DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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July 20, 2017

Microlife Intellectual Property GmbH
% Susan Goldstein-Falk
MDI Consultants, Inc.
55 Northern Boulevard
Suite 200
Great Neck, New York 11021

Re: K170219
Trade/Device Name: Microlife Digital Infrared Ear Thermometer, Model IR1DR1-1
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: June 1, 2017
Received: June 1, 2017

Dear Ms. 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,

Tara A. Ryan -S

for
Lori Wiggins
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170219

Device Name
Microlife Digital Infrared Ear Thermometer, Model IR1DR1-1

Indications for Use *(Describe)*

The Microlife Digital Infrared Ear Thermometer, Model IR1DR1-1 device, is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.

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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K170219 510(K) SUMMARY

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
Telephone Number:	+41 79 216 0070
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Preparation Date:	July 13, 2017
Trade Name:	Microlife Digital Infrared Ear Thermometer, Model IR1DR1-1
Common or Usual Name:	Clinical Electronic Thermometer
Regulation Name:	Clinical Electronic Thermometer
Regulation Number:	21 CFR 880.2910
Product Code:	FLL
Device Class:	Class II
Primary Predicate Device:	K034023 Microlife Digital Infrared Ear thermometer, Model IR1DE1-1

Device Description:

The Microlife Digital Infrared Ear Thermometer, Model IR1DR1-1 is an electronic thermometer using an infrared sensor (thermopile) to detect body temperature from the auditory canal. Its operation is based on measuring the natural thermal radiation emanating from the tympanic membrane and the adjacent surfaces.

Mode of operation:
The unit measures the infrared energy emitting from the middle ear and the surrounding tissue. This energy is absorbed by lenses and converted into temperature values.

The Microlife Digital Infrared Ear thermometer, Model IR1DR1-1, consists of the following parts:
a) Thermopile Sensor
b) Application-Specific Integrated Circuit
d) Lens

e) LCD and Backlight
f) 2 Keys (Start key, O/I key)
g) 1 battery 3.0V

The new Model IR1DR1-1 has the same intended use and temperature measurement fundamental algorithm as the predicate device 510(k) K034023 Microlife Model IR1DE1-1.

Indications For Use

The Microlife Digital Infrared Ear Thermometer, Model IR1DR1-1 device, is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.

Substantial Equivalence Discussion

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

Microlife Digital Infrared Ear Thermometer IR1DR1-1 (cover free series products) has been compared to the cleared "Microlife Digital Infrared Ear Thermometer IR1DE1-1" (510(k) K#034023) as a reference for substantial equivalence. A table comparing the two devices is provided as follow:

Attribute	Subject Device – K170219: Microlife Ear Thermometer 1R1DR1-1	Predicate Device - K034023 : Microlife Ear Thermometer 1R1DE1-1	Comparison
Thermometer Type:	Infrared Thermometer	Infrared Thermometer	Same
Intended use	The device is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.	The device is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.	Same
Indications for use	The Microlife Digital Infrared Ear Thermometer, Model IR1DR1-1 device, is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the	The device is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.	Same

	neonatal, pediatric and adult population used in the home setting.		
Thermometer Measurements			
Device Measurement Technology	Infrared	Same	-
Measurement location	Ear Canal	Same	-
Probe cover needed?	No	Same	-
Measurement Range	32.0- 42.2°C (89.6 -108.0 °F)	0 - 100°C (32.0 - 212.0°F)	Different
Display Resolution	0.1°C or 0.1°F	Same	-
Accuracy Tested (blackbody)	<35.5°C ±0.3°C 35.5°C-42.0°C ±0.2°C >42.0°C ±0.3°C	Same	-
Positioning Indication	Yes	No	Different
Elevated Temperature Alarm	Yes (10 short beeps when measured temperature is greater than 37.5 °C)	Same	-
Operating/Storage Environment			
Operating Conditions	10.0°C-40°C (50.0°F~104.0°F) with relative humidity 95%	5°C-40°C (41°F~104°F) with relative humidity 95%	Different
Storage Conditions	-25°C to 55 °C/-13°F ~131°F with relative humidity 95%	Same	-
Device Internal Components			
Display type	LCD	Same	-
Memory	One temperature memory	Twelve temperatures memory	Different
Sensor Type	TPS23B sensor	Same	-
Lens Type	Transparent	Same	-
Probe Head Dimensions			
Probe head : Tip Width	7.3 mm	Same	-
Probe Head: Thickness at 5 mm height	8.56 mm	8.35 mm	Different
Probe Head: Thickness at 10	10.32 mm	10.22 mm	Different

Item	Test Name	Results

mm height			
Integrated Circuit Model and Features			
Power Supply Voltage	2.2-3.6 V	2.4- 5.5 V	Different
RAM Space	512 Bytes	256 Bytes	Different

The indications for use statement and the intended use of the subject device is identical to the predicate device. The differences in the device are:

1. Measurement temperature range has been narrowed to more physiologically relevant temperatures. This does not introduce any new risk to the device.
2. Addition of the Position Indication Feature, which has been validated and verified through performance testing and clinical testing.
3. The integrated circuit model and its features have changed. These changes have been verified through performance testing.
4. The thermometer's memory can recall the last temperature measurement, which has been decreased from predicate which recalled the last 12 temperature measurements.
5. The Probe head and the rest of the device is dimensionally larger than the predicate device. This does not change how the device operates. The size difference was validated through clinical studies.
6. The operating condition has been narrowed. .

Based on the aforementioned modifications to the subject device, the subject device does not raise different types of safety and effectiveness questions when compared to the predicate device.
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Performance Testing Testing information demonstrating performance of the Microlife Digital Infrared Ear Thermometer, Model IR1DR1-1 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 prove safety and effectiveness as well as substantial equivalence to the predicate devices:

1	IEC 60601-1: 2005 and A1:2012	Passed all testing requirements
2	ANSI/AAMI ES60601-1:2005/(R2012) and A1:2012, C1:2009/(R)2012 and A2:2010/(R2012)	Passed all testing requirements
3	IEC 60601-1-2: 2014	Passed all testing requirements
4	ASTM E 1965-98 (2009)	Passed all testing requirements
5	ISO 14971: 2007	Passed all testing requirements
6	AAMI/ANSI/ISO 10993-1: 2010	Passed all testing requirements
7	AAMI/ANSI/ISO 10993-5: 2010	Passed all testing requirements
8	AAMI/ANSI/ISO 10993-10: 2010	Passed all testing requirements
9	AAMI/ANSI/ISO 10993-12: 2012	Passed all testing requirements
10	AAMI/ANSI/ISO 80606-2-56: 2009	Passed all testing requirements
11	IEC 60601-1-11:2010	Passed all testing requirements

Performance Testing Summary:
Measurement accuracy of the subject thermometer was tested per and complies with the following standard:
Specification for IR thermometers : ASTM E1965-98 (2009)
Electrical and Electromagnetic Compatibility testing were conducted in accordance with the following standards:

Electrical Safety: IEC 60601-1, IEC 60601-1-11
EMC: IEC 60601-1-2

Software Verification and Validation: per the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices dated May 11, 2005

Clinical Tests
Controlled human clinical studies were conducted in accordance with ASTM E1965-98, IEC80601-2-56 Test Report using the Microlife Digital Infrared Ear Thermometer r Model IR1DR1-1. Clinical data was presented evaluating clinical bias, clinical uncertainty and clinical repeatability per clinical validation for Microlife IR1DR1-1.

Conclusions
The modifications to the subject device include the addition of the position indication feature, the measurement reading range, the operating conditions, the integrated circuit system, temperature memory, and the physical dimensions of the device. There are no changes to the basic measurement technology. The modifications do not raise new or different questions of safety and effectiveness and are supported by non-clinical and clinical testing.

The Microlife Digital Infrared Ear Thermometer IR1DR1-1 is substantially equivalent to the Microlife Digital Infrared Ear Thermometer IR1DE1-1, cleared under K034023.