June 5, 2024

Radiant Innovation Inc.
Lynn Chen
QA Manager
1F, No.3 Industrial E. 9th Rd.,
Science-Based Industrial Park
HsinChu, 300
Taiwan

Re: K240648
Trade/Device Name: Non-contact Forehead Thermomete (TH48FE, TH09F, THD2FE)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: February 26, 2024
Received: March 7, 2024

Dear Lynn Chen:

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240648

Device Name

Non-contact Forehead Thermometer (TH48FE, TH09F, THD2FE)

Indications for Use *(Describe)*

The non-contact forehead thermometer is an electronic thermometer using an infrared detector (thermopile detector) to detect body temperature from forehead center in people 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K240648 – 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. Submitter's Identification:

Radiant Innovation Inc.,
1F, No.3 Industrial E. 9th Rd., Science-Based Industrial Park, HsinChu, Taiwan
Name of contact person: Ms. Lynn Chen
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E-mail: lynnchen@radiantek.com.tw
Date Summary Prepared: Jun/05/2024

2. Device:

Device Trade Name: Non-contact Forehead Thermometer (TH48FE, TH09F, THD2FE)
Classification Name: Thermometer, Electronic, Clinical
Device Classification: Class II
Regulation Number: 21CFR 880.2910
Device Panel: General Hospital
Product Code(s): FLL

3. Predicate Device :

510(k) #K121428
Device Trade Name: RII, Non-Contact Clinical Thermometer, Model THB0F
Classification Name: Thermometer, Electronic, Clinical
Device Classification: Class II
Regulation Number: 21CFR 880.2910
Device Panel: General Hospital
Product Code(s): FLL

4. Device Description:

The thermometer (Mode: TH48FE, TH09F, THD2FE) are electronic thermometer using an IR sensor to measure infrared energy radiated from the forehead. This energy is collected through the lens and converted to an oral temperature value.
The thermometer (Mode: TH48FE, TH09F, THD2FE), consists of the following parts:

(1) IR sensor with a built-in ambient temperature sensor (Function: Receives infrared signals radiated by temperature)

(2) Application-Specific Integrated Circuitry include software (Function: Calculate the infrared signal from the forehead and convert it into oral temperature)

(3) LCD display (Function: Display measurement results)

(4) 2 buttons (Star button, Scan button), 1 button for TH09F (Function: Start booting and measuring actions)

(5) 2×1.5V AAA dry batteries, 1 x 3.0V CR2032 battery for TH09F) (Function: Provide product power)

5. Indications for Use:

The non-contact forehead thermometer is an electronic thermometer using an infrared detector (thermopile detector) to detect body temperature from forehead center in people of all ages.

6. Comparison of technological characteristics with the predicate device:

Characteristics	**Subject device (TH48FE/TH09F/THD2FE)**	**Predicate device (THB0F)**	**Comment**
510(k)#	K240648	K121428	/
Manufacturer	Radiant Innovation Inc.	Radiant Innovation Inc.	Same
Indications for use	The non-contact forehead thermometer is an electronic thermometer using an infrared detector (thermopile detector) to detect body temperature from forehead center in 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
Intended user	Lay person	Lay person	Same
Measuring Range	Forehead mode: 82.4~109.4°F(28~43℃) for TH48F/TH09F 93.2~108°F(34~42.2℃) for THD2Fe Surface mode: -7.6~176°F(-22~80℃) for TH48FE/THD2FE	Forehead mode: 93.2~108°F(34~42.2℃) Surface mode: -7.6~176°F(-22~80℃)	Different [1]
Accuracy	Forehead mode: ±0.4 °F (0.2℃) within 95~107.6°F (35~42°C), ±0.5 °F (0.3℃) for other range. Surface mode (for TH48FE/ THD2FE): 0.5°F (±0.3°C) within	Forehead mode: ±0.4°F(0.2℃) within 96.8~102°F(36~39℃), ±0.5 °F(0.3℃) for other range Surface mode: ±4% of reading or ±4°F(2℃) whichever is greater	

	93.2~109.4°F (34~43°C), others ±4% or ±4°F (2°C) whichever is greater.		
Display Resolution	0.1℉(0.1℃)	0.1℉(0.1℃)	Same
Memory	25 sets for TH48FE/THD2FE 1 set for TH09F	60 sets	Different [2]
Scale Selection	℉/℃	℉/℃	Same
Display Type	LCD	LCD	Same
Sensor Type	Thermopile	Thermopile	Same
Case	ABS	ABS	Same
Power Source	AAA(1.5V)*2 for TH48FE/THD2FE CR2032(3V)*1 for TH09F	AAA(1.5V)*2	Different [3]
Operating Condition	50~104℉(10~40℃)	50~104℉(10~40℃)	Same
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10	Same
Performance	ASTM 1965-98 ISO 80601-2-56	ASTM 1965-98 ISO 80601-2-56	Same
Electric Safety and EMC	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11	Same

Justification for the differences:

1) Different Measurement range/ Accuracy:

The measurement range and accuracy of the device under evaluation is different from the marked equivalent device. While the device under evaluation have been tested and validated according to standard ISO 80601-2-56 including accuracy and the measuring range of the device under evaluation meet the accuracy and the minimum rated output range of clinical thermometer requirement, therefore, such difference will not affect the safety and performance of the device under evaluation.

2) Different of Memory:

The memory function of subject devices has been validated in accordance IEC 62304 and FDA Guidance for the Content of Premarket Submissions for Software Contained. The difference will not raise safety or effectiveness issues on the subject devices.

3) Different of Power Supply:

The power supply of TH09F is 1 x CR2032 battery that different from other models, all devices have been proven to be safe and effective based on the IEC 60601-1 and IEC 60601-1-2 testing.

The Non-contact Forehead Thermometer, Model TH48FE, TH09F, THD2FE have the similar characteristics as the predicate device. Moreover, the subject devices demonstrate product safety by successful completion of testing to the IEC 60601-1 standard and electromagnetic standard IEC 60601-1-2. The performance test demonstrates the TH48FE, TH09F, THD2FE meet the ISO 80601-2-56 standard and concludes that any difference in their characteristics do not raise any safety and effectiveness issues. Thus, the Non-contact Forehead Thermometer, Model TH48FE, TH09F, THD2FE are substantially equivalent to the predicate device.

7. Summary of non-clinical testing (Performance testing-bench):

The following performance data were provided to verify that the subject device met all design specifications and provided support of the substantial equivalence determination.

- Risk Analysis developed in according with ISO 14971:2019
- The recognized consensus standards for safety of medical electrical equipment: IEC 60601-1, IEC 60601-1-11 for safety and IEC 60601-1-2 for electromagnetic compatibility are complied.
- Biocompatibility Evaluation for patient contacting components: ISO 10993-5, ISO 10993-10 and ISO 10993-23 are complied.
- Bench testing was conducted on the thermometer device. The system complies with the ISO 80601-2-56.
- Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions". The software for this device was considered as a "Basic" documentation level.

8. Summary of clinical Accuracy Validation Test:

Clinical testing is conducted per ISO 80601-2-56 Clause 201.102 Clinical Accuracy Validation. The Clinical tests were evaluated on 113 subjects and thermometer was evaluated in three age groups including subgroup A1 and A2: A1-one month up to three months and A2-three months to one year, B-older than one years and younger than five years and C-older than five years old. Subjects selected for each model in this clinical trial are: A1) group 15, A2) group 21, B) group 38 and C) group 39. Total number of subjects is 113.

The test report showed the clinical performance of the subject devices complied with the

requirement of ISO 80601-2-56.

9. Conclusions:

Based on comparison of the Indications for use and technological characteristics applicable safety standards, verification and validation testing, the differences between Non-contact forehead thermometer (TH48FE, TH09F, THD2FE) and predicate device do not raise new or different questions of safety and effectiveness. Thus, the Non-contact Forehead Thermometer, Model TH48FE, TH09F, THD2FE are substantially equivalent to the predicate device.