DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 19, 2017

Vivalnk Inc.
Christine Kuo
Director, RA/QA
4655 Old Ironsides Dr. #390
Santa Clara, California 95054

Re: K162137
Trade/Device Name: Fever Scout™ Continuous Monitoring thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: December 20, 2016
Received: December 23, 2016

Dear Christine Kuo:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tina Kiang -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162137

Device Name
Fever Scout™ Continuous Monitoring thermometer

Indications for Use *(Describe)*
The wireless Fever Scout™ Continuous Monitoring thermometer is a non-invasive 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.

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."

Section 5 – 510(k) Summary

K162137

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92.

Type of Submission: Traditional 510(k); this is the first submission for this device

510(k) Submitter:
VivaLnk Inc.
4655 Old Ironsides Dr. #390
Santa Clara, CA 95054 USA
Phone: 408-868-2898

Contact Person: Christine Kuo

Date Prepared: January 19, 2017

Device Identification:

Trade Name:	Fever Scout™ Continuous Monitoring thermometer
Device Common Name:	Armpit thermometer
Classification:	21 CFR Sec. 880.2910, Clinical electronic thermometer
Product Code:	FLL
Classification Panel:	General Hospital
Class:	II

Indications for Use: The wireless Fever Scout™ Continuous Monitoring thermometer is a non-invasive 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.

Device Description: Fever Scout Continuous Monitoring thermometer is an ambulatory continuous body temperature monitor designed for armpit location, and uses Bluetooth Low Energy (BLE) for wireless communication with the Smartphone app for temperature display, trending and alert.

This product is composed of

- The Fever Scout VV-200 patch
- The Smartphone app (supporting iOS)
- AAA charging system with BLE relay function
- Eight adhesives

The patch hardware primarily includes the following function modules: 1) temperature sensor, 2) control module, 3) Bluetooth Low Energy (BLE) communication module and 4) battery. All are integrated onto a flexible electronic printed circuit board. A MS Lithium rechargeable battery is attached to the board to supply 3.0V DC internal power.

The app includes 1) User account, profile and alert temperature setup and 2) GUI for temperature display, trending and alerts.

The charging system provides a cordless charging method to the patch, a storage to the replaceable double-sided adhesives, as well as an alternative BLE communication channel from the patch to the charger and then to the iPhone, in order to extend communication range.

This product contains Type B applied part (per IEC 60601-1: 2012). All components, the patch, charger and adhesives are all user accessible parts. However, the user is only expected to change the charger AAA batteries, but not to open or modify any other parts of the product.

Predicates: TempTraq Model TT-100 by Blue Spark Technologies (K143267)

Trade Name:	TempTraq Model TT-100
Device Common Name:	Armpit thermometer
Classification:	21 CFR Sec. 880.2910, Clinical electronic thermometer
Product Code:	FLL
Classification Panel:	General Hospital
Class:	II

Summary of Substantial Equivalence: Fever Scout Continuous Monitoring thermometer is substantially equivalent to the predicate, TempTraq TT-100.

Device Comparison

Characteristics	**Proposed Device Fever Scout**	**Primary Predicate TempTraq TT-100**	**Reference Predicate iThermonitor WT-701**	**Comparison**
510(k) Number	NA	K143267	K132761	NA
Product Code	FLL			Identical

Regulation #	21CFR880.2910			Identical
Class	Clinical electronic thermometers			Identical
Indications for Use	The wireless Fever Scout Continuous Monitoring thermometer is a non-invasive 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.	The Wireless thermometer, model TT-100, is a battery-operated electronic device with intended use of measuring human body temperature precisely. This device is single use and intended for armpit temperature measurement for persons of all age.	The Wireless Thermometer is a battery operated electronic device with intended use of measuring human armpit temperature continuously via wireless signal transmission of the measuring results. This system is reusable and intended for armpit monitoring for persons over two years old.	Equivalent. All three devices are for human armpit temperature measurements. Difference are demonstrated to not raise questions of safety and effectiveness per requirements set forth in the standards listed in Section 5-510(k) Summary
Display Use Specification	iOS device display	iOS and Android device display	iOS device display	Equivalent iOS is what all three devices support. Not supporting Android will not impact safety or efficacy concerns, but limit market share (number of users who can use this device).
Working Voltage	3.0 V DC			Identical
Battery	MS Lithium Rechargeable Battery 3.0V	Two (2) Blue Spark 1.5 V batteries (103-UT1)	The button battery 3.0 V, 210mAh	Equivalent per UL 1642 5th Edition
Reuse	Yes	No	Yes	Equivalent The reusability

				is demonstrated to not raise questions of safety and efficacy through functional verification and cleaning testing.
Measurement Range	35 ~ 42°C	30 ~ 42.4˚C	25 ~ 45˚ C	Equivalent All three devices cover the needed range per ASTM_1112 Temperature range.
Accuracy	±0.1°C From 37 ~ 39°C, ±0.2°C from 35 ~ 37°C and 39 ~ 42°C	±0.1°C between 30 ~ 42.4°C	±0.05˚ C (35 - 38.5˚ C); ±0.1˚ C (25 - 34.99˚ C); ±0.1˚ C (38.51 -45˚ C)	Equivalent All three devices meet the maximum error temperature ranges per ASTM_1112.
Signal Transmission	Wireless 2.4G Bluetooth BLE			Identical
Receiver	Wireless 2.4G Bluetooth BLE enabled smart devices running Apple operating system iPhone 5S+ or newer.	Wireless 2.4G Bluetooth BLE enabled smart devices running Apple operating system iOS 7.1 through 8.1 or Android operating system 4.3 through 4.4.4	Wireless 2.4G Bluetooth BLE enabled smart devices running Apple operating system iPhone 4S, iPhone 5, iPad (3rd generation), iPad (4th generation), iPad mini, iPod (5th generation)	Equivalent All three devices support 2.4G BLE enabled devices. The difference in supported operating systems doesn't impact safety and efficacy.
Valid Transmission	Up to 40 meters (with relay)	Up to 40 feet	Up to 5 meters	Equivalent The device is demonstrated to function as

					intended.
Operating Condition		10 ~40˚C 15-85% humidity	16 ~ 40°C 15 -95% humidity	5 ~ 40 ˚C 15-85% humidity	Equivalent The operating range is compliant with ASTM_1112.
Anatomical Application		Armpit peel-and-stick contact thermometer sensor			Identical/ Equivalent
Temperature Measurement Interval		Continuous transmitter measures body temperature every 15 seconds	Continuous transmitter measures body temperature every 10 seconds	Continuous transmitter measures body temperature every 4 seconds	Equivalent The maximum difference in temperature measurements is 11 seconds, which does not raise questions of safety and efficacy.
Safety and Performance	**Biocompatibility**	Conformed to ISO 10993-1, ISO 10993-5, and ISO 10993-10			Identical/ Equivalent Test against the same standards for safety and performance
	Electrical Safety	Conformed to IEC 60601-1			Identical/ Equivalent Test against the same standard for safety and performance
	Electromagnetic Compatibility	Conformed to IEC 60601-1-2 and FCC			Identical/ Equivalent Test against the same standard for safety and performance
	Performance	Conformed to ASTM E1112			Identical/ Equivalent Test against the same standard for safety and performance

Technological Characteristics: Fever Scout Continuous Monitoring thermometer is technologically substantially equivalent to the predicate device. Both devices use equivalent temperature technology to sense, process and transmit temperature data continuously from the patch affixed to the skin under the armpit to a mobile application.

Performance Data: The substantially equivalent performance of Fever Scout Continuous Monitoring thermometer has been demonstrated by product verification, software verification, user/usability validation, biocompatibility test, mechanical hazards test, EMC test and IEC 60601-1 safety compliance test.

Performance data demonstrates conformance with 21 CFR Part 1020 or compliance with voluntary standards includes but not limited to the following:

IEC 60601-1:2005/(R) 2012: Medical Electrical Equipment -- Part 1: General Requirements For Basic Safety And Essential Performance

IEC 60601-1-2:2014: Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility – Requirements And Tests

IEC 60601-1-11: 2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC 62304:2006 Medical Device Software – Software lifecycle Processes

ISO 10993-1: 2009 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process

ASTM E1112-2000 (Reapproved 2011), standard specification for electronic thermometer for intermittent determination of patient temperature.

Conclusion: VivaLnk concludes that the device is substantially equivalent to the currently legally marketed predicate devices. Fever Scout Continuous Monitoring thermometer has equivalent indications for use and technological characteristics, and does not introduce different questions of safety and effectiveness.