March 1, 2022

Microlife Intellectual Property GmbH
℅ Vaibhav Rajal
Official Correspondent for Microlife Intellectual Property GmbH
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K211776
Trade/Device Name: Microlife Non-Contact Infrared Forehead Thermometer, Model FR1MF1-B (NC150 BT)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: January 27, 2022
Received: January 28, 2022

Dear Vaibhav Rajal:

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,

Gang Peng for
Payal Patel
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

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)*
K211484

Device Name
Disposable Sterile Syringe with Safety Needle; Disposable Sterile Syringe with Needle; Disposable Sterile Syringe; Disposable Safety Needles

Indications for Use *(Describe)*

Disposable Sterile Syringe with Safety Needle

The disposable sterile syringe with safety needle is intended for use in the aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle sticks.

Disposable Sterile Syringe with Needle

The disposable sterile syringe with needle is intended for use the aspiration and injection of fluids for medical purpose.

Disposable Sterile Syringe

The disposable sterile syringe is a sterile luer lock or luer slip syringe which is intended to be used with a hypodermic needle for the aspiration and injection of fluids for medical purpose.

Disposable Safety Needles

The disposable safety needles are intended to be used with a luer slip or luer lock syringe for aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

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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510(k) SUMMARY

The assigned 510(k) number is: K211776

Applicant's Name: Microlife Intellectual Property GmbH, Switzerland
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Preparation Date: Jan 13, 2022

Trade Name: Microlife Non-Contact Infrared Forehead Thermometer, Model FR1MF1-B (NC150 BT)

Common or Usual Name: Clinical Electronic Thermometer

Regulation Name: Clinical Electronic Thermometer
Regulation Number: 21 CFR 880.2910
Product Code: FLL
Regulatory Class: Class II
Primary Predicate Device: K191829, Microlife Non-Contact Infrared Forehead Thermometer, Model FR1DG1 (NC200)

Device Description and Mode of Operation

The Microlife Non-Contact Infrared Forehead Thermometer, Model FR1MF1-B (NC150 BT) is an electronic thermometer using an infrared sensor, which is composed of thermistor and thermopile, to measures infrared energy radiated from the forehead as well as objects. This energy is collected through the lens and converted to a temperature value. The thermistor measures the ambient temperature of the sensor by changing the resistance. The function of thermopile is to measure the voltage difference between the temperature corresponding to the infrared radiation induction and the temperature difference measured by thermistor. Based on the voltage difference, difference temperature can be calculated, and the target temperature can be obtained by adding thermistor's temperature.

The Microlife Non-Contact Infrared forehead thermometer, Model FR1MF1-B (NC150 BT), consists of the following parts:

a) Thermopile Sensor
b) Microcontroller Unit
c) LCD and Backlight
d) 4 buttons (“START” button, “ON/OFF” button, “M” button, “MODE” button)
e) Alkaline batteries; size AAA, 2 x 1.5 V
f) Lens
g) Bluetooth module

The Model FR1MF1-B (NC150 BT) has the same intended use, temperature measurement fundamental algorithm, as the predicate device 510(k) K191829 Microlife Non-Contact Infrared Forehead Thermometer, Model FR1DG1 (NC200) , even though a Bluetooth function is added. The modified device FR1MF1-B (NC150 BT) and predicate device FR1DG1 (NC200) are using an infrared sensor (thermopile) to measure infrared energy radiated from the forehead as well as objects.

Indications for Use:

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.

Substantial Equivalence Discussion:

Both devices use infrared technology to measure and monitor the body temperature by the site of Forehead.

Microlife Non-Contact Infrared Forehead Thermometer FR1MF1-B (NC150 BT) has been compared to the Microlife Non-Contact Infrared Forehead Thermometer FR1DG1 (NC200) (510(k) K#191829) as a predicate device for substantial equivalence. A table comparing the two devices is provided as follows:

Item	1. Subject Device Microlife Non-Contact Infrared Forehead Thermometer FR1MF1-B (NC150 BT) K211776	2. Predicate Device Microlife Non-Contact Infrared Forehead Thermometer FR1DG1(NC200) K191829	Similar or Different 1 vs 2
Indications for use	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.	The Microlife Non-Contact Infrared Forehead Thermometer, Model FR1DG1 (NC200) 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.	Different see below (1)
Thermometer type	Infrared thermometer	Infrared thermometer	√
	Non-Contact	Non-Contact	
Device Measurement Technology	Infrared	Infrared	√
Temperature Measurement distance	Appropriate within 5 cm	Appropriate within 5 cm	√
Operating Mode	Adjusted mode	Adjusted mode	√
Measuring location(human)	Forehead	Forehead	√
Appearance (ID design)			Different see below (2)
Physical Dimension	141.1 x 43.3 x 36.9 mm	156.7 x 43 x 47 mm	Different see below (2)
Weight	90 g (with batteries), 67 g (w/o batteries)	91.5 g (with batteries), 68.5 g (w/o batteries)	Different see below (2)

Item	1. Subject Device Microlife Non-Contact Infrared Forehead Thermometer FR1MF1-B (NC150 BT) K211776	2. Predicate Device Microlife Non-Contact Infrared Forehead Thermometer FR1DG1(NC200) K191829	Similar or Different 1 vs 2
Power supply	3.0V DC with 2 AAA batteries	3.0V DC with 2 AAA batteries	√
Display resolution	0.1°C or 0.1°F	0.1°C or 0.1°F	√
Measuring range	34.0-43 °C / 93.2-109.4 °F	34.0-43 °C / 93.2-109.4 °F	√
Accuracy (Body mode/ laboratory)	±0.2 °C: 35.0 ~ 42.0 °C ±0.3 °C: 34.0 ~ 34.9 °C，42.1 ~ 43.0 °C ±0.4 °F: 95.0 ~ 107.6 °F ±0.5 °F: 93.2 ~94.8 °F，107.8~109.4 °F	±0.2 °C: 35.0 ~ 42.0 °C ±0.3 °C: 34.0 ~ 34.9 °C，42.1 ~ 43.0 °C ±0.4 °F: 95.0 ~ 107.6 °F ±0.5 °F: 93.2 ~94.8 °F，107.8~109.4 °F	√
Operating conditions	Body mode: 15~40°C (59°F~104°F), 15-95 % relative maximum humidity	Body mode: 15~40°C (59°F~104°F), 15-95 % relative maximum humidity	√
Storage conditions	-25 ~ 55 °C(-13°F ~131°F) 15-95 % relative maximum humidity	-25 ~ 55 °C(-13°F ~131°F) 15-95 % relative maximum humidity	√
Object mode	Yes	Yes	√
Reference site	Oral	Oral	√
Display type	LCD display	LCD display	√
Date, time, and beeper setting	Yes	Yes	√
Memory	30 sets memories	30 sets memories	√
Error display user interface (known as UI)	Display  When system has a malfunction	Display  or  When system has a malfunction.	Different see below (3)
Backlight	Green and red backlight according to the measured temperature	Green and red backlight according to the measured temperature	√
Automatic Switch-off	Approx. 1 minute after last measurement has been taken	Approx. 1 minute after last measurement has been taken	√
Beeper indication	Yes	Yes	√

Item	1. Subject Device Microlife Non-Contact Infrared Forehead Thermometer FR1MF1-B (NC150 BT) K211776	2. Predicate Device Microlife Non-Contact Infrared Forehead Thermometer FR1DG1(NC200) K191829	Similar or Different 1 vs 2
High temperature alarm	10 short beeps and a red LCD backlight alert the patient that he/she may have a temperature equal to or higher than 37.5 °C	10 short beeps and a red LCD backlight alert the patient that he/she may have a temperature equal to or higher than 37.5 °C	√
Auto measurement	None.	The device can take a measurement automatically when the device detects the distance is appropriate within 5 cm.	Different **see below(4)**
Measuring Algorithm	Measuring algorithm	Measuring algorithm	√
Firmware version	PH18.1	PH15.0	Different **see below(5)**
Signal processing	24 bit analog-to digital converter	24 bit analog-to digital converter	√
Sensor type	Thermopile (TPS336)	Thermopile (TPS336)	√
IC(Integrated Circuitry)	Microprocessor	Microprocessor	√
Bluetooth Function	Yes. Using Bluetooth BT4.0 to connect with the smart mobile devices running the APP.	None	Different **see below(6)**
Offset	With	With	√
Materials	Button:ABS Housing and battery cover: ABS	Button: PMMA Housing and battery cover: ABS	Different **see below**(7)
Biocompatibility	Cytotoxicity, ISO 10993-5 Skin Irritation, ISO 10993-10 Skin Sensitization, ISO 10993-10	Cytotoxicity, ISO 10993-5 Skin Irritation, ISO 10993-10 Skin Sensitization, ISO 10993-10	√

Based on above comparison chart, differences between predicate FR1DG1 (NC200) and subject device FR1MF1-B (NC150 BT) are as below:

1. Indication for Use
Based on above comparison chart, both subject and predicate device indicate for use is intended for "the intermittent measurement and monitoring of human body temperature for people of all ages in the home", while subject device FR1MF1-B (NC150 BT) indicates Bluetooth function "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." Refer to the below section 6. Bluetooth function for details.
As Microlife states Bluetooth® function will not affect the performance of the device as its only function is to transfer data, though indication for use is different, it does not affect subject device's performance, safety and effectiveness.

2. Appearance, Physical Dimension and Weight
The physical dimension of the subject device FR1MF1-B (NC150 BT) is 141.1 x 43.3 x 36.9 mm, while predicate device FR1DG1 (NC200) is 156.7 x 43 x 47 mm. The weight of the subject device FR1MF1-B (NC150 BT) is 90 g (with batteries), 67 g (w/o batteries), while predicate device FR1DG1 (NC200) is 91.5 g (with batteries), 68.5 g (w/o batteries). Those differences are caused because of their different appearance, but the difference does not raise any new safety and effectiveness questions. This has been tested and confirmed according to IEC 60601-1-2 EMC Test Report, IEC 60601-1, AAMIANSI ES60601-1 Safety Test Report and MISC 003 ISO 80601-2-56 Test Report.

3. Error display user interface (known as UI)
Both subject device FR1MF1-B (NC150 BT) and the predicate device FR1DG1 (NC200) have self-test function. And both devices perform self-test every time when it is switched on to always guarantee the specified accuracy of any measurement. When it has error, it will display error icon on LCD of the device. Subject device FR1MF1-B (NC150 BT) will display icon "Err", while predicate device FR1DG1 (NC200) will display icon "Er0", "Er6". Although the icons are different, the purposes are the same. It does not affect device's performance, safety and effectiveness.

4. Auto measurement
The predicate device FR1DG1 (NC200) has auto measurement function, while subject device FR1MF1-B (NC150 BT) doesn't. Auto measurement is a feature that enables device to start measurement if detecting the distance is within 5cm (the appropriate measuring distance). As to the subject device FR1MF1-B (NC150 BT), in order to obtain correct measurement, the appropriate measurement distance would be the same as the predicate device which is within 5 cm. The appropriate measurement distance for the subject device, FR1MF1-B (NC150 BT), is clearly stated in Draft Instruction Manual for FR1MF1-B(NC150 BT) page 9, section 7 "Direction of use", point 4 and 5 that "*Aim the thermometer perpendicularly at the center of the forehead with a distance of no more than 5 cm. Press the START button…*".
Therefore, the appropriate measuring distance is supposed to be used regardless auto or manual measurement method is carried out. That is why the measurement algorithm for the predicate device and the subject device is identical and won't affect performance or accuracy of the subject device.

5. Firmware version
The firmware versions for the predicate device, FR1DG1 (NC200), and the subject device, FR1MF1-B (NC150BT), are PH15.0 & PH18.1 respectively.
The only difference between firmware version PH15.0 and PH18.1 is auto measurement function, please refer to the above section 4.Auto measurement for details.
Since the measurement algorithm itself in the predicate and subject device is identical, firmware version differences does not affect performance and accuracy. And the predicate

device has been validated in accordance with ISO 80601-2-56 and ASTM 1965-98. For the details, please refer to the clinical test report, Clinical Test Report of FR1DG1 NC200. Therefore, Microlife believes another clinical test for the identical measurement algorithm used in the subject device is not required.

6. Bluetooth Function

As Microlife states in Draft Instruction Manual for FR1MF1-B(NC150 BT) Page 12 “Notes” section, “The Bluetooth® of this thermometer is a medical device data system (MDDS) as its only function is for records and no additional functions. It does not modify the data or modify the display of the data, and it does not by itself control the functions or parameters of any other medical device. It is not active when the thermometer is recording data or during measurement. The thermometer will not sound any alarm with or without Bluetooth®. The Bluetooth® is used only to transfer data from point A to point B. The App on your smart devices cannot be used to start or stop the thermometer, nor update the firmware of thermometer via Bluetooth®.”

Microlife states Bluetooth® function of subject device will not affect the clinical performance of the subject device, and provided FCC Certification (MISC 004, 001), Bluetooth RF Test Report (MISC 004, 002) and Bluetooth RF Exposure Evaluation Report (MISC 004, 003) for reference.

7. Materials

The button material of subject device FR1MF1-B (NC150 BT) is ABS, whereas the button material of predicate device FR1DG1 (NC200) is PMMA. However, the button materials of subject device is identical to the button materials of the Microlife Non-contact Infrared Forehead thermometer FR1DZ1 as it was approved under K100953 in formulation, processing, and sterilization, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).

Based upon the aforementioned information, the two devices are substantially equivalent.

Non-Clinical Performance Testing

Testing information demonstrating performance of the Microlife Non-Contact Infrared Forehead Thermometer, Model FR1MF1-B (NC150 BT) in the intended environment of use is supported by testing that was conducted in accordance with Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers.

The Non-Contact Infrared Forehead Thermometer has been tested according to the following standards:

1. AAMI/ANSI ES60601-1:2005/(R2012) and A1:2012, C1:2009/(R)2012 and A2:2010/(R2012): Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2: 2014:Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests
3. ISO 14971: 2007: Medical devices - Applications of risk management to medical devices
4. AAMI/ANSI/ISO 10993-1: 2018: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
5. AAMI/ANSI/ISO 10993-5: 2009/(R)2014 :Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

6. AAMI/ANSI/ISO 10993-10: 2010/(R)2014 :Biological evaluation of medical devices -Part 10: Tests for irritation and skin sensitization
7. AAMI/ANSI/ISO 10993-12: 2012 :Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
8. ISO 80601-2-56: 2017+A1:2018: Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.
9. 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 equipment and medical electrical systems used in the home healthcare environment

Software Information:

Software validation was conducted in accordance with a moderate level of concern designation in accordance with the FDA November 2005 document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”.

Discussion of Clinical Tests Performed:

Clinical validation concerning the compliance of ASTM E1965-98 and ISO 80601-2-56.The subject device Model FR1MF1-B (NC150 BT) is from the technical point of view, identical to the predicate Model FR1DG1 (NC200). The IC, sensor and measuring algorithm of the subject device Model FR1MF1-B (NC150 BT) is the same as the predicate device Model FR1DG1 (NC200). Therefore the performance of the FR1MF1-B (NC150 BT) in terms of temperature measurement would be identical with performance of the predicate device FR1DG1 (NC200). Repeat clinical testing in accordance with the standard ASTM E1965-98 and ISO 80601-2-56 for the subject device FR1MF1-B (NC150 BT) is therefore not necessary as clinical testing results were not affected by the changes to the subject device.

Conclusions

The performance testing, comparison, analysis, and risk assessment, demonstrated that the Microlife Non-Contact Infrared Forehead Thermometer FR1MF1-B (NC150 BT) is substantially equivalent to the Microlife Non-Contact Infrared Forehead Thermometer FR1DG1 (NC200), cleared under K191829.