DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 2, 2015

Blue Spark Technologies Inc.
c/o Jennifer Cartledge
REU Associates, Incorporated
409 Woodridge Drive
Seneca, South Carolina 29672

Re: K143267
Trade/Device Name: TempTraq, Model TT-100
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: July 6, 2015
Received: July 31, 2015

Dear Ms. Cartledge:

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 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" (21CFR 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 yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Digital Signature Concurrence Table	
Reviewer Sign-Off William M. Burdick	
Branch Chief Sign-Off Richard Chapman	
Division Sign-Off Erin Keith	

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)*

K143267

Device Name

TempTraq, model TT-100

Indications for Use *(Describe)*

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

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"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."

5. 510(k) Summary

K143267

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

Preparation of this 510(k) Summary: This 510(k) summary was prepared by Jennifer Cartledge, Submission Correspondent. The contents of the 510(k) were provided by and approved by Blue Spark Technologies.

Date of Submission: November 11, 2014

Name and Address of Manufacturer and 510(k) Owner:

Blue Spark Technologies Inc.
806 Sharon Drive, Suite G,
Westlake, OH 44145 USA
Phone: 440-249 5400
Fax: 440-249 5421
Establishment registration number: Blue Spark Technologies is not currently registered. This submission represents the first 510(k) and medical device for Blue Spark Technologies. Blue Spark will complete registration within 30 days of manufacturing and distributing the device.

Contact: Jennifer Cartledge, Submission Correspondent
864-506-0097

US contact person:

Jennifer Cartledge
REU Associates Inc.
409 Woodridge Drive
Seneca, SC 29672
Tel.: (864) 500-0097
Email: jcartledge@reuassociates.com

Device Identification

Trade Name:	***TempTraq™, Model TT-100***
Common names:	Clinical electronic thermometer
Classification(s) of the device:	Thermometer, electronic, clinical, 21CFR 880.2910

Product Code: FLL
Classification Panel: General Hospital
Class II

Equivalent legally marketed devices:

- Wireless Thermometer (ST323C/F) by Mesure Technology Co., Ltd (K063542)

The Raiing Medical iThermonitor (K132761) provides an example of a cleared device that affixes the sensor to the skin under the armpit with an adhesive backed foam and that communicates wirelessly to a smart phone application as the receiver.

Device Description:

The TempTraq™, Model TT-100 patch consists of a temperature sensor integrated circuit mounted to a flexible electronic printed circuit board that also contains a microprocessor and a Bluetooth Low Energy (BLE) radio transmitter. Two 1.5V flexible batteries are attached to the circuit board to supply 3.0V DC internal power. The temperature sensor integrated circuit utilizes diode technology where voltage varies with temperature. The sensor circuit is factory calibrated and converts the voltage to an output temperature. The algorithm for conversion is a proprietary algorithm which compensates for the nearly linear behavior of the diode voltage, providing an extremely accurate temperature measurement.

The TempTraq™, Model TT-100 Device is functionally identical to the Mesure Wireless Temperature models ST323C and ST323F in intended use, apart from fact that the TempTraq™, Model TT-100 device is single use. They both utilize equivalent temperature technology to sense, process, store and transmit temperature data. Like the predicate, the TempTraq™, Model TT-100 device functions to transmit continuous measurements of body temperature wirelessly to a receiver. In the case of the predicate, the Wireless Thermometer (K063542), this information is transmitted to a custom receiver, while the TempTraq™, Model TT-100 device transmits the information to a mobile app, similar to the reference device, the iThermonitor (K132761).
The concept of affixing a temperature sensor to the skin under the armpit with an adhesive backed foam has also received pre- market clearance, under K132761, for use with the iThermonitor.

Intended Use:

The TempTraq™ app is compatible with 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

The Indication for Use for the TempTraq™, Model TT-100 Device identical to that of the predicate, apart from the fact that the TempTraq™, Model TT-100 Device is a single use device as compared to the reuseable predicate, and is as follows:

> *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.

Comparison to Predicate Device

The TempTraq™, Model TT-100 Device is substantially equivalent to the cleared Mesure Wireless Temperature models ST323C and ST323F in terms of intended use, technology, and performance. Table 5-1 compares the proposed TempTraq™, Model TT-100 with the predicate.

Table 5-1: Substantial Equivalence Table

Characteristics	**Proposed Device TempTraqTM, Model TT-100** (TT-100) Blue Spark Technologies	**Primary Predicate** **Wireless Thermometer** (ST323C/F) Mesure Technology Co., Ltd.	**Reference Predicate** **iThermonitor** (WT701) Raiing Medical Company	**Discussion**
510(k) Number	N/A	K063542	K132761	N/A
Product Code	FLL	FLL	FLL	Identical
Regulation #	21CFR880.2910	21CFR880.2910	21CFR880.2910	Identical
Class	Clinical electronic thermometers	Clinical electronic thermometers	Clinical electronic thermometers	Identical

Intended Use	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, model ST323C and ST323F is the battery-operated electronic devices with intended use of measuring human body temperature precisely. This device is reusable 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	Equivalent

			system is reusable and intended for armpit monitoring for persons over two years old.	
Display Use Specification	iOS device display and Android device display	Custom receiver	iOS device display	Equivalent
Working Voltage	3.0V DC	3.0V DC	3.0V DC	Identical
Battery	Two (2) Blue Spark 1.5 V batteries (103-UT1)	3V x 1 (CR2032)	The button battery 3.0 V, 210mAh	Equivalent
Measurement Range	30 ~ 42.4 C	10.0°C ~ 43.0°C (50.0°F~ 109.4°F)	25 ~ 45˚ C	Equivalent
Accuracy	±0.1°C between 30°C ~ 42.4°C	0.1°C / 0.2°F between 32°C ~ 43.0°C (89.6°F ~ 109.4°F)	±0.05˚ C (35-38.5˚ C); ±0.1˚ C (25-34.99˚ C); ±0.1˚ C (38.51-45˚ C)	Equivalent
Temperature Unit	˚C or ˚F	˚C or ˚F	˚C or ˚F	Identical
Signal Transmission	Wireless 2.4G Bluetooth BLE	Wireless	Wireless 2.4G Bluetooth BLE	Identical
Receiver	Wireless 2.4G Bluetooth BLE enabled smart devices running Apple operating system iOS 7.1 through	Custom receiver	Wireless 2.4G Bluetooth BLE enabled smart devices running Apple operating system iPhone 4S, iPhone 5,	Equivalent

	8.1 or Android operating system 4.3 through 4.4.4		iPad (3rd generation), iPad (4th generation), iPad mini, iPod (5th generation)	
Valid Transmission	Up to 40 feet	160 feet distance (approx.50M) in an open space. If there are objects in that space, the transmission distance will be affected	Up to 5 meters	Equivalent
Operating Temperature	16°C ~ 40°C	N/A	5˚C ~ 40 ˚C	Identical/ Equivalent
Operating Humidity	15% -95% RH	15% -95% RH	15-85%	Equivalent
Anatomical Application	Armpit peel-and-stick contact thermometer sensor	Armpit wearable w/out adhesive	Armpit peel-and-stick contact thermometer sensor	Identical/ Equivalent
Patient Usage	Single-use	reusable	reusable	Equivalent
Temperature Measurement Interval :	Continuous - transmitter measures body temperature every 10 seconds	Continuous - transmitter measures body temperature once every 15 seconds	Continuous - transmitter measures body temperature every 4 seconds	Equivalent
Memory Function :	Can store up to 24 hours of readings	200 sets	can store up to 72 hours of readings	Equivalent
Storage:	Data back-up	Data back-up	Cloud Storage	Equivalent

Summary of technological characteristics / performance data:

The TempTraq™, Model TT-100 device has equivalent indications for use and technological characteristics as the predicate device.

1.) There is no major change or modification in the intended use of the device (cf. 21 CFR 807.81 (a) (3) (ii)) in comparison to the predicate. Compared to the Mesure Wireless Temperature models ST323C and ST323F, the intended use of the device is equivalent, apart from the fact that the TempTraq™, Model TT-100 device is intended to be a single use, disposable sensor.

2.) There is no difference in the used technologies.

> Like the predicate, the TempTraq™, Model TT-100 device functions to transmit continuous measurements of body wirelessly to a receiver. In the case of the predicate, the Wireless Thermometer (K063542), this information is transmitted to a custom receiver, while the TempTraq™, Model TT-100 device transmits the information to a mobile app, similar to the reference device, the iThermonitor (K132761).
> Additionally, the Wireless Thermometer (K063542), utilizes elastic/compression to secure the temperature sensor, while the TempTraq™, Model TT-100 device secures the sensor with a biocompatible adhesive like the reference device, the iThermonitor (K132761).

3.) The identified differences in technological characteristics do not raise different questions of safety and effectiveness than the predicate devices (cf. section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)).

4.) Although some specifications are slightly different than the predicate device, the Wireless Thermometer (K063542), the hypothetical resulting difference does not impact the intended use, as demonstrated in the system verification.

5.) Performance information and evidence of compliance to recognized standards demonstrate the device is as safe and effective as the predicate devices.

Based upon the intended use, and upon the similarity of materials, product configuration and administration, it can be concluded the TempTraq™, Model TT-100 device is substantially equivalent to the identified predicate device in terms of intended use, safety and effectiveness.

Description of Testing

The safe and effective performance of the TempTraq™ System has been clearly demonstrated by bench tests:

- System Verification

- Software Verification and Validation, in accordance with the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*

Performance data demonstrates conformance with 21 CFR Part 1020 or compliance with voluntary standards:

ES60601-1:2005/(R) 2012 And C1:2009/(R) 2012: Medical Electrical Equipment -- Part 1: General Requirements For Basic Safety And Essential Performance

IEC 60601-1-2:2007: Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests

ISO 14971: 2007 Ed. 2 Medical Devices-Application of Risk Management to Medical Devices

IEC 62304:2006 Ed. 1 Medical Device Software – Software lifecycle Processes

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

E1112-00 (Reapproved 2011), standard specification for electronic thermometer for intermittent determination of patient temperature. (General Plastic Surgery/General Hospital)

Clinical testing was not required to establish equivalency of the device.

The comparison of technological characteristics, non-clinical performance data and software validation, demonstrates that the device is as safe, as effective, and performs as well or better than the predicate devices.

Conclusion:

Blue Spark Technologies concludes that the device is substantially equivalent to the currently legally marketed predicate devices. The TempTraq™, Model TT-100 has equivalent indications for use or intended use, has identical or equivalent technological characteristics, and does not introduce new potential hazards or safety risks. The device is as safe and effective as the predicate device.