February 13, 2020

Microlife Intellectual Property GmbH
℅ Susan D. Goldstein-Falk
Official Correspondent for Microlife Property GmbH
mdi Consultants, Inc.
55 Northern Blvd, Suite 200
Great Neck, New York 11021

Re: K191829
Trade/Device Name: Microlife Non-Contact Infrared Forehead Thermometer, Model FR1DG1(NC200)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: January 15, 2020
Received: January 16, 2020

Dear Susan Goldstein-Falk:

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,

for Geeta Pamidimukkala
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191829

Device Name
Microlife Non-Contact Infrared Forehead Thermometer, Model FR1DG1 (NC200)

Indications for Use *(Describe)*
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.

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: K191829

Manufacturer's Name: Microlife Intellectual Property GmbH, Switzerland
Espenstrasse 139
9443 Widnau / Switzerland

Corresponding Official: Mr. Gerhard Frick
Vice President of Technical and Service
Microlife Intellectual Property GmbH, Switzerland

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Preparation Date: February 12, 2020

Trade Name: Microlife Non-Contact Infrared Forehead Thermometer, Model FR1DG1 (NC200)

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: K100953 Microlife Non-Contact Infrared Forehead Thermometer, Model FR1DZ1

Device Description and Mode of Operation

The Microlife Non-Contact Infrared Forehead Thermometer, Model FR1DG1 (NC200) is an electronic thermometer using an infrared sensor to measure infrared energy radiated from the forehead. This energy is collected through the lens and converted to a temperature value.

The device uses CapSense Technology to detect distance this technology is used to assist measurement. The concept of proximity sensor detects human electrical proximity level to transform to distance.

The distance control feature is added to the user interface to identify the measurement distances are in the correct parameter. In other words, the device will enter into measurement mode after the correct measurement distance is detected. This device can

take a measurement automatically when the device detects the distance is appropriate within 5 cm.

The Microlife Non-Contact Infrared forehead thermometer, Model FR1DG1 (NC200), consists of the following parts:

a) Thermopile Sensor
b) Application-Specific Integrated Circuitry
c) Erasable Programmable Read-Only Memory Integrated Circuit
d) Capacitance-touch Integrated Circuit
e) LCD and Backlight
f) 3 buttons (“START/POWER” button, “M” button, “MODE” button)
g) Alkaline batteries; size AAA, 2 x 1.5 V
h) Lens

The new Model FR1DG1 (NC200) has the same intended use, temperature measurement fundamental algorithm, as the predicate device 510(k) K100953 Microlife Model FR1DZ1, even though a new automatically measurement function is added. The modified model FR1DG1 and predicate model FR1DZ1 using an infrared sensor (thermopile) measures infrared energy radiated from the forehead. The difference between these two models is, FR1DG1 has distance indicator function, when the distance is appropriate within 5 cm, it will trigger the automatic measurement.

Indications for Use:

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.

Substantial Equivalence Discussion:

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

Microlife Non-Contact Infrared Forehead Thermometer FR1DG1 (NC200) K191829 (non-contact series products) has been compared to the Forehead “Microlife Non-Contact Infrared Forehead Thermometer FR1DZ1 (510(k) K#100953) 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 FR1DG1(NC200) K191829	2. Predicate Device Microlife Non-Contact Infrared Forehead Thermometer FR1DZ1 K100953	Similar or Different 1 vs 2
Indications for use	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.	The Microlife Non-Contact Infrared Forehead Thermometer, Model FR1DZ1 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.	√
Thermometer type	Infrared thermometer Non-Contact	Infrared thermometer Non-Contact	√
Device Measurement Technology	Infrared	Infrared	√
Temperature Measurement distance	Appropriate within 5 cm	About 2 inches (5 cm)	√
Measuring location(human)	Forehead	Forehead	√
Appearance (ID design)			Different
Physical dimension	156.7 x 43 x 47 mm	150 x 40 x 39 mm	Different **(1) see below**
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	32.0-43.0 °C (89.6-109.4 °F)	32.0°C ~42.2°C (89.6°F ~108.0°F)	Different (2) see below

Item	1. Subject Device Microlife Non-Contact Infrared Forehead Thermometer FR1DG1(NC200) K191829	2. Predicate Device Microlife Non-Contact Infrared Forehead Thermometer FR1DZ1 K100953	Similar or Different 1 vs 2
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: 36°C to 39°C ±0.3 °C: 34°C to 35.9°C，39.1°C to 42.2°C ±0.4 °F: 96.8 - 102.2°F ±0.5 °F: 93.2 - 96.6°F，102.4 - 108.0°F	Different **(3) see below**
Operating conditions	Body mode: 15~40°C (59°F~104°F), 15-95 % relative maximum humidity	Body mode: 16~ 40°C (60.8 ~104°F) 15-95 % relative maximum humidity	Different **(4) see below**
Storage conditions	-25 ~ 55 °C(-13°F ~131°F) 15-95 % relative maximum humidity	-20~ 50 °C(-4 ~122°F) 15-95 % relative maximum humidity	Different **(5) see below**
Reference site	Oral	Oral	√
Display type	LCD display	LCD display	√
Date, time, and beeper setting	Yes	None	Different **(6) see below**
Memory	30 sets memories	30 sets memories	√
Error	Display  or  hen system has a malfunction	Display  When system has a malfunction.	Different **(7) see below**
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. 3 minute after last measurement has been taken	Different **(8) see below**
Beeper indication	Yes	Yes	√
High temperature alarm	10 short beeps and a red LCD backlight alerts that the temperature equal to or higher than 37.5 °C	10 short beeps and a red LCD backlight alerts that the temperature equal to or higher than 37.5 °C	√
Auto measurement	The device can take a measurement automatically when the device detects the distance is appropriate within 5 cm.	None	Different **(9) see below**

Item	1. Subject Device Microlife Non-Contact Infrared Forehead Thermometer FR1DG1(NC200) K191829	2. Predicate Device Microlife Non-Contact Infrared Forehead Thermometer FR1DZ1 K100953	Similar or Different 1 vs 2
Algorithm	PH15.0 Algorithm	PS12 Algorithm	Different (10) see below
Signal processing	24 bit analog-to digital converter	16 bit analog-to digital converter	Different (11) see below
Sensor type	TPS336	TPS336	√
IC(Integrated Circuitry)	HY11P14	SN8P1919	Different (12) see below
Touch IC (Integrated Circuitry)	Have	None	Different (13) see below
Clinical Study Support	Yes. Clinical test report	Yes. Clinical test report	√
Patient-Contact Button material	PMMA	ABS707	Different (14) see below
Housing and battery cover material	ABS707	ABS707	√
Biocompatibility	Change in Material same as K183663 (Microlife Digital Infrared Ear Thermometer, Model IR1 DN1 (IR210))	Cytotoxicity, ISO 10993-5 Skin Irritation, ISO 10993-10 Skin Sensitization, ISO 10993-10	

The major differences between the subject modified device FR1DG1 (NC200), and the predicate device FR1DZ1 are the measurement range, auto measurement, and button material.

The Indications for Use statement of the subject device is identical to the predicate device. Other differences between the devices are:

1. Physical Dimension

The physical dimension of the subject device FR1DG1 is 156.7 x 43 x 47 mm, while predicate device FR1DZ1 is 150 x 40 x 39 mm. The difference is 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; IEC 60601-1, AAMI/ANSI ES60601-1 Safety Test Report and ISO 80601-2-56 Test Report.

2. Measurement range

The subject device IR1DN1 (IR210) body mode measurement range is 32.0-43.0 °C (89.6-109.4 °F), whereas the predicate device IR1DB1 measurement range is 32.0°C ~42.2°C (89.6 ~108.0 °F). The subject device has a wider body mode measurement range to

accommodate more physiologically relevant temperatures. This does not introduce any new risk to the device.

3. Accuracy (blackbody mode/laboratory)
The modified device's accuracy:
±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

The predicate device's accuracy:
±0.2 °C: 36°C to 39°C, ±0.3 °C: 34°C to 35.9°C & 39.1°C to 42.2°C
±0.4 °F: 96.8 - 102.2°F, ±0.5 °F: 93.2 - 96.6°F) &102.4 - 108.0°F

The modified device's measurement range is wider than predicated model; these are based on device's performance standards and client's requirement. These differences do not affect the performance and accuracy.

4. Operating conditions
The operating temperature range of modified device FR1DG1 (NC200) body mode is15~40°C (59°F~104°F),whereas the temperature range of predicate device FR1DZ1 is 16~ 40°C (60.8 ~104°F).The modified device's operating temperature range is wider than predicated model; this is based on device's performance standards . The difference does not affect the performance and accuracy which was evaluated in the performance testing.

5. Storage conditions
The storage temperature range of modified device FR1DG1 (NC200) is -25 ~ 55 °C (-13°F ~131°F), whereas storage temperature range of predicate device FR1DZ1 is -20~ 50 °C (-4 ~122°F).The modified device's storage temperature range is wider than predicated model; this is based on device's performance standards and client's requirement. The difference does not affect the performance and accuracy which was evaluated in the performance testing.

6. Date, time, beeper setting
The modified device FR1DG1 (NC200) has date, time, and beeper setting functions, whereas predicate device FRD1Z1 does not have these functions, and these functions do not affect device's performance, safety and effectiveness.

7. Error
Both modified device FR1DG1 (NC200) and the predicate device FR1DZ1 have self-test function. The principle of self-test is the same. Devices can perform a 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 signal. FR1DG1 (NC200) device will display icon "Er6", "Er 0", FR1DZ1 will display icon "Err". Although the icons are different, but the purpose means are the same. It does not affect device's performance, safety and effectiveness.

8. Automatic switch-off
The modified device FR1DG1 (NC200) will automatic switch-off approx. 1 minute after last measurement has been taken, whereas predicate device FR1DZ1 will automatic switch-off approximately 3 minute after last measurement has been taken. This is based on client's requirement and it does not affect device's performance, safety and effectiveness.

9. Auto measurement
The software of modified device FR1DG1 (NC200) allows the user to take a simple way to test the body temperature. The software using CapSense Technology to detect distance,

this technology is used to assist measurement, a capacitive sensor detects changes in capacitance to determine the presence of a proximity to conductive objects, the capacitive sensor is embedded in the device probe, the CapSense Controller connects the capacitive sensor and the output to the MCU through a communication interface, such as an I2C. When the device detects the distance is appropriate within 5cm, the device will start measurement automatically, whereas predicate device FR1DZ1 does not have this function, as user need to aim the probe at the center of the forehead with any distance of no more than 5cm and keep pressing the “Start “button to take measurement. The Description and Verification Report of FR1DG1 (NC200) auto measurement function has a detailed description of auto measurement function. It does not affect the performance, safety and effectiveness which was evaluated in the performance testing.

10. Algorithm

The algorithm of Subject model FR1DG1 is PH15.0, while predicate model FR1DZ1 is PS12.The only difference is the algorithm version, because these two models have different UI. However, their temperature calculation algorithm is the same. It does not affect performance and accuracy which was evaluated in the performance testing.

11. Signal processing

For the Subject model FR1DG1,thermopile and thermistor of the sensor convert the digit signal via 24 bit analog-to digital converter, then calculate the temperate via temperature calculation algorithm, while predicate model FR1DZ1 using 16 bit analog-to digital converter. Their principle is the same, only different bits. 24 bit is more precise than 16 bit. It does not affect performance and accuracy which was evaluated in the performance testing.

12. IC (Integrated Circuitry)

The main IC of the modified device is HY11P14, whereas the IC of the predicate device is SN8P1919. Their temperature calculation algorithms are the same. Just the model is different, and it does not affect performance and accuracy which was evaluated in the performance testing.

13. Touch IC (Integrated Circuitry)

The modified device FR1DG1 (NC200) has touch IC, whereas predicate device FR1DZ1 does not have touch IC. The difference does not affect the performance, safety and effectiveness which was evaluated in the performance testing.

14. Patient-Contact Button material

The button material of modified device FR1DG1 (NC200) is Polymethyl methacrylate (PMMA), whereas the button material of predicate device FR1DZ1 is ABS707. Biocompatibility testing was leveraged from Microlife Digital Infrared Ear Thermometer, Model IR1 DN1 (IR210) (K183663 reference device).

Non-Clinical Performance Testing

Testing information demonstrating performance of the Microlife Non-Contact Infrared Forehead Thermometer, Model FR1DG1 (NC200) 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. AAMI/ANSI /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. AAMI/ANSI /ISO 14971: 2007/(R)2010: Medical devices - Applications of risk management to medical devices
4. ISO 80601-2-56: 2017: Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.
5. AAMI/ANSI HA60601-1-11:2015: 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”.

Clinical Tests Conducted

Clinical testing was conducted according to ASTM E1965-98. This clinical study is a randomization, simple blind homologous control, pairing design of clinical investigation, consisting of 116 subjects, of which 38 subjects are infants, 41 subjects are children and the rest 37 subjects are adults (NOTE: Infants---newborn to one year; Children--- greater than one to five years; Adults---greater than five years old.). The test report demonstrated that the clinical data, represented by clinical bias met the acceptance criteria of the clinical study protocol.

Conclusions

The performance testing, comparison, analysis, and risk assessment, demonstrated that the Microlife Non-Contact Infrared Forehead Thermometer FR1DG1 (NC200) is substantially equivalent to the Microlife Non-Contact Infrared Forehead Thermometer FR1DZ1, cleared under K100953.