U.S. FOOD & DRUG ADMINISTRATION

August 21, 2018

VivaLnk Inc.
Christine Kuo
Director, Regulatory Affairs and Quality Assurance
4655 Old Ironsides Drive, Suite 390
Santa Clara, California 95054

Re: K181013
Trade/Device Name: Fever Scout™ Continuous Monitoring Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: June 29, 2018
Received: July 3, 2018

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.

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,

Geeta K.
Pamidimukkala -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)*
K181013

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 and a non-invasive and single patient use in the hospital. 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."

K181013

510(k) Summary

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, this information serves as a Summary of Safety and Effectiveness for the use of the Fever Scout™ Continuous Monitoring thermometer.

Type of Submission: Traditional 510(k) for expanded indications of K162137

510(k) Submitter:
VivaLNK Inc.
51 East Campbell Avenue Suite #160
Campbell, CA 95008 USA
Phone: 408-868-2898

Contact Person: Christine Kuo

Date Prepared: July13, 2018

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

Device Description: The VivaLnk Fever Scout VV-200 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.

The product is composed of

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

Indications for Use: The wireless Fever Scout™ Continuous Monitoring thermometer is a non-invasive and re-usable electronic device for home use and a non-invasive and single patient use in the hospital. This product

	is intended for non-urgent ambulatory continuous armpit body temperature monitoring from ages 29 days and older.
Reason for Submission:	Expanded Indications for Use of the predicate
Predicates:	Fever Scout Continuous Monitoring thermometer (K162137)
Trade Name: Device Common Name: Classification: Product Code: Classification Panel: Class:	Fever Scout Continuous Monitoring thermometer Armpit thermometer 21 CFR Sec. 880.2910, Clinical electronic thermometer FLL General Hospital II
Summary of Substantial Equivalence:	Fever Scout is substantially equivalent to the primary predicate (K162137) and is the identical product as the predicates with the expanded indications adding and a non-invasive and single patient use in the hospital. The expanded indications is comparable to the secondary predicate (K160306) used for household and medical institutions.

Device Substantial Equivalent Comparison

	Technology Characteristics			
Characteristics	**Proposed Device (K181013)**	**Primary Predicate (K162137)**	**Secondary Predicate (K160306)**	**Comparison**
Product code	FLL	FLL	FLL	Identical
Regulation #	21 CFR 880.2910	21 CFR 880.2910	21 CFR 880.2910	Identical
Regulation description	Clinical electronic thermometer	Clinical electronic thermometer	Clinical electronic thermometer	Identical
Device class	II	II	II	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	The wireless Fever Scout Continuous Monitoring thermometer is a non-invasive and re-usable electronic device for home use and a non-invasive and	The Cloud Smart Thermometer is a battery-operated electronic device with intended use of measuring and monitoring human axillary	Home use is identical to primary predicate and comparable to secondary predicate (household use). Hospital use: comparable to secondary predicate (used for

	body temperature monitoring from ages 29 days and older.	single patient use in the hospital. This product is intended for non-urgent ambulatory continuous armpit body temperature monitoring from ages 29 days and older.	temperature continuously via wireless signal transmission of the measuring result. Meanwhile, the device is reusable and is intended for axillary temperature monitoring for persons over two years old, and it is used for household and medical institutions	institutions)
Display Use Specification	Apple device and Android device display	Apple device and Android device display	iOS or Android device display	Identical
Working Voltage	3.0 V DC	3.0 V DC	3V DC	Identical
Battery	MS Lithium Rechargeable Battery 3.0V	MS Lithium Rechargeable Battery 3.0V	MAXELL CR2025 Button battery (3.0 V, 170mAh)	Comparable
Reuse	Re-usable for home use and single patient use in the hospital	Re-usable for home use	Reusable for household and medical institutions	Comparable to primary/secondary predicates for home use; comparable to secondary predicate for hospitable/medical institution use
Measurement Range	35 ~ 42°C	35 ~ 42°C	25 ~ 45°C	Comparable
Accuracy	±0.1°C From 37 ~ 39°C, ±0.2°C from 35 ~ 37°C and 39 ~ 42°C	±0.1°C From 37 ~ 39°C, ±0.2°C from 35 ~ 37°C and 39 ~ 42°C	±0.1°C (at 36.0 to 40.0°C) ±0.2°C at other temperature range	Comparable
Signal Transmission	Wireless 2.4G Bluetooth BLE	Wireless 2.4G Bluetooth BLE	Wireless 2.4 G Bluetooth 4.0	Comparable
Receiver	Wireless 2.4G Bluetooth BLE enabled smart devices running	Wireless 2.4G Bluetooth BLE enabled smart devices running	iOS7.0 or above smartphone or tablet; Android 4.3 or	Comparable

	Apple devices: iPhone 5S+ or later, and iOS 8.0 or later, and Android device: 4.3 or later.	Apple devices: iPhone 5S+ or later, and iOS 8.0 or later, and Android device: 4.3 or later.	above smartphone, tablet or television	
Valid Transmission	Up to 40 meters (with relay)	Up to 40 meters (with relay)	Up to 15 meters (under barrier-free environment)	Comparable
Operating Condition	10~40°C 15-85% humidity	10~40°C 15-85% humidity	0~40°C 15-85% (non-condensing)	Comparable
Anatomical Application	Axillary (armpit) temperature measuring and monitoring	Axillary (armpit) temperature measuring and monitoring	Axillary (armpit) temperature measuring and monitoring	Identical
Temperature Measurement Interval	Continuous transmitter measures body temperature every 15 seconds	Continuous transmitter measures body temperature every 15 seconds	Every 4 seconds	Comparable
	Performance Data: Safety and Performance			
Performance	**Proposed Device (K181013)**	**Primary Predicate (K162137)**	**Secondary Predicate (K160306)**	**Comparison**
Biocompatibility	Conformed to ISO 10993-1, ISO 10993-5, and ISO 10993-10	Conformed to ISO 10993-1, ISO 10993-5, and ISO 10993-10	Conformed to ISO 10993-1. ISO 10993-5 and ISO 10993-10	Identical
Electrical Safety	Conformed to IEC 60601-1	Conformed to IEC 60601-1	Complied with IEC 60601-1	Identical
Electromagnetic Compatibility	Conformed to IEC 60601-1	Conformed to IEC 60601-1	Complied with IEC 60601-1	Identical
Performance	Conformed to ASTM E1112	Conformed to ASTM E1112	Complied with ASTM E 1112	Identical

Technological Characteristics:

The Fever Scout product is technologically substantially equivalent to the primary predicate device (K162137) and is the identical product as the primary predicates with the expanded indications adding "and a non-invasive and single patient use in the hospital".

The expanded indications for hospital use is comparable to the secondary predicate (K160306) used for household and medical institutions.

Performance Data (Safety and Performance):

The primary mode of action for measuring temperature is by thermistor.

The performance and safety compliance testes of the Fever Scout product with the expanded indications is substantially equivalent to the primary predicate device (K162137) and is the identical product as the primary predicates with the expanded indications adding "and a non-invasive and single patient use in the hospital.

The expanded indications for hospital use is comparable to the secondary predicate (K160306) used for household and medical institution.

Safety Measure for Single Patient Use in the Hospital

VivaLNK would establish procedure to segregate the device shipping to the hospital with a box label "stating "Single Patient Use in the hospital". The risks associated with single patient use in the hospital are summarized in Fever Scout Risk Management Report which identifies and mitigates the hazard of cross contamination between the patient use in the hospital.

VivaLNK will control the products shipping to the hospital with a box label stating "Single Patient Use in the Hospital" and the precautions in the Instructions for Use (IFU) stating "The device is for single patient use in the hospital.

Conclusion:

VivaLNK concludes that the device with the expanded indications by adding "and a non-invasive and single patient use in the hospital" is substantially equivalent to the currently legally marketed primary predicate device (K162137) and secondary predicate device (K160306).