DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 5, 2016

Microfile Intellectual Property GmbH
c/o Ms. Susan Goldstein-Falk
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K161728
Trade/Device Name: Microlife Digital Infrared Forehead Thermometer, Model FR1MN1-1
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: November 2, 2016
Received: November 3, 2016

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161728

Device Name
Microlife Digital Infrared Forehead Thermometer, Model FR1MN1-1

Indications for Use *(Describe)*
The Microlife Digital Infrared Forehead Thermometer, Model FR1MN1-1 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 5l0(k) number is: K161728

1. Submitter's Identification:

Microlife Intellectual Property GmbH, Switzerland
Espenstrasse 139
9443 Widnau / Switzerland

Date Summary Prepared: November 2, 2016

Contact: Mr. Gerhard Frick
Vice President of Technical and Service
Microlife Intellectual Property GmbH, Switzerland
Tel: +41 79 216 0070
E-Mail: gerhard.frick@microlife.ch

2. Name of the Device:

Microlife Digital Infrared Forehead Thermometer, Model FR1MN1-1

Regulation Number: 21 CFR Part 880.2910
Regulation Name: Clinical Electronic Thermometer Regulatory Class: II
Product Code: FLL

3. Information for the 510(k) Cleared Device (Predicate Device):

Microlife Digital Infrared Forehead Thermometer, Model FR1DM1, K033820, Microlife Intellectual Property GmbH

4. Device Description:

The Microlife Digital Infrared Forehead Thermometer, Model FR1MN1-1 is an electronic thermometer using an infrared sensor (thermopile) to detect body temperature from the forehead. Microlife FR1MN1-1 especially enables the user to take measurements and be alerted for possible elevated temperature readings accordingly.

The Microlife Digital Infrared Forehead Thermometer, Model FR1MN1-1, consists of mainly seven parts:

a) Thermopile Sensor
b) Application-Specific Intergrated Circuit
c) Erasable Programmable Read-Only Memory Integrated Circuit
d) Lens
e) LCD and Backlight
f) 2 Keys (Start key, O/I key)
g) 2 batteries AAA (LR03) 1.5V

The new Model FR1MN1-1 has the same intended use and temperature measurement fundamental algorithm as the 510(k) cleared devices.

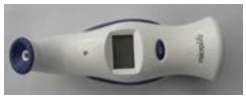
Auto-Display memory
The last reading is automatically displayed for 2 seconds when the unit is switched ON.

5. Indications for Use:

The Microlife Digital Infrared Forehead Thermometer, Model FR1MN1-1 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.

6. Comparison to the 510(k) Cleared Devices (Predicate Devices):

Item	Predicate device: Microlife Digital Infared Forehead Thermometer FR1DM1, Microlife Intellectual Property GmbH, K033820	Modified device: Microlife Digital Infrared Forehead Thermometer FR1MN1-1, Microlife Intellectual Property GmbH	Assessment of Differences
Thermometer type	Infrared thermometer	Infrared thermometer	same
	Contact	Contact	same
Intended use	Intended for the intermittent measurement and monitoring of human body temperature in the home, for use on people of all ages.	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.	same
Device technology	Infrared	Infrared	same

Item	Predicate device: Microlife Digital Infared Forehead Thermometer FR1DM1, Microlife Intellectual Property GmbH, K033820	Modified device: Microlife Digital Infrared Forehead Thermometer FR1MN1-1, Microlife Intellectual Property GmbH	Assessment of Differences
Measurement target	Human	Human	same
Measuring location	Forehead	Forehead	same
Appearance (ID design)			different shape
Physical dimension	(141.0±0.5)mm (L) *(26.0±0.5)mm (W) *(20.0±0.5)mm (D)	(157.0+0.5)mm (L) *(53.0±0.5)mm (W) *(36.0±0.5)mm (D)	different
Power supply	1 battery CR2032 3.0V	2 batteries AAA (LR03) 1.5V	different
Measuring range (Body Mode)	34°C ~42.2°C (93.2~108.0°F)	34°C ~42.2°C (93.2~108.0°F)	same
Measuring range (Non-clinical mode /laboratory)	32~212°F (0~100 °C)	80.6~109.4°F (27~43 °C)	different
Accuracy (Clinical Mode)	±0.3 °C, 34.0 ~ 42.2 °C (±0.5 °F, 93.2 ~ 108.0 °F)	0.4 °F, 96.8 ~ 102.2 °F	different
Display resolution	0.1°C or 0.1°F	0.1°C or 0.1°F	same
Operating temperature (Body Mode)	16.0°C-40°C (60.8°F~104.0°F	16.0°C-40°C (60.8°F~104.0°F)	same
Storage conditions	–25°C~55°C (–13°F~131°F)	–25°C~55°C (–13°F~131°F)	same
Display type	LCD	LCD	same
Memory	12 set, last measurement	last measurement	different

Item	Predicate device: Microlife Digital Infared Forehead Thermometer FR1DM1, Microlife Intellectual Property GmbH, K033820	Modified device: Microlife Digital Infrared Forehead Thermometer FR1MN1-1, Microlife Intellectual Property GmbH	Assessment of Differences
Power auto off	Approx. 1 minute after the last measurement has been taken	Approx. 20 seconds, after the last measurement has been taken	different
Low/dead battery indications	Low battery at 2.7V Dead battery at 2.55V	Low battery at 2.6V Dead battery at 2.5V	different
Backlight	Single backlight	Green, yellow and red backlight according to the measured temperature	different
Reference site	No	No	same
Beeper indication	Yes	Yes	same
Sensor type	Same	Same	same
Lens	Yes	Yes	same
Labeling	Microlife	Microlife	same
Error	Display “Err” when the system has a malfunction.	Display “Err” when the system has a malfunction.	same
IC	Same	Same	same
Sensor	OTP-668D2	OTP-668D2	same
Software algorithm	FW table "xyz" rev.1	FW table "xyz" rev. 1.1	different

The subject FR1MN1-1 device uses the same infrared technology, measures and monitor body temperature at the forehead site as the predicate Microlife FR1DM1.

The major differences are as below:

a) Power supply, memory sets, low/dead battery indications, backlight, etc. These are mainly user- friendly features.

b) Software Algorithm
The modified device uses slightly adjusted clinical offset tables for additional improved accuracy. Our algorithm was adjusted to improve accuracy. A clinical study was performed to validate this.

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

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating performance of the Microlife Digital Infrared Forehead Thermometer, Model FR1MN1-1 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 following testing was conducted to demonstrate performance as well as substantial equivalence to the predicate devices:

The following National and International Standards were utilized for testing the subject device:

Item	Test name	Pass/Fail Criteria	Results
1.	IEC 60601-1:2005+A1:2012	Pass/Fail Criteria is Outlined in this Standard	Passed All Testing Requirements
2	AAMI/IEC 60601-1:2005/(R) 2012 And A1:2012,C1:2009/(R)2012 And A2:2010/(R)2012	Pass/Fail Criteria is Outlined in this Standard	Passed All Testing Requirements
3	IEC 60601-1-2:2007	Pass/Fail Criteria is Outlined in this Standard	Passed All Testing Requirements
4	ASTM E 1965-98（2009）	Pass/Fail Criteria is Outlined in this Standard	Passed All Testing Requirements
5	ISO 14971:2007	Pass/Fail Criteria is Outlined in this Standard	Passed All Testing Requirements
6	AAMI/ANSI/ISO 10993-1:2010	Pass/Fail Criteria is Outlined in this Standard	Passed All Testing Requirements
7	AAMI/ANSI/ISO 10993-5:2009	Pass/Fail Criteria is Outlined in this Standard	Passed All Testing Requirements

8	AAMI/ANSI/ISO 10993-10:2010	Pass/Fail Criteria is Outlined in this Standard	Passed All Testing Requirements
9	AAMI/ANSI/ISO 10993-12:2012	Pass/Fail Criteria is Outlined in this Standard	Passed All Testing Requirements
10	AAMI/ANSI/ISO 80601-2-56:2009	Pass/Fail Criteria is Outlined in this Standard	Passed All Testing Requirements
11	IEC 60601-1-11:2010	Pass/Fail Criteria is Outlined in this Standard	Passed All Testing Requirements

It was our conclusion that Microlife Digital Infrared Forehead Thermometer, Model FR1MN1-1 tested meets all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

Controlled human clinical studies were conducted in accordance with ASTM E1965-98, IEC 80601-2-56 Test Report using the Microlife Digital Infrared Forehead Thermometer Model FR1MN1-1. Clinical data was presented evaluating clinical bias, clinical uncertainty and clinical repeatability per clinical validation for Microlife FR1MN1-1.

9. 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".

10. Conclusions:

Conclusions drawn from the non-clinical and clinical tests demonstrate that the subject device is substantially equivalent to the predicate device.