



June 21, 2024

SteadySense GmbH
% Brodie Pedersen
Chief Regulatory Officer
Borderless MedDev LLC
7118 Teakwood Cir
Maple Grove, Minnesota 55369

Re: K233280
Trade/Device Name: SteadyTemp
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: May 23, 2024
Received: May 24, 2024

Dear Brodie Pedersen:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

A handwritten signature in black ink that reads "David Wolloscheck". The signature is written in a cursive style. In the background, there is a large, light blue watermark of the letters "FDA".

David Wolloscheck, Ph.D.
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

Indications for Use

510(k) Number (if known)

K233280

Device Name

SteadyTemp

Indications for Use (Describe)

The SteadyTemp system is a wireless thermometer intended to provide precise body temperature for users of all ages. The SteadyTemp system comprises a single-use temperature measuring sensor, the SteadySense Patch, and the SteadyTemp application. SteadySense Patch measures and stores axillary skin temperature data up to 10 days. The typical application duration when using the system is 7 days.

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
PRASStaff@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."

510(k) SUMMARY

(as required by 21CFR 807.92)

K233280

I. SUBMITTER

SteadySense GmbH
Kärntner Strasse 518
Seiersberg Pirka 8054 Austria
Phone: +43 660 8850100
Phone: 612-272-5541
Contact: Brodie Pedersen
Brodiecp@BorderlessMD.com
Phone: 612-272-5541
Date Prepared: May 31, 2024

II. DEVICE

Name of Device: SteadyTemp
Classification Name: Clinical electronic thermometer.
Common or Usual Name: Thermometer, Electronic, Clinical
Device Panel: General Hospital Devices, and Human Factors
Regulation Number: 880.2910
Regulatory Class: Class 2
Product Code: FLL

III. PREDICATE DEVICE

The Steady Temp system is similar in technological characteristics to the predicate device except in the communication technology, NFC vs BLE in the predicate. This yields a difference in the distance of transmission and the reduction in the power consumption of the Steady Temp versus the predicate. These differences do not impact safety or effectiveness.

Name of Device: TempTraq, Model: TT-100, TT-200, TT-300
Predicate submission number: K201977
Regulation Number: 880.2910
Product Code: FLL

IV. DEVICE DESCRIPTION

SteadyTemp is a wireless thermometer designed to provide users of all ages with information about their body temperature. The device has two components, the SteadyTemp app, and the battery operated SteadySense patch. Both are required to measure temperature.

The SteadySense patch is a non-invasive, non-sterile, active temperature measurement device capable of detecting sub-degree ($< 0.18^{\circ}\text{F}/ 0.1^{\circ}\text{C}$) changes in body temperature by continuously measuring armpit temperature. The SteadySense patch is a disposable bandage product that is applied only to healthy skin under the arm. The top is flexible textile over insulating foam and the bottom is a thin adhesive layer to adhere the thermal sensor to the axilla for measurement recording.

SteadySense temperature measurement is a direct mode, solid state contact temperature transducer embedded in the patch. The patch records up to the last 77 hours of temperature data for download to the SteadyTemp app.

The typical application duration is 7 days. The SteadySense patch continuously records body temperature.

The SteadyTemp app serves as an interface for the user and for interacting with the SteadySense patch and displaying the measured temperature data. The data measured by the patch is transmitted via near-field communication (NFC).

V. INDICATIONS FOR USE

The SteadyTemp system is a wireless thermometer intended to provide precise body temperature for users of all ages. The SteadyTemp system comprises a single-use temperature measuring sensor, the SteadySense Patch, and the SteadyTemp application. SteadySense Patch measures and stores axillary skin temperature data up to 10 days. The typical application duration when using the system is 7 days.

VI. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Steady Temp system is similar in technological characteristics to the predicate device except in the communication technology, NFC vs BLE in the predicate. This yields a difference in the distance of transmission and the reduction in the power consumption of the Steady Temp versus the predicate. These differences do not impact safety or effectiveness.

Item	Predicate Device <i>TempTraq, models TT-100, TT-200 and TT-300 K201977</i>	Subject Device <i>SteadyTemp K233280</i>	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 SteadyTemp system is a wireless thermometer intended to provide precise body temperature for users of all ages. The SteadyTemp system comprises a single-use temperature measuring sensor, the SteadySense Patch, and the SteadyTemp application. SteadySense Patch measures and stores axillary skin temperature data up to 10 days. The typical application duration when using the system is 7 days.	Similar See <i>Note 1.</i>
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, Android device display	Similar See <i>Note 2.</i>
Working Voltage	3.0V DC	3.0V DC	Identical
Battery	Two (2) Blue Spark 1.5 V batteries (103-UT1) zinc manganese dioxide	3.0 V manganese dioxide lithium button cell battery	Similar See <i>Note 3.</i>
Measurement Range	30 – 42 °C (86 °F ~ 108°F)	30 – 42 °C (86 °F ~ 108°F)	Identical
Accuracy	+/- 0.1 °C between 30 °C ~ 42.4 °C	Measurement accuracy of +/- 0.3°C. 30-42 °C	Similar See <i>Note 4.</i>
Temperature Unit	°C or °F	°C or °F	Identical
Signal Transmission	Wireless Bluetooth BLE 4.0 operating at 2.4Ghz	Near-Field-Communication (NFC): For data transmission between Patch and software application	Difference See <i>Note 5.</i>
Receiver	Wireless Bluetooth BLE 4.0 enabled smart devices running Apple operating system iOS or Android operating system	Near Field Communication (NFC) enabled smart devices running Apple operating system iOS or Android operating system	Similar See <i>Note 5.</i>
Valid Transmission	Up to 40 feet	2.5 cm	Difference See <i>Note 5.</i>

Item	Predicate Device <i>TempTraq, models TT-100, TT-200 and TT-300 K201977</i>	Subject Device <i>SteadyTemp K233280</i>	Comparison
Operating Temperature	16 C ~ 40 °C (60.8 °F ~ 104 °F)	15 C ~ 40 °C (59 °F ~ 104 °F)	Similar See Note 12.
Operating Humidity	15%-95% RH	5%-95% RH	Similar See Note 12.
Anatomical Application	Armpit peel-and-stick contact thermometer sensor	Armpit 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 300 seconds	Similar See Note 6.
Memory Function	TT-100: Can store up to 24 hours of readings. TT-200: Can store up to 48 hours of readings. TT-300: Can store up to 72 hours of readings	SteadySense Patch: can store up to 77 hours of readings.	Similar See Note 6.
Storage	Data back-up- Stored in app and optionally TempTraq Connect	Data back-up- Stored in app.	Similar See Note 7.
Run Time	TT-100: 24-Hours TT-200: 48-Hours TT-300: 72-Hours	SteadySense Patch: 10 days	Difference See Note 8.
Patient Contacting Materials	ISO 10993-1: Compliant Silicone Gel Adhesive	ISO 10993-1: Compliant adhesive and bandage material	Similar See Note 9.
Applications	TempTraq Consumer Mobile Application TempTraq Patient Mobile Application TempTraq Clinician Mobile Application	STEADYTEMP Application	Similar See Note 10.
Dimensions	Length: 100.0 mm Height: 50.0 mm Thickness: 2.0 mm Weight: 5.1 g	Length: 65 mm Height: 60 mm Thickness: 3 mm Weight: 3 g	Similar See Note 11.
Printed Circuit	Printed circuit	Printed circuit	Similar See Note 12.
Storage Temperature	-4 to 122 °F (-20 °C to 50 °C)	+0°C to +40°C	Similar See Note 12.

Item	Predicate Device <i>TempTraq, models TT-100, TT-200 and TT-300 K201977</i>	Subject Device <i>SteadyTemp K233280</i>	Comparison
Storage Humidity Range	15 - 95% RH (non-condensing)	15 to 95% RH (non-condensing)	Identical

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

Note 2. The Display Use Specification for the predicate TempTraq System is similar to the proposed 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 battery used in the proposed SteadyTemp System differs from the predicate device, with two discrete 1.5V cells vs. a single 3V cell. This difference does not affect safety and effectiveness. Electrical safety testing was conducted in accordance with IEC 60601-1:2021 3rd Edition with amendment 1 and 2.

Note 4. The temperature accuracy for the proposed system SteadyTemp differs from the predicate Temp Traq device. Performance testing was conducted to demonstrate the subject device conforms with IEC 80601-2-56 for absolute temperature accuracy. The difference does not raise new or different safety and effectiveness questions.

Note 5. The signal transmission for the proposed system (NFC) differs from the predicate Temp Traq device (BLE). Performance testing was conducted to demonstrate this difference does not affect safety and effectiveness. The NFC communication is passive and much lower power the BLE.

Note 6. The Memory Function for the proposed SteadyTemp system differs from the predicate device. Performance testing was conducted to demonstrate this difference does not affect safety and effectiveness.

Note 7. The Storage for the proposed SteadyTemp 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 8. The Run Time for two new models (TT-200 and TT-300) of the predicate TempTraq System differs from the proposed SteadyTemp system. Performance testing was conducted to demonstrate this difference does not affect safety and effectiveness.

Note 9. The patient contacting material for the proposed SteadyTemp 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 10. The Applications for the proposed SteadyTemp 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 11. The dimensions for the proposed SteadyTemp system differ from the predicate device. This difference does not have any impact on safety or effectiveness.

Note 12. The Printed Circuit for the proposed SteadyTemp system is similar to the predicate device. Storage temperature difference is due to the battery in the device for optimal life and safe storage. Electrical Safety (IEC 60601-1 Edition 3.2) and EMC testing (IEC 60601-1-2 4.1 Edition) was conducted to demonstrate these differences do not impact safety and effectiveness.

VII. PERFORMANCE TESTING

The following non-clinical performance tests have been passed successfully:

- ISO 80601-2-56:2018 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.
- IEC 60601-1:2021 3rd Edition with amendment 1 and 2, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2: 2021 4th Edition with amendment 1, Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance– Collateral standard: Electromagnetic compatibility – Requirements and tests.
- IEC 60601-1-11:2021 Edition 1.2, 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 62304:2016 Edition 1.1, Medical device software - Software life cycle processes.
- Biocompatibility testing of patient contacting materials according to ISO 10993-1 including Irritation, Sensitization and Cytotoxicity.
- Bench test results verify that SteadyTemp system can continuously record temperature, store temperature data in the device memory, and transmit recordings to the SteadyTemp app via NFC app connection for display by the user. Test results verify that all requirements were met and that the SteadyTemp System performs as designed.
- Software documentation following enhanced documentation level of FDA guidance and prepared in accordance with IEC 62304 to verify and validate software performance of the SteadyTemp system.
- Cyber Security of the system has been addressed following FDA guidance assessing threats and addressing the subsequent potential risk to the system through design controls, access limitation and monitoring of software components for new threats.

VIII. CONCLUSIONS

The analysis of the differences between SteadyTemp and the predicate device does not raise new questions of safety and effectiveness. Based on device technological characteristics comparison, analysis, and performance test results, SteadySense determines that the SteadyTemp system performs within its design specifications and is substantially equivalent to the predicate device.