January 22, 2019

Life Science Technology Inc.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA Inc.
690 Roosevelt
Irvine, California 92620

Re: K180767
Trade/Device Name: FEMON Banana Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: December 19, 2018
Received: December 21, 2018

Dear Priscilla Chung:

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,

Sapana Patel -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180767

Device Name
FEMON Banana Thermometer

Indications for Use *(Describe)*
The FEMON Banana Thermometer is a battery operated electronic device with intended use of measuring human body temperature. This device is intended for armpit temperature measurement for patients from ages 29 days and older.

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

(K180767)

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: January 22, 2019

1. 510K Applicant / Submitter:

Life Science Technology Inc.
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2. Submission Contact Person

LK Consulting Group USA, Inc.
690 Roosevelt, Irvine CA 92620
Priscilla Juhee Chung
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Email: juhee.c@lkconsultinggroup.com

3. Device

- Proprietary Name: FEMON Banana Thermometer
- Common Name: Electronic Thermometer
- Classification: Class II (21 CFR 880.2910), Clinical Electronic Thermometer
- Product Code: FLL

4. Predicate Device

- **Primary Predicate Device:**
  Fever Scout by VivaLink (K162137)

5. Description:

The FEMON Banana Thermometer is a thermometer composed of a body patch to be directly attached to the patient's skin on armpit. The temperature information is then to be retrieved from the patch to the mobile phone application via Bluetooth.

8. Indications for Use

The FEMON Banana Thermometer is a battery operated electronic device with intended use of measuring human body temperature. This device is intended for armpit temperature measurement for patients from ages 29 days and older.

9. Substantial Equivalence Discussion:

The subject device, FEMON Banana Thermometer, has same intended use as the predicate device, and employs similar technology. The differences in the indications for use statement do not raise any different questions of safety or effectiveness.
The differences in technology do not raise different questions of safety and effectiveness. Like the predicate, the subject device functions to transmit continuous measurements of body temperature wirelessly to a mobile app. The device utilizes an adhesive that was evaluated for biocompatibility.

The technical specifications such as display device, working voltage, signal transmission, and receiver between the subject device and the predicate device are similar. The performance specifications such as measurement and accuracy range are similar as well.

The difference is that the subject device has 4 measurement interval options, whereas, the predicate device has only one option. The interval options of the subject device are offered to save battery life and also to choose intensive monitoring. This difference does not raise different questions in safety and performance because the user can choose the interval option for each situation.

	Subject Device	**Primary Predicate Device**
Device Name	FEMON Banana Thermometer	Fever Scout
Manufacturer	LIFE SCIENCE TECHNOLOGY Inc.	VivaLink
510(k) Number	K180767	K162137
Product Code	FLL	FLL
Indications for Use	The FEMON Banana Thermometer is a battery operated electronic device with intended use of measuring human body temperature. This device is intended for armpit temperature measurement for patients from ages 29 days and older.	The wireless Fever Scout Continuous Monitoring thermometer is a noninvasive and re-usable electronic device for home use. This product is intended for non-urgent ambulatory continuous armpit body temperature monitoring from ages 29 days and older.
Display Use Specification	iOS device display and Android device display	iOS device display

Working Voltage	3.0V DC	3.0V DC
Battery	3.0v Lithium Button Cell	MS Lithium Rechargeable Battery 3.0V
Reusability	Yes	Yes
Measurement Range (℃)	35~ 42°C	35~ 42°C
Accuracy (℃)	±0.1°C: 35~42°C	±0.1°C: 37 ~39°C, ±0.2°C: 35 ~ 37°C and 39 ~42°C
Temperature Unit	˚C or ˚F	˚C or ˚F
Signal Transmission	Wireless 2.4G Bluetooth BLE	Wireless 2.4G Bluetooth BLE
Receiver	Wireless 2.4G Bluetooth BLE enabled smart devices running Apple operating system iOS 9+ or Android operating system 4.4+	Wireless 2.4G Bluetooth BLE enabled smart devices running Apple operating system iPhone 5S+ or newer.
Operating Condition	5 ~40˚C 15-90% RH	10 ~40˚C 15-85% RH
Anatomical Application	Armpit peel-and-stick contact thermometer sensor	Armpit peel-and-stick contact thermometer sensor
Temperature Measurement Interval	• Fever Check option for intensive monitoring: continuous measurement every second for 20 secs. • Continuous transmitter measures body temperature every 5 seconds (default setting). User can change the setting to 30 seconds or 60 seconds.	Continuous transmitter measures body temperature every 15 seconds
Standard Conformance	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, ISO 80601-2-56, ISO 10993-1, ISO 10993-5, ISO 10993-10	IEC 60601-1, IEC 60601-1-2, ISO 10993-1, ISO 10993-5, ISO 10993-10

10. Performance Tests

The following performance testing was included to support a determination of substantial equivalence of the device to the predicate:

- Clinical Accuracy Performance Testing (per ISO80601-2-56)
- The EMC and Electrical Safety Testing (per IEC 60601-1 and IEC 60601-1-2
- Software Verification and Validation Testing in according with FDA Guidance for Software in Medical Devices
- Biocompatibility Tests (Cytotoxicity, Sensitization, Irritation) per ISO 10993.

The test results of the above tests performed on the subject device supported that it is substantially equivalent to the predicate device.

11. Conclusions:

Based on the information provided in this premarket notification, Life Science Technology Inc. concludes that the FEMON Banana Thermometer is substantially equivalent to the predicate device as described herein in.