June 11, 2021

Masimo Corporation
Sindura Penubarthi
Regulatory Affairs Manager
52 Discovery
Irvine, California 92618

Re: K203215
Trade/Device Name: Radius T Wearable Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: May 6, 2021
Received: May 17, 2021

Dear Sindura Penubarthi:

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,

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)*
K203215

Device Name
Radius T Wearable Thermometer

Indications for Use *(Describe)*
Radius T wearable thermometer is intended for single-use, continuous noninvasive measurement of body temperature on the upper chest via wireless communication to a smart device application or compatible patient monitor (i.e., Masimo Root, Masimo Rad-97).

The Radius T is indicated for single-use, continuous body temperature measurements of persons 5 years of age or older in hospitals, hospital-type facilities, and home environments.

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.

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MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

# 510(k) Summary - K203215

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|---|---|
| Submitter and Address of Manufacturing Facility: | Masimo Corporation<br>52 Discovery<br>Irvine, CA 92618<br>Phone: (949) 297-7541<br>FAX: (949) 297-7592 |
| Date: | June 8, 2021 |
| Contact: | Sindura Penubarthi<br>Regulatory Affairs Manager<br>Masimo Corporation<br>Phone: (949) 396-4041 |
| Trade Name: | Radius T Wearable Thermometer |
| Common Name: | Electronic Clinical Thermometer |
| Classification Regulation/ Product Code: | 21 CFR 880.2910, Class II/ FLL |
| Establishment Registration Number: | 3011353843 |
| Reason for Premarket Notification: | New device |
| Predicate Device: | K181013- FeverScout Continuous Monitoring Thermometer |

## 1. Device Description

Radius T is a wearable, battery powered thermometer that is applied to the body to continuously provide body temperature measurements. The Radius T continuously approximates body temperatures based upon the surface temperature at the application site. The body temperature data from the Radius T is transferred wirelessly to a monitoring device (e.g., Root, Rad-97) or smart device application for continuous display and monitoring.

As part of this submission, the software of the Root (K191882) and Rad-97 (K193626) is being modified to support the communication and display compatibility for the Radius T.

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# 510(k) Summary

The performance specifications for Radius T are listed in **Table 1.1-1** below:

| Radius T Specifications | |
|---|---|
| **Feature** | **Specification** |
| Temperature Accuracy - Laboratory | ±0.1°C (±0.18°F) in the range of 25°C to 43°C (77°F to 109.4°F) |
| Temperature Accuracy - Clinical | Clinical bias of -0.2ºC (-0.36ºF) with limits of agreement ≤ 1.0ºC (1.8ºF). |
| Intended Population | 5 years or older |
| Application site | Upper Chest |
| Product use life/Battery life | Minimum of 8 days (192 hours) of continuous run time |
| **Environmental** | |
| Storage/Transport Temperature | -20°C to 50°C (-4°F to 122°F) |
| Operating Temperature | 10°C to 40°C (50°F to 104°F) |
| Storage/Transport Humidity | 10% RH to 95% RH (non-condensing) |
| Operating Humidity | 10% RH to 95% RH (non-condensing) |
| Atmospheric Pressure | 700 to 1060 hPa @ ambient temperature and humidity |
| **Wireless** | |
| Type | Bluetooth Low Energy |

## 2. Intended Use/ Indications For Use

Radius T wearable thermometer is intended for single-use, continuous noninvasive measurement of body temperature on the upper chest via wireless communication to a smart device application or compatible patient monitor (i.e., Masimo Root, Masimo Rad-97).

The Radius T is indicated for single-use, continuous body temperature measurements of persons 5 years of age or older in hospitals, hospital-type facilities, and home environments.

## 3. Technological Characteristics

### Principle of Action

To achieve its intended purpose, the Radius T relies on the principle that the heat flux generated by the body temperature can be inferred by measuring the skin surface temperature to allow for the estimation of the body temperature.

### Mechanism of Action for Achieving the Intended Effect

The Radius T achieves its intended effect through application of the battery powered thermometer to the skin surface on the patient's chest. The thermometer measures the skin surface temperature and estimates the body

# 510(k) Summary

temperature continuously. The estimated body temperature is transmitted wirelessly through a secure Bluetooth connection to a compatible device or software application. Once displayed, the temperature data can be stored or used to trigger threshold alarms on the connected device or software application.

## 4. Summary of Technological Characteristics of a Subject Device to the Predicate

The subject device, Radius T, and the predicate device, FeverScout (K181013), have the following key similarities:

- Both devices have the same intended use to continuously measure body temperature;
- Both devices estimate body temperature from a sensor applied to the skin surface;
- Both devices include single use adhesive sensors;
- Both devices rely on wireless communication for display of the body temperature.

The subject device, Radius T and the predicate device, FeverScout (K181013), have the following key differences:

- Subject device is applied to the chest while the predicate device is applied to an axial site;
- Subject device is intended for adults and pediatrics 5 years and older while the predicate is indicated for adults and pediatrics 29 days and older;
- Subject device includes a disposable sensor while the predicate device includes reusable patch with disposable tabs.

The subject device and predicate device were found to be substantially equivalent based upon both devices having the same intended use and no technological differences that raise new concerns of safety and effectiveness.

Between to the subject device and predicate device, the main technological difference is that the predicate device estimates body temperature from the armpit while the subject device estimates the body temperature from the chest. To support that this difference along with other technological difference do not significant affect the safety and effectiveness of the Radius T clinical and non-clinical testing was conducted. The test results supported the substantial equivalence of the Radius T.

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# 510(k) Summary

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|---|---|---|---|
| | **Radius T Wearable Thermometer** | **FeverScout (K181013)** | **Comparison to Predicate Device** |
| **510(k) Number** | **Subject Device** | **Predicate Device** | |
| **General Information** | | | |
| Indications for Use (IFU) | Radius T wearable thermometer is intended for single-use, continuous noninvasive measurement of body temperature on the upper chest via wireless communication to a smart device application or compatible patient monitor (i.e., Masimo Root, Masimo Rad-97).<br><br>The Radius T is indicated for single-use, continuous body temperature measurements of persons 5 years of age or older in hospitals, hospital-type facilities, and home environments. | The Wireless FeverScout TM continuous Monitoring thermometer is a non-invasive and re-usable electronic device for home use and non-invasive and single patient use in the hospital. This product is intended for non-urgent ambulatory continuous armpit temperature monitoring from ages 29 days and older | Subject device has a narrower indicated population of persons 5 years of age or older versus the predicate which is indicated for ages 29 days and older. The indicated population of the subject device was narrowed to align to the clinically tested population, age group C (older than 5 years) in accordance with ISO 80601-2-56.<br><br>The indication difference does not result in a new intended use as both devices are intended to be used as continuous monitoring thermometers. |
| Classification Regulation/ Product Code | 21 CFR 880.2910/ FLL | 21 CFR 880.2910/ FLL | Same |
| Regulation Description | Clinical electronic thermometer | Clinical electronic thermometer | Same |
| Principle of Operation | The Radius T relies on the principle that the temperature measured at the skin surface can be extrapolated to the body temperature.<br><br>The sensor within the Radius T detects the heat and measures the temperature using a resistance that changes with heat. | FeverScout relies on the principle that the temperature measured at skin surface can be extrapolated to the body temperature.<br><br>The sensor within the FeverScout detects the heat and measures the temperature using a resistance that changes with heat. | Similar. The subject device and predicate device are similar in that they both are based upon the principle that the body temperature can be extrapolated from the skin surface temperature. Both devices utilize a thermistor to detect the heat and measure the temperature based upon a resistance that changes with heat. The predicate device utilizes the adjustment from the armpit temperature, while the |

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|---|---|---|---|
| | **Radius T Wearable Thermometer** | **FeverScout (K181013)** | **Comparison to Predicate Device** |
| **510(k) Number** | **Subject Device** | **Predicate Device** | |
| | | | subject device utilizes temperature at the upper chest.<br><br>To support the difference does not significantly affect the safety and effectiveness of the subject device, the test methods described in the ISO 80601-2-56 standard were used. |
| **Technological Characteristics** | | | |
| Laboratory Accuracy | ±0.1°C in the range of 25°C to 43°C (±0.18°F in the range of 77°F to 109.4°F) | ±0.1°C in the range of 37 to 39°C (±0.18°F in the range of 98.6 to 102.2°F),<br><br>±0.2°C in the range of 35 to 37°C and 39 to 42°C (±0.36°F in the range of 95 to 98.6°F and 102.2 to 107.6°F) | Similar. Subject device has a tighter accuracy specification across a wider performance range. Provided the wider performance range there is no significant impact to the safety and effectiveness of the subject device. |
| Application Site | Upper Chest | Axillary | Different. The difference in application site was address through performance testing in accordance with ISO 80601-2-56. The testing supported the difference does not raise different questions of safety and effectiveness. |
| Validation Method | Conformed to ISO 80601-2-56 | Conformed to ASTM E1112 | Subject device is validated in accordance with ISO 80601-2-56 while the predicate device was validated in accordance with ASTM E1112. As the ISO 80601-2-56 is also recognized by the FDA, the use of |

# 510(k) Summary

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|---|---|---|---|
| | **Radius T Wearable Thermometer** | **FeverScout (K181013)** | **Comparison to Predicate Device** |
| **510(k) Number** | **Subject Device** | **Predicate Device** | |
| | | | the standard was not found to create a meaningful difference. |
| Type of Use (Sensor) | Disposable | Disposable for hospital use; Reusable for OTC | Similar. As both the subject and predicate devices can be used as a disposable, the difference was not found to result in a new intended use. |
| Type of Sensor | Thermistor | Thermistor | Same |
| Temperature Measurement Intervals | Transmits every 60 seconds | Transmits every 15 seconds | Similar. Subject device transmits data less frequently than the predicate. Although the data transmission frequencies are different, the difference is not significant as compared the expected timeframe for a meaningful change in body temperature. |
| **Wireless communication** | | | |
| Supported Devices | Mobile (Android, Apple), Masimo Patient Monitoring Devices (i.e., Rad-97, Root) | Mobile (Android, Apple) | Subject device includes communication to Masimo Patient Monitoring Devices (Root and Rad-97).<br><br>Software integration testing performed supports the difference is not significant. |
| Types | Bluetooth BLE | Bluetooth BLE | Same |
| **Mechanical** | | | |
| Type of Applicable | Wearable | Wearable | Same |
| Overall Dimension | 5” x 5” x 0.5” | 2.4” x 1.6” x 0.2” | Subject device is provided with a different form factor.<br><br>Human factors and usability evaluation supports the difference in form factor |

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|---|---|---|---|
| | **Radius T Wearable Thermometer** | **FeverScout (K181013)** | **Comparison to Predicate Device** |
| **510(k) Number** | **Subject Device** | **Predicate Device** | |
| | | | does not significantly affect the safety and effectiveness of the subject device. |
| Weight | 30 gms | 7.2 gms | Subject device has a different weight.<br><br>Human factors and usability evaluation supports the difference in form factor does not significantly affect the safety and effectiveness of the subject device. |
| **Biocompatibility** | | | |
| Biocompatibility | Conformed to ISO 10993-1, 5, 10 | Conformed to ISO 10993-1, 5, 10 | Same |
| **Electrical** | | | |
| Power Source | Internal Battery (Lithium Coin Cell) | Internal Battery (Lithium Rechargeable) | Similar. Both devices are provided with internal batteries. Subject device is disposable and therefore a rechargeable battery is not applicable. Therefore, the difference was not significant. |
| Battery Life | Minimum of 8 days (192 hours) of continuous run time | Minimum of 7 days of continuous run time | Similar. Subject device has a longer battery life. As the battery life was longer, the difference was not found to be significant. |
| Electrical Safety | Conformed to IEC 60601-1 | Conformed to IEC 60601-1 | Same |
| Electromagnetic compatibility | Conformed to IEC 60601-1-2 | Conformed to IEC 60601-1-2 | Same |
| **Environmental** | | | |
| Operating Temperature | 10°C to 40°C<br>50°F to 104°F | 10°C to 40°C<br>50°F to 104°F | Same |
| Operating Humidity | 10% RH to 95% RH (non-condensing) | 15% RH to 85% RH | Similar. Subject device is provided with a wider environmental specification; |

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|---|---|---|---|
| | **Radius T Wearable Thermometer** | **FeverScout (K181013)** | **Comparison to Predicate Device** |
| **510(k) Number** | **Subject Device** | **Predicate Device** | |
| | | | therefore, the difference was not found to be significant. |
| Atmospheric Pressure | 700 to 1060 hPa | 700 to 1060 hPa | Same |
| Operating Temperature | 10°C to 40°C<br>50°F to 104°F | 10°C to 40°C<br>50°F to 104°F | Same |
| Storage/ Transport Temperature | -20°C to 50°C<br>-4°F to 122°F | - | Predicate device does not disclose the storage or transport environmental conditions. The environmental condition testing conducted supports the subject device specifications for reasonable transport and storage conditions. As result, any difference was not found to be significant. |
| Storage/ Transport Humidity | 10% RH to 95% RH (non-condensing) | - | Predicate device does not disclose the storage or transport environmental conditions. The environmental condition testing conducted supports the subject device specifications for reasonable transport and storage conditions. As result, any difference was not found to be significant. |
| **Mode of Operation per IEC 60601-1** | | | |
| Mode of Operation | Continuous | Continuous | Same |

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# 510(k) Summary

## 5. Performance Data

### Performance Bench Testing

To support the temperature measurement performance of the Radius T, performance bench testing was conducted in accordance with ISO 80601-2-56 that compared the accuracy of the surface temperature measurements made by the Radius T against a reference temperature source to establish the laboratory accuracy. The performance bench testing supported the performance of the Radius T.

### Biocompatibility Testing

The patient contacting materials of the Radius T were tested in accordance with ISO 10993-1, 5 and 10 found to have acceptable biocompatibility.

### Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning

To support the safe use of the Radius T, testing to support EMC compliance with the IEC 60601-1-2 standard, Electrical Safety according to IEC 60601-1 standard, environmental, and mechanical requirements were provided as part of the submission. As the Radius T is disposable, considerations for cleaning were not applicable.

### Software Verification and Validation Testing

Software verification and validation testing was conducted and the documentation was provided as recommended by FDA's Guidance, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, dated May 11, 2005. The software for Radius T was considered as a "moderate" level of concern, because a failure or latent flaw in the software could directly result in minor to moderate injury to the patient. The testing was found to support the substantial equivalence of the subject device.

The software for Rad-97 and Root are considered as a "moderate" level of concern, because a failure or latent flaw in the software could directly result in minor to moderate injury to the patient. The testing to support the communication capability with the Rad-97 and Root software was provided to support this submission.

### Wireless and Cybersecurity Testing

As the Radius T uses wireless communication to the host device, wireless and cybersecurity considerations were made in accordance with FDA *Guidance for Industry and Food and Drug Administration Staff-Content of Premarket Submissions for Management of Cybersecurity in Medical Devices,* dated October 2, 2014 and draft guidance dated October 18, 2018.

In accordance with the FDA guidance for Cybersecurity, the Radius T was considered a Tier 2 cybersecurity risk device. To support the cybersecurity of the Radius T, a risk-based approach was used to

identify cybersecurity threats and mitigations. Cybersecurity testing was conducted to support the acceptability of the subject device's cybersecurity risk.

As the compatibility of the Radius T to the Rad-97 and Root did not affect the software architecture, the modification did not affect the acceptability of the cybersecurity risks of those devices.

**Human Factors and Usability Testing**

Human factors engineering/usability engineering (HFE/UE) activities for Radius T relied upon the representative testing of a previously cleared device with similar human factor and use characteristics. The HFE/UE activities were conducted in accordance with the FDA Guidance, *Applying Human Factors and Usability Engineering to Medical Devices, February 3, 2016.* The HFE/UE testing which used a risk-based approach accounted for the expected user related tasks to the use of the Radius T. The representative testing was found to support acceptability of the human factors and usability risks of the subject device.

**Non-clinical Testing**

Non-clinical bench testing was included to support the submission of the Radius T. The non-clinical testing was conducted in accordance with Masimo requirements to ensure that the specifications of the subject device were met. The following non-clinical testing was performed:

- Electrical safety testing per IEC 60601-1
- EMC testing per IEC 60601-1-2
- Usability testing per FDA Human Factors and Usability Guidance
- Software verification and validation testing per FDA Software Guidance
- Biocompatibility testing per ISO 10993-1
- Mechanical testing per IEC 60601-1

The testing was found to support the subject device met its design requirements.

**Clinical Testing**

To support the performance of the Radius T, clinical validation study was performed. The study evaluated the clinical performance of the Radius T to a reference clinical thermometer in accordance with ISO 80601-2-56.

**6. Conclusion**

The non-clinical and clinical data was found to support the Radius T is substantially equivalent to the predicate device.