) raise no new issues of safety or effectiveness. The nonclinical data support the safety of the device and the hardware and software verification and validation demonstrate that the LiveOne LM1P device should perform as intended in the specified use conditions. The clinical testing demonstrated that the LiveOne LM1P device is accurate according to the applicable ISO 81060-2-2018 standard. Thus, the LiveOne LM1P is substantially equivalent to the predicate.