December 5, 2023

T&R BIOFAB CO., LTD.
% Edward Park
CEO
LightenBridge LLC
4408 Tortuga Ln
McKinney, Texas 75070

Re: K222057
Trade/Device Name: Thermoclick, Model MT-3000
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: November 4, 2023
Received: November 6, 2023

Dear Edward Park:

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

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.

510(k) Number *(if known)*
K222057

Device Name
THERMOCLICK, Model MT-3000

Indications for Use *(Describe)*
The THERMOCLICK is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home. The device can be used in connection with a smart phone running the THERMOCLICK Mobile Application. The memory data can be transferred to the smart phone via Bluetooth.

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.

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T&R BIOFAB CO., LTD.
542, KOREA POLYTECHNIC UNIVERSITY,
237, Sangidaehak-ro, Siheung-si, Gyeonggi-do
15073 Republic of Korea
Tel. +82-31-431-3344 / Fax. +82-31-8041-1783

510(k) Summary – Traditional 510(k)

K222057

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

Submitter Information

Submitter Name:	T&R BIOFAB CO., LTD.
Address:	96, Mayu-ro, Siheung-si, Gyeonggi-do 15111 Republic of Korea
Phone/Fax	+82-31-431-3344 / +82-31-8041-1783
Contact Person:	Edward Park, official correspondent of T&R BIOFAB CO., LTD.
Preparation Date:	Nov 28, 2023

Device Information

Proprietary Name(s):	THERMOCLICK
Model Name:	MT-3000
Common Name:	Non-contact Infrared Thermometer
Regulation Name:	Clinical Electronic Thermometer
Product Code:	FLL
Regulation Number:	21 CFR 880.2910
Classification Panel:	General Hospital
Device Class:	II

Device Description

THERMOCLICK is a battery powered non-contact infrared thermometer that is intended to be used for the monitoring of body temperature of people of all ages. The reference body site of the output temperature is the axilla. With a sensor built into the product, it measures the infrared energy emitted from the skin surface of the forehead within 2cm so there is no need for contact with the skin. It can be used in the home or by a doctor in a clinic. It is indicated for use by people of all ages. After measurement, the temperature is directly displayed on the LED screen. The functions of the THERMOCLICK are controlled by software (firmware), and the user can also receive temperature data from a smartphone application via Bluetooth.

T&R BIOFAB CO., LTD.
542, KOREA POLYTECHNIC UNIVERSITY,
237, Sangidaehak-ro, Siheung-si, Gyeonggi-do
15073 Republic of Korea
Tel. +82-31-431-3344 / Fax. +82-31-8041-1783

These thermometers have the following features:

1) Body temperature mode
2) Fahrenheit and Celsius temperature unit setting
3) LED display screen with automatic range selection, resolution is 0.1°C (0.1°F)
4) Body temperature measurement results can be checked through Bluetooth communication.
5) Memorize the latest 1000 measurement results
6) Low battery indication
7) Over range prompt (High temperature indication & Low temperature indication is available by being displayed in color on the screen)
   : Below 36°C = Orange
   36°C ~ 37.6°C (96.8°F ~ 99.7°F) = Green
   37.6°C ~ 38.5°C (99.7°F ~ 101.3°F) = Orange
   Over 38.5°C (101.3°F) = Red
8) Auto shutdown when the device is idle for 15 seconds when Bluetooth operation is turned off. In the case of Bluetooth operation, the power is automatically turned off after 1 minute and 15 seconds.

The THERMOCLICK hardware device can work with THERMOCLICK, a mobile application via Bluetooth connection. The application receives and manages the measured temperature data from the thermometer. This app is not a mandatory component to use THERMOCLICK, but an option for the additional function to provide the users. The mobile app is operated on Android and iOS systems and can be downloaded/installed from each app store.

Predicate Device

- Microlife Non-Contact Infrared Forehead Thermometer, Model FR1MF1-B (NC150 BT)
  - 510(k) Number: K211776
  - Regulation Name: Clinical Electronic Thermometer
  - Device Class: II
  - Product Code: FLL
  - Regulation Number: 21 CFR 880.2910
  - Classification Panel: General Hospital

Indications for Use

The THERMOCLICK is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home. The device can be used in connection with a smart phone running the THERMOCLICK Mobile Application. The memory data can be transferred to the smart phone via Bluetooth.

T&R BIOFAB CO., LTD.
542, KOREA POLYTECHNIC UNIVERSITY,
237, Sangidaehak-ro, Siheung-si, Gyeonggi-do
15073 Republic of Korea
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Technological Characteristics

The THERMOCLICK retains the same basic design components and operating features as the predicate device, Microlife Non-Contact Infrared Forehead Thermometer, Model FR1MF1-B (NC150 BT) (K211776). The functionality of the user interface is also the same as the predicate device including mobile application. The power is supplied by AA type battery. The design of the subject device is also similar to the predicate device.

Substantial Equivalence Discussion

THERMOCLICK has been compared to the Microlife Non-Contact Infrared Forehead Thermometer Model FR1MF1-B (NC150 BT) (K211776) for demonstrating substantial equivalence. A table comparing these devices is provided as follows.

Device Name	Proposed Device	Predicate	Remark
	THERMOCLICK, Model MT-3000	**Microlife Non-Contact Infrared Forehead Thermometer Model FR1MF1-B (NC150 BT)**	
510k number	**K222057**	**K211776**	
Manufacturer	**T&R BIOFAB CO., LTD.**	**Microlife Intellectual Property GmbH**	
Product Code	FLL	FLL	Identical
Regulation Number	880.2910	880.2910	Identical
Indications for Use	The THERMOCLICK is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home. The device can be used in connection with a smart phone running the THERMOCLICK Mobile Application. The memory data can be transferred to the smart phone via Bluetooth.	The Microlife Non-Contact Infrared Forehead Thermometer, Model FR1MF1-B (NC150 BT) is intended for the intermittent measurement and monitoring of human body temperature. The device is indicated for use by people of all ages in the home. The device can be used in connection with a smart phone running the «Microlife Connected Health +» APP. The memory data can be transferred to the smart phone via Bluetooth.	Similar

T&R BIOFAB CO., LTD.
542, KOREA POLYTECHNIC UNIVERSITY,
237, Sangidaehak-ro, Siheung-si, Gyeonggi-do
15073 Republic of Korea
Tel. +82-31-431-3344 / Fax. +82-31-8041-1783

Device Name	**Proposed Device**	**Predicate**	**Remark**
	THERMOCLICK	**Microlife Non-Contact Infrared Forehead Thermometer Model FR1MF1-B (NC150 BT)**	
510k number	**K222057**	**K211776**	
Manufacturer	**T&R BIOFAB CO., LTD.**	**Microlife Intellectual Property GmbH**	
Prescription/OTC	Over-the-Counter use	Over-the-Counter use	Identical
Intended User	Lay user and professional	Lay user and professional	Identical
Intended Patient Population	All ages	All ages	Identical
Sensor Type	Thermopile (Name: JEDS74)	Thermopile & Thermistor	Similar
Operational Principle	Infrared radiation detection	Infrared radiation detection	Identical
Contact type	Non-contact use	Non-contact use	Identical
Display type	LED display	LCD display	Different
Measuring location (human)	Forehead	Forehead	Identical
Reference body Site	Axilla	Axilla	Identical
User Interface	Display panel, exposure buttons, application on the mobile device	Display panel, exposure buttons, application on the mobile device	Identical
Dimension	148.5 × 38.5 × 46.0 mm	141.1 × 43.3 × 36.9 mm	Similar
Weight (w/o batteries)	85 g	67 g	Similar

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Device Name	Proposed Device	Predicate	Remark
	THERMOCLICK	**Microlife Non-Contact Infrared Forehead Thermometer Model FR1MF1-B (NC150 BT)**	
510k number	**K222057**	**K211776**	
Manufacturer	**T&R BIOFAB CO., LTD.**	**Microlife Intellectual Property GmbH**	
Measurement Range	22.0°C (71.6°F) ~ 42.2°C (107.9°F)	34°C (93.2°F) ~ 43°C (109.4°F)	Similar
Measurement Accuracy	36 °C ~ 39 °C (96.8 °F ~102.2 °F) ➔ ± 0.2 °C (± 0.4 °F) Other range ➔ ± 0.3 °C (± 0.6 °F)	34.0°C~ 34.9°C (93.2°F~94.8°F) ➔ ±0.3°C (±0.6°F) 35.0°C~ 42.0°C (95°F~107.6°F) ➔ ±0.2°C (±0.4°F) 42.1°C~ 43.0°C (107.8°F~109.4°F) ➔ ±0.3°C (±0.6°F)	Similar
Measurement Distance	Within 2 cm	Within 5 cm	Different
Power Supply	3V DC (2 ea of AA type batteries)	3V DC (2 ea of AAA type batteries)	Different
Measurement Time	Within 1 second	Unknown	
Memory Capacity	1000 sets	30 sets	Different
Auto-Shutdown time	When Bluetooth operation is turned off: 15 seconds In case of Bluetooth operation : 1 minute and 15 seconds	60 seconds	Different

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237, Sangidaehak-ro, Siheung-si, Gyeonggi-do
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Device Name	Proposed Device	Predicate	Remark
	THERMOCLICK	Microlife Non-Contact Infrared Forehead Thermometer Model FR1MF1-B (NC150 BT)	
510k number	K222057	K211776	
Manufacturer	T&R BIOFAB CO., LTD.	Microlife Intellectual Property GmbH	
Operation Condition	Temperature: 15°C ~ 40°C Humidity: 15% ~ 90% Atmospheric Pressure : 80kPa~106kPa Altitude: Less than 2000 m	Temperature : 15°C~40°C(59°F~104°F) Relative Humidity: 15%~95% Atmospheric Pressure: Unknown	Similar
Storage and Transportation Condition	Temperature: -20°C ~ 50°C Humidity: 0% ~ 95% Atmospheric Pressure: 50kPa~106kPa	Temperature : -25°C~55°C(-13°F~131°F) Relative Humidity: 15%~95% Atmospheric Pressure: Unknown	Similar
Materials of Skin-Contacting Components	ABS	ABS	Identical
Electrical Safety	IEC 60601-1	IEC 60601-1	Identical
EMC	IEC 60601-1-2	IEC 60601-1-2	Identical
Performance	ASTM E1965-98 & ISO80601-2-56	ASTM E1965-98 & ISO80601-2-56	Identical
Bluetooth version	4.2 LE	4.0	Different
Compatible Mobile Application	Yes, (name: THERMOCLICK)	Yes (Name: Microlife Connected Health +)	Identical

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15073 Republic of Korea
Tel. +82-31-431-3344 / Fax. +82-31-8041-1783

Device Name	Proposed Device	Predicate	Remark
	THERMOCLICK	**Microlife Non-Contact Infrared Forehead Thermometer Model FR1MF1-B (NC150 BT)**	
510k number	**K222057**	**K211776**	
Manufacturer	**T&R BIOFAB CO., LTD.**	**Microlife Intellectual Property GmbH**	
Purpose of Mobile Application	The memory data can be transferred to the smart phone via Bluetooth to record patient temperature history	The memory data can be transferred to the smart phone via Bluetooth to record patient temperature history	Identical

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542, KOREA POLYTECHNIC UNIVERSITY,
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Discussion

Based on above comparison chart, differences between predicate and subject device are as follows,

A. Indications for Use

The proprietary name of the proposed device is THERMOCLICK, and the predicate device is Microlife Non-Contact Infrared Forehead Thermometer Model FR1MF1-B. This difference does not raise any new safety and effectiveness questions.

B. Sensor Type

The sensor type of the proposed device is only thermopile, whereas the predicate device has both thermopile and thermistor. It is not identical, but the safety and efficacy of the subject device is evaluated through performance testing. Therefore, the difference doesn't raise new or different safety and effectiveness questions.

C. Display type

The display type is also different. But the LED display of THERMOCLICK operates identically to the display of the predicate device. The color-coded light on the LED display of the proposed device simply helps users to recognize which temperature range their measured body temperature is currently within. Software verification and validation testing have been performed on the subject device, and the results complied with the requirements. This doesn't raise new or different safety and effectiveness questions.

D. Weight

Considering the weight of the two batteries, the THERMOCLICK weighs 133g, while the predicate device weighs 91g. Despite their weights, both devices are significantly lighter than a tall size cup of water, ensuring ease of handling. Therefore, the weight difference between the two devices is negligible and does not raise any safety or effectiveness concerns.

E. Measurement Range

The THERMOCLICK has a broader range compared to the predicate device, extending coverage to include the 22~34°C range. However, the total measurement range of THERMOCLICK is in compliance with the ASTM E 1965-98 standard and does not raise any new safety and effectiveness questions.

F. Measurement Accuracy

THERMOCLICK' measurement accuracy is ± 0.3 °C within 22.0 ~ 36.0 °C and 39.0 ~ 42.2°C ranges. But within 36.0 ~ 39.0 °C, the accuracy is ± 0.2 °C.
Compared to the predicate device, THERMOCLICK performs with different accuracy in the 35 ~ 36 °C and 39 ~ 42 °C ranges. In these particular ranges, THERMOCLICK's accuracy varies by ± 0.3 °C, while the reference device maintains an accuracy of ± 0.2 °C.

However, the accuracy performance of THERMOCLICK complies with the established standards of ASTM E1965-98. The difference does not raise new safety and effectiveness questions.

G. Measurement Distance

The difference in measurement distances between the THERMOCLICK (within 2 cm) and the predicate device (within 5 cm) is indeed notable. However, the clinical accuracy was conducted in accordance with ISO 80601-2-56 and the test results met the requirements. Therefore, this difference does not lead to any new safety or effectiveness concerns.

H. Power supply and Memory Capacity

The subject device incorporates bigger batteries, which means bigger power capacity. The electrical safety testing and software validation were conducted. The test results met the requirements. The differences do not raise any safety and effectiveness questions.

I. Auto Shutdown Time

The proposed device differs from the predicate device in terms of the 'lead time for Auto-Shutdown', which varies based on the status of the Bluetooth operation. With Bluetooth operation turned off, the proposed device has a shorter lead time compared to the predicate device. Conversely, when the Bluetooth operation is turned on, the lead time extends beyond that of the predicate device. However, software verification and validation were conducted for the proposed device, demonstrating these differences do not raise any new or different safety and effectiveness concerns.

J. Operating Condition

The difference in operating condition is humidity factor. However, THERMOCLICK has passed humidity testing under conditions exceeding 95% humidity, in accordance with the ASTM E1965-98 standard requirements. The measurement accuracy results of THERMOCLICK fall within the acceptance criteria set in the Standard. Therefore, this discrepancy raises no concerns regarding safety and effectiveness.

K. Storage and Transport Condition

The storage and transportation conditions of both THERMOCLICK and the predicate device fall within safe and functional ranges for medical devices. The temperature range for THERMOCLICK is -20°C to 50°C, which is slightly narrower than the predicate device's range of -25°C to 55°C. However, THERMOCLICK's intended temperature and humidity ranges align precisely with the ASTM E1965-98 standard requirements for storage & transport conditions. Moreover, THERMOCLICK has successfully undergone the accuracy test after storage and/or transport under these specific conditions and

requirements. Therefore, this discrepancy does not raise any safety or effectiveness concerns.

L. Bluetooth version

THERMOCLICK uses a Bluetooth version of 4.2 LE, whereas the predicate device uses 4.0. THERMOCLICK has successfully undergone the Bluetooth RF Test in accordance with EN 300 328 V.2.2.2 (2019-07), and the result met the requirement of data transfer. The difference does not raise any new safety and effectiveness questions.

Non-Clincial Test Summary

Non-clinical test was performed in accordance with the following international standards,

A. Electromagnetic Compatibility and Electrical Safety Test

- AAMI ANSI ES60601-1:2005+A1:2012, Medical Electrical Equipment – Part 1; General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2:2015, Medical Electrical Equipment – Part 1-2: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements And Tests
- IEC 60601-1-11:2015, 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

B. Biocompatibility Test

- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-23: 2021 Biological evaluation of medical devices - Part 23: Tests for Irritation

C. Performance Test-Bench

- ASTM E1965-98 (Reapproved 2016) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
- Clinical accuracy validation was conducted in according to ISO 80601-2-56:2017+A1:2018, EN ISO 80601-2-56:2017+A1:2020. This clinical study is a randomization, simple blind homologous control, pairing design of clinical investigation, consisting of 140 subjects, of which 50 subjects are Infants, 45 subjects are Children, and the rest 45 subjects are greater than five years old. The clinical validation results

demonstrated that the clinical data, represented by clinical bias and clinical repeatability met the acceptance criteria of the clinical validation protocol.

D. Software Verification and Validation

- ANSI AAMI IEC 62304:2006+A1:2015, Medical Device Software – Software Life Cycle Processes
- ANSI AAMI IEC 62366-1:2015+A1:2020, Medical devices Part 1: Application of usability engineering to medical devices
- EN ISO 14971:2019 Medical devices - Applications of risk management to medical devices
- IEC 60601-1-6:2010+A1:2013, Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety And Essential Performance – Collateral Standard: Usability
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- FDA Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- The software of the subject device is consistent with moderate level of concern. System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met, and all software hazards have been mitigated to acceptable risk levels.

Conclusion

The subject device is substantially equivalent in the areas of indications for use, general functions & features, principle of operation, technological characteristics, and applicable safety standards. The new device does not introduce fundamentally new scientific technology, and the successful results of bench testing and clinical accuracy validation should be sufficient evidence of substantial equivalence. Therefore, we conclude that the subject device described in this submission is substantially equivalent to the predicate device.