December 3, 2020

Blue Spark Technologies Inc.
% Rita King
CEO
MethodSense, Inc.
1 Copley Pkwy, Ste. 410
Morrisville, North Carolina 27560

Re: K201977
Trade/Device Name: TempTraq, Model: TT-100, TT-200, TT-300
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: November 3, 2020
Received: November 4, 2020

Dear Rita King:

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,

for Payal Patel
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology 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)*
K201977

Device Name

TempTraq, Model: TT-100, TT-200, TT-300

Indications for Use *(Describe)*

The Wireless thermometers are battery-operated electronic devices with intended use of measuring human body temperature precisely. The devices are single-use and intended for armpit temperature measurement for persons of all ages.

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.**

**Summary of 510(k)**

**Blue Spark Technologies Inc. K201977**

This 510(k) Summary is in conformance with 21CFR 807.92


**Submitter:** Blue Spark Technologies Inc.
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**Date Prepared:** November 3rd 2020

**Device Name and Classification**

**Trade Name:** TempTraq TT-100, TT-200, TT-300
**Common Name:** Clinical electronic thermometer
**Classification:** Class II
**Regulation Number:** 21 CFR 820.2910
**Classification Panel:** General Hospital
**Product Code:** FLL

**Predicate Device:**

| | **Predicate** |
|---|---|
| **Trade Name** | TempTraq TT-100 |
| **Common Name** | Clinical Electronic Thermometer |
| **510(k) Submitter / Holder** | Blue Spark Technologies Inc. |
| **510(k) Number** | K143267 |
| **Regulation Number** | 21 CFR 820.2910 |
| **Classification Panel** | General Hospital |
| **Product Code** | FLL |

**Device Description**
TempTraq is a single-use device used to monitor temperature. The type of temperature that can be taken by the TempTraq patch is axillary only. The TempTraq temperature patches consist of a flexible circuit board that is positioned between two pieces of foam.

The TempTraq temperature sensor patch is applied to the patient via foam that is backed with a biocompatible adhesive and transmits body temperature data via low energy Bluetooth transmission to a smart device running a TempTraq application. The patch is worn on the underarm and senses, processes, stores, and transmits temperature data to a smart device running a compatible TempTraq application using Bluetooth LE.

The TempTraq temperature sensor patch is available in three (3) different configurations: TT-100 (24-hour operating time), TT-200 (48-hour operating time), and TT-300 (72-hour operating time). The TempTraq temperature sensor patches are intended to be used in different use environments. The patches can only be connected to specific TempTraq applications depending on their intended use environment:

*Table 1: Compatible TempTraq Patches, Applications, and Use Environments*

| Patch Model | Compatible TempTraq Applications | Use Environment |
|---|---|---|
| **TT-100** | TempTraq Consumer Mobile Application<br>TempTraq Patient Mobile Application<br>TempTraq Clinician Mobile Application<br>TempTraq Clinician Web Application | Home and Clinical |
| **TT-200** | TempTraq Consumer Mobile Application | Home |
| **TT-300** | TempTraq Patient Mobile Application<br>TempTraq Clinician Mobile Application<br>TempTraq Clinician Web Application | Clinical |

To view temperature data from the TempTraq temperature sensor patch, a user can use one of four configurations of the TempTraq application, depending on the role of the user:

*Table 2: TempTraq Applications Use Environments and End Users*

| TempTraq Application | Use Environment | End Users |
|---|---|---|
| TempTraq Consumer Mobile Application | Home | Home User |
| TempTraq Patient Mobile Application | Clinical | Hospital Patient |
| TempTraq Clinician Mobile Application | Clinical | Clinician |
| TempTraq Clinician Web Application | Clinical | Clinician |

The TempTraq Consumer Mobile Application is intended to be used by home users to receive data to their smart device from TempTraq TT-100 and TT-200 patches via Bluetooth connection. Multiple patches can transmit data to the application so that multiple patients' temperatures can be monitored. Additionally, the application features an optional TempTraq Connect cloud service that allows temperature data to be shared with other TempTraq Connect users and an export function that allows data to be shared with others via email.

The TempTraq Patient Mobile application is intended to be used by hospital patients to receive data to their smart device from TempTraq TT-100 and TT-300 patches. Only the patient's own data can be viewed in the patient application and all data is shared with their clinician via TempTraq Connect cloud services. The patient's Clinician can then view the temperature data via the TempTraq Clinician Mobile Application or TempTraq Clinician Web Application. Multiple patients can be added to and monitored via the Clinician Mobile and Web Applications. If patients do not own a smart device, data from the TempTraq patches can also be obtained via Bluetooth gateways strategically placed throughout a hospital which then transmit data directly to the TempTraq Connect cloud services.

**Indications for Use**

The Wireless thermometers are battery-operated electronic devices with intended use of measuring human body temperature precisely. The devices are single-use and intended for armpit temperature measurement for persons of all ages.

**Substantial Equivalence**

The table below provides a detailed comparison of TempTraq to the predicate device.

| Item | **Subject Device**<br>*TempTraq, models TT-100, TT-200 and TT-300* | **Predicate Device**<br>*TempTraq, model TT-100* | **Comparison** |
|---|---|---|---|
| **Indications for Use** | The Wireless thermometers are battery-operated electronic devices with intended use of measuring human body temperature precisely. The devices are single-use and intended for armpit temperature measurement for persons of all ages. | 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. | Similar.<br>See Note 1. |
| **Product Code** | FLL | FLL | Identical |
| **Regulation #** | 21CFR880.2910 | 21CFR880.2910 | Identical |
| **Display Use Specification** | iOS device display, Android device display, Web based | iOS device display and Android device display | Similar.<br>See Note 2. |
| **Working Voltage** | 3.0V DC | 3.0V DC | Identical |
| **Battery** | Two (2) Blue Spark 1.5 V batteries (103-UT1) | Two (2) Blue Spark 1.5 V batteries (103-UT1) | Identical |
| **Measurement Range** | 30 – 42.4 °C (86 °F ~ 108.3 °F) | 30 – 42.4 °C (86 °F ~ 108.3 °F) | Identical |
| **Accuracy** | +/- 0.1 °C (0.2 °F) between 30 °C ~ 42.4 °C (86 °F ~ 108.3 °F) | +/- 0.1 °C (0.2 °F) between 30 °C ~ 42.4 °C (86 °F ~ 108.3 °F) | Identical |
| **Temperature Unit** | °C or °F | °C or °F | Identical |
| **Signal Transmission** | Wireless Bluetooth BLE 4.0 operating at 2.4Ghz | Wireless Bluetooth BLE 4.0 operating at 2.4Ghz | Identical |
| **Receiver** | Wireless Bluetooth BLE 4.0 enabled smart devices running Apple operating system iOS 9.0 and further or Android operating system 4.3 and further | Wireless Bluetooth BLE 4.0 enabled smart devices running Apple operating system iOS 7.1 through 8.1 or Android operating system 4.3 through 4.4.4 | Similar.<br>See Note 3. |
| **Valid Transmission** | Up to 40 feet | Up to 40 feet | Identical |

| Item | **Subject Device**<br>*TempTraq, models TT-100, TT-200 and TT-300* | **Predicate Device**<br>*TempTraq, model TT-100* | **Comparison** |
|---|---|---|---|
| **Operating Temperature** | 16 C ~ 40 °C (60.8 °F ~ 104 °F) | 16 C ~ 40 °C (60.8 °F ~ 104 °F) | Identical |
| **Operating Humidity** | 15%-95% RH | 15%-95% RH | Identical |
| **Anatomical Application** | Armpit<br><br>peel-and-stick contact thermometer sensor | Armpit<br><br>peel-and-stick contact thermometer sensor | Identical |
| **Patient Usage** | Single-Use | Single-use | Identical |
| **Temperature Measurement Interval** | Continuous-transmitter measures body temperature every 10 seconds | Continuous-transmitter measures body temperature every 10 seconds | Identical |
| **Memory Function** | TT-100: Can store up to 24 hours of readings<br><br>TT-200: Can store up to 48 hours of readings<br><br>TT-300: Can store up to 72 hours of readings | TT-100: Can store up to 24 hours of readings | Different.<br>See Note 4. |
| **Storage** | Data back-up- Stored in app and optionally TempTraq Connect | Data back-up- stored in App | Different.<br>See Note 5. |
| **Run Time** | TT-100: 24-Hours<br><br>TT-200: 48-Hours<br><br>TT-300: 72-Hours | TT-100: 24-Hours | Different.<br>See Note 6. |
| **Patient Contacting Materials** | ISO 10993-1:2009(R)2013 Compliant Silicone Gel Adhesive | ISO 10993-1:2009(R)2013 Compliant Acrylic Adhesive | Different.<br>See Note 7. |
| **Applications** | TempTraq Consumer Mobile Application<br><br>TempTraq Patient Mobile Application<br><br>TempTraq Clinician Mobile Application<br><br>TempTraq Clinician Web Application | TempTraq Mobile Application | Different.<br>See Note 8. |
| **Dimensions** | Length: 100.0 mm<br>Height: 50.0 mm<br>Thickness: 2.0 mm<br>Weight: 5.1 grams | Length: 98.2 mm<br>Height: 46.6 mm<br>Thickness: 3.0 mm<br>Weight: 4.5 grams | Different.<br>See Note 9. |

| Item | Subject Device<br>*TempTraq, models TT-100, TT-200 and TT-300* | Predicate Device<br>*TempTraq, model TT-100* | Comparison |
|---|---|---|---|
| **Flexible Printed Circuit** | Version 6.0 | Version 4.0 | Similar.<br>See Note 10. |
| **Storage Temperature** | -4 to 122 °F (-20 °C to 50 °C) | -4 to 122 °F (-20 °C to 50 °C) | Identical |
| **Storage Humidity Range** | 15 - 95% RH (non-condensing) | 15 - 95% RH (non-condensing) | Identical |

*Note 1.* The Indications for Use of the proposed TempTraq System, models TT-100, TT-200 and TT-300, is similar to the predicate device, but is inclusive of all models. This difference does not affect safety and effectiveness.

*Note 2.* The Display Use Specification for the proposed TempTraq System is similar to the predicate device, with an additional web-based display use specification. Software Verification and Validation and Performance testing was conducted to demonstrate this difference does not affect safety and effectiveness.

*Note 3.* The Receiver for the proposed TempTraq System differs from the predicate device, with different operating system compatibility. Software Verification and Validation testing was conducted to demonstrate this difference does not affect safety and effectiveness.

*Note 4.* The Memory Function for the proposed TempTraq System differs from the predicate device. Performance testing was conducted to demonstrate this difference does not affect safety and effectiveness.

*Note 5.* The Storage for the proposed TempTraq System differs from the predicate device. Software Verification and Validation and Performance testing was conducted to demonstrate this difference does not affect safety and effectiveness.

*Note 6.* The Run Time for two new models (TT-200 and TT-300) of the proposed TempTraq System differs from the predicate device. Performance testing was conducted to demonstrate this difference does not affect safety and effectiveness.

*Note 7.* The patient contacting material for the proposed TempTraq System differs from the predicate device. Biocompatibility testing was conducted in accordance with ISO 10993-1 to demonstrate this difference does not affect safety and effectiveness.

*Note 8.* The Applications for the proposed TempTraq System differ from the predicate device. Software Verification and Validation and Performance testing was conducted to demonstrate this difference does not affect safety and effectiveness.

*Note 9.* The dimensions for the proposed TempTraq System differ from the predicate device. This difference does not have any impact on safety or effectiveness.

*Note 10.* The Flexible Printed Circuit for the proposed TempTraq System is similar to the predicate device. Electrical Safety (IEC 60601-1 Edition 3.1) and EMC testing (IEC 60601-1-2 4th Edition) was conducted to demonstrate this difference does not affect safety and effectiveness.

**Non-Clinical Testing to Determine Substantial Equivalence**
As part of the previously cleared submission (K143267), the following testing was performed for the TempTraq TT-100 device. This testing is still applicable for this submission:

- System verification was performed via bench testing, including testing to E1112-00 standard specification for electronic thermometer for intermittent determination of patient temperature, temperature range testing, operating time testing, and distance testing.

Blue Spark performed the following additional testing in order to demonstrate substantial equivalence for the proposed TempTraq System (TT-100, TT-200, and TT-300):

- Real time aging tests were completed. The shelf life of all packaged TempTraq models was confirmed to be four years.
- Biocompatibility testing for the TempTraq devices of TT-100, TT-200, and TT-300 was repeated for the updated materials of the TempTraq device.
- Battery capacity for the TempTraq devices of TT-200 and TT-300 was tested in order to confirm the battery life of the TT-200 supports a 48-hour operational life and TT-300 supports a 72-hour operational life. The testing was performed similar to the previous testing done on the TT-100 from the previously cleared submission (K143267).
- Electrical safety (IEC 60601-1 Edition 3.1) and EMC testing (IEC 60601-1-2 4$^{th}$ Edition) was repeated for the updated circuit board of TempTraq.
- Engineering Analysis and Verification Testing to confirm that the updated TempTraq System (with updated circuit and device design) meets the requirements of the predicate (K143267).
- Bench testing was completed for the TempTraq System (models TT-100, TT-200 and TT-300) to confirm the performance of the patch. These additional tests contain an accuracy test, temperature stabilization test, and an operating time test. They confirmed that the additional TT-200 and TT-300 models meet the performance of the TT-100 model previously cleared.
- Adherence properties of the TT-200 and TT-300 were tested in order to confirm that they are consistent with the adherence performance of the previously cleared TT-100 model.
- Software verification and validation was performed for the different configurations of the TempTraq Application (TempTraq Consumer Mobile Application, TempTraq Patient Mobile Application, and TempTraq Clinician Mobile Application for iOS and Android and TempTraq Web Application for Chrome, Safari, and Firefox) in accordance with FDA's "Guidance for Industry and FDA Staff: General Principles of Software Validation" (January 11, 2002) and IEC 62304:2015.
- Cybersecurity testing was performed for the TempTraq system. This includes Software Penetration Verification and Validation Testing, performed for both the Android App and iOS App. This testing confirmed that appropriate information security controls are implemented within the network and host environment to preserve the integrity,

confidentiality, and availability of its information and computing resources based on considerations from “Guidance for Industry and Food and Drug Administration Staff: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices” (October 2, 2014).

- Software verification and validation was performed for TempTraq Connect cloud services in order to determine that the sharing data functionality was safe and effective.
- Usability testing was performed for the TempTraq System in accordance with IEC 60601-1-6 and based on considerations from “Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering to Medical Devices” (February 3, 2016).

**Conclusions**

Based on the performance testing, comparison, and analysis, the subject device is substantially equivalent to the predicate device.