Section 6 510(K) Summary

K171578

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4. Subject Device Information

Trade name	Infrared thermometer (Model A200 & A201)
Model	A200 & A201
Common name	Infrared thermometer
Classification name	Thermometer, Electronic, Clinical
Regulation number	21 CFR 880.2910
Product code	FLL

5. Predicate Device

Non-contact Clinical Thermometer, Model THB0F. (Radiant Innovation Inc, K121428)

RII Multi-function Infrared Thermometer, Model TH52Z. (Radiant Innovation Inc, K162083)

6. Description

The Infrared thermometers are hand-held, battery powered devices designed to measure human body temperature from the auditory canal or central forehead. Its operation is based on measuring the natural thermal radiation from the tympanic membrane or central forehead.

The thermometers use a thermopile sensor with integrated thermistor for the target reading, a thermistor mounted in the head of the thermometer for ambient temperature readings, a parabolic mirror to help focus the infrared energy emitted from the forehead, and an infrared distance sensor for detection of contact or no-contact use and compensation of the temperature reading.

The device consists of the MCU, enclosure and LED and the device is powered by 2 AAA alkaline batteries.

The device has a memory function that automatically stores 25 sets data of the latest measurements. It can also display the latest measurement result.

The Infrared thermometer included A200 & A201. A200 unit is a no- contact Infrared forehead thermometer, A201 unit is multi-function infrared thermometer and it can be selected Ear mode or Forehead mode.

7. Indications for Use

The Infrared thermometer model A200 is a non-contact infrared thermometer intended for the intermittent measurement of human body temperature by Forehead mode for people of all ages.

The Infrared thermometer model A201 is a multi-function infrared thermometer intended for the intermittent measurement of human body temperature by Ear mode or Forehead mode for people of all ages.

8. Summary of technological characteristics of device compared to the predicate devices, see the table1 and table2

A comparison of key similarities and differences between the subject devices (Model A200 and Model A201) and the predicate devices (K121428 and K162083) is provided below.

Table 1

SE Comparisons	Subject device(SD) A200	Predicate device(PD) Rdiant THB0F	Note
510K number	Present application	K121428	--
Regulation number	21 CFR 880.2910	21 CFR 880.2910	Same
Product code	FLL	FLL	Same
Intended Use& Indications for use	The Infrared thermometer model A200 is a non-contact infrared thermometer intended for the intermittent measurement of human body temperature by Forehead mode for people of all ages.	The Non-contact Clinical Thermometer, Model THB0F is an infrared thermometer intended for the intermittent measurement of human body temperature in people of all ages.	Same
Measurement Method	Infrared radiation detection	Infrared radiation detection	Same
Measurement Range	Forehead mode: 32.0°C ~42.9°C (89.6 to 109.22 ° F) Surface mode: 0°C ~99.9°C (32 ~210.2°F)	Forehead mode: 34.0°C ~42.2°C (93.2°F ~108.0°F) Surface mode: -22°C ~80°C (-7.6°F ~176°F)	Similar
Accuracy	Forehead mode: ±0.2°C (0.4°F) within 36.0°C ~39.0°C (96.8°F ~102.2°F), ±0.3°C(0.5°F) other range Surface mode: ±2% of reading or±1°C (±1.8°F) whichever is greater	Forehead mode: ±0.2°C (0.4°F) within 36~39°C(96.8~102°F), ±0.3°C(0.5°F) other range Surface mode: ±4% of reading or±2°C (±4°F) whichever is greater	Similar
Display	0.1°C(0.1°F)	0.1°C(0.1°F)	Same

Measurement distance	≤3cm	2-3cm	Similar
Measurement place	Forehead Surface	Forehead Surface	Same
Response time	1S	1S	Same
Sensor type	Thermopile	Thermopile	Same
Scale Selection	°C /°F	°C /°F	Same
Memory	25 sets	60sets	Similar
Buzzer	Yes	Yes	Same
Auto power-off while no operation	Yes	Yes	Same
Power supply	2 X 1.5V AAA	2 x AAA	Same
Display screen	LCD	LCD	Same
Contact materials	ABS	ABS	Same
Operation Environment	10~40°C(50°F ~104 °F) RH 15~95%	10~40°C(50°F ~104 °F) 15-85% RH	Similar
Storage Environment	-25 ~+55°C（-13~+131°F） RH:15~95%	-20~ +55°C（-4~+131°F） RH≤90%	Similar
Dimension	170*47*53mm	180.3*47.5*29.2mm	---
Weight	75g	104.7g	---
Conformance standard	ISO80601-2-56(performance), EN60601-1(Safety), IEC60601-1-2(EMC) ASTM E1965-98	ISO80601-2-56(performance), EN60601-1(Safety), IEC60601-1-2(EMC) ASTM E1965-98	Same

Table 2

SE Comparisons	Subject device(SD) A201	Predicate device(PD) TH52Z	Note
510K number	Present application	K162083	--
Regulation number	21 CFR 880.2910	21 CFR 880.2910	Same
Product code	FLL	FLL	Same
Intended Use& Indications for use	The Infrared thermometer model A201 is a multi-	The RII Multi-function Infrared Thermometer, Model	Same

	function infrared thermometer intended for the intermittent measurement of human body temperature by Ear mode or Forehead mode for people of all ages.	TH52Z is intended for the intermittent measurement of human body temperatures. The device is intended for the use at home by people of all ages including neonates and it can be selected Ear mode or Forehead mode.	
Measurement Method	Infrared radiation detection	Infrared radiation detection	Same
Measurement Range	Ear mode: 35.0 °C to 42.9°C (95～109.3℉) Forehead mode: 32.0 °C to 42.9°C (89.6～109.3℉)	Ear / Forehead mode: 93.2~108℉ (34~42.2℃)	Similar
Accuracy	±0.4°F (0.2°C) within 96.8~102.2°F (36~39°C), ±0.5°F (0.3°C) for other range.	±0.4°F (0.2°C) within 95~107.6°F (35~42°C), ±0.5°F (0.3°C) for other range.	Similar
Display resolution	0.1°C(0.1°F)	0.1°C(0.1°F)	Same
Measurement distance	≤3cm	≤1cm	Similar
Measurement place	Forehead Ear	Forehead Ear	Same
Response time	1S	1S	Same
Sensor type	Thermopile	Thermopile	Same
Scale selection	°C /°F	°C /°F	Same
Memory	25 sets	9sets	Similar
Buzzer	Yes	Yes	Same

Auto power-off while no operation	Yes	Yes	Same
Power supply	2 X 1.5V AAA	CR2032 *1	Same
Display screen	LCD	LCD	Same
Contact materials	ABS	ABS	Same
Operation Environment	+5°C to +40 °C (41 °F to 104 °F), humidity: 15 to 93% R.H.	10~40°C(50°F ~104 °F) 15-85% RH	Similar
Storage Environment	-25 °C to +70 °C (-13 °F to 158 °F), humidity: 15 to 93 % R.H.	-20~ +55°C（-4~+131°F） RH≤90%	Similar
Dimension	170*47*53mm	146.4*38.3*54.8mm	---
Weight	65g	63.3g	---
Conformance standard	ISO80601-2-56(performance), EN60601-1(Safety), IEC60601-1-2(EMC) ASTM E1965-98	ISO80601-2-56(performance), EN60601-1(Safety), IEC60601-1-2(EMC) ASTM E1965-98	Same

Analysis

From the comparison table1 and table2, the subject devices and predicate devices have the same Intended use & Indications for Use, Measurement place, Scale selection, Display screen, Auto power-off while no operation & Conformance standard. There are slightly differences between the devices and predicate devices as follows.

Difference clause	Discussion
Measurement Range& Accuracy	Both devices have different measurement range, but they have the same accuracy and the measurement range of subject devices meet the requirements of ISO80601-2-56.
Measurement distance	Measurement distance of the subject devices is not more than 3 cm, the predicate device's will be in the range of 2-3 cm. But the performance test result of A200 & A201 shows the accuracy meets the requirements within the distance range.

Memory	The memory capacity of predicate devices in K121428 and K162083 is difference from subject devices, but that does not impact on the safety and effectiveness of subject devices.
Operation &Storage Environment	Both devices have slightly different Operation & Storage Environment, but the A200 & A201 meets the requirements of ISO80601-2-56 & IEC60601-1.

Performance Data

- Compliance to applicable standards includes ISO80601-2-56, as well as IEC 60601-1, IEC 60601-1-2 and IEC60601-1-11 requirements.
- Biocompatibility Evaluation for contacting patient components meets the requirements of ISO 10993-5 and ISO10993-10.
- According to the standard of AAMI TIR30：2011,Effectiveness validation of cleaning method referenced in the User's Manual.
- Shelf life test result shows the subject device will be safe and effective using under the specified condition within 2 years.
- And then the following performance is verified.
  -Measurement Range& Accuracy
  -Measurement distance
  -Response time

Clinical data

According to the ASTM E 1965-98, the clinical trial was performed for people of all ages. The test report shows clinical accuracy meets the range claimed by manufacturer. It can conclude that the subject devices, model A200 & A201, are acceptable to measure human body's temperature.

Conclusion

Based on performance testing and compliance with acceptable voluntary standards, we believe that the Infrared thermometers model A200 & A201 are substantially equivalent to its predicate devices in K121428 & K162083.