July 16, 2019

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

Re: K183663
Trade/Device Name: Microlife Digital Infrared Ear Thermometer, Model IR1DN1 (IR210)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: June 14, 2019
Received: June 17, 2019

Dear Susan D. 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 Alan Stevens
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)*

K183663

Device Name
Microlife Digital Infrared Ear Thermometer, Model IR1DN1(IR210)

Indications for Use *(Describe)*
The Microlife Digital Infrared Ear Thermometer, Model IR1DN1 (IR210) 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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510(k) SUMMARY

The assigned 510(k) number is K183663

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

Corresponding Official: Mr. Gerhard Frick
Vice President of Technical and Service
Microlife Intellectual Property GmbH,
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Preparation Date: June 26, 2019

Trade Name: Microlife Digital Infrared Ear Thermometer, Model IR1DN1 (IR210)

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: K003308 Microlife Digital Infrared Ear Thermometer, Model IR1DB1

Device Description:

The Microlife Digital Infrared Ear Thermometer, Model IR1DN1 (IR210) 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 IR1DN1 (IR210), consists of the following parts:

a) Thermopile Sensor
b) Application-Specific Integrated Circuitry
c) EEPROM IC
d) Capacitance-touch IC
e) LCD and Backlight
f) 3 buttons ("START/POWER" button, "M" button, "MODE" button)
g) 1 battery CR2032 3.0V
h) Probe cover
I) Lens

The new Model IR1DN1 (IR210) has the same intended use and temperature measurement fundamental algorithm as the predicate device 510(k) K#003308 Microlife Model IR1DB1.

Indications for Use

The Microlife Digital Infrared Ear Thermometer, Model IR1DN1 (IR210) 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 subject device and predicate device use infrared technology to measure and monitor the body temperature by the site of ear canal.

Microlife Digital Infrared Ear Thermometer IR1DN1 (IR210) has been compared to the cleared "Microlife Digital Infrared Ear Thermometer IR1DB1" (510(k) K#003308). A table comparing the two devices is provided as follows:

Item	1. Subject Device Microlife Digital Infrared Ear Thermometer IR1DN1(IR210) K183663	2. Predicate Device Microlife Digital Infrared Ear Thermometer IR1DB1 K003308	Comparison 1 vs 2
Indications for Use	The Microlife Digital Infrared Ear Thermometer, Model IR1DN1(IR 210) 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
Thermometer type	Infrared thermometer	Infrared thermometer	Same
Device Measurement Technology	Infrared	Infrared	Same
Measurement target	Human Ear	Human Ear	Same
Measuring location	Ear Canal	Ear Canal	Same
Physical dimension	159mm(L)*43mm(W)*60mm(H)	128mm(L)*48mm(W)*30mm (H)	Different
Power supply	3.0V DC with 1 CR2032 battery	3.0V DC with 1 CR2032 battery	Same
Display resolution	0.1°C or 0.1°F	0.1°C or 0.1°F	Same

Item	1. Subject Device Microlife Digital Infrared Ear Thermometer IR1DN1(IR210) K183663	2. Predicate Device Microlife Digital Infrared Ear Thermometer IR1DB1,K003308	Comparison 1 vs 2
Inspect the accuracy of blackbody	The sample must be pressed "Start" button for 8 seconds when the unit turns off, after two short beep sounds, release "Start" button, enters the blackbody measurement mode. The unit display 0.01°C or 0.01°F resolution in this mode.	The sample must be pressed "Start" button for 8 seconds when the unit turns off, after two short beep sounds, release "Start" button, enters the blackbody measurement mode. The unit display 0.01°C or 0.01°F resolution in this mode.	Same
Measuring range(body mode)	32.0-43.0 °C (89.6-109.4 °F)	32.0°C ~42.2°C (89.6°F ~108.0°F)	Different **(1) See below**
Accuracy(black body mode)	±0.2 °C: 35.0 ~ 42.0 °C ±0.3 °C: 32.0 ~ 34.9 °C & 42.1 ~ 43.0 °C ±0.4 °F: 95.0 ~ 107.6 °F ±0.5 °F: 89.6 ~94.8 °F & 107.8~109.4 °F	±0.2°C: 32.0~42.2°C ±0.4°F:89.6~108.0°F	Different **(2) See below**
Operating conditions	10°C~40°C (50°F~104°F) 15-95 % relative maximum humidity	10°C~40°C (50°F~104°F) 15-95 % relative maximum humidity	Same
Storage conditions	-25°C ~ 55 °C/-13°F ~131°F 15-95 % relative maximum humidity	-25°C ~ 55 °C/-13°F ~131°F 15-95 % relative maximum humidity	Same
Display type	LCD display	LCD display	Same
Memory	30 sets memories	One set memory	Different **(3) See below**
Error	Display Er6 if system malfunction.	Display Err if system malfunction.	Different (4) **See below**
Power auto off in clinical mode and blackbody mode	Approx. 1 minute after last measurement has been taken	Approx. 1 minute after last measurement has been taken	Same

Item	1. Subject Device Microlife Digital Infrared Ear Thermometer IR1DN1(IR210) K183663	2. Predicate Device Microlife Digital Infrared Ear Thermometer IR1DB1,K003308	Comparison 1 vs 2
Sensor type	TPS23B	OTP-668D2	Different (5) See below
Lens type	Transparent	Transparent	Same
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.	Same
Measuring probe material	PCTG(TX2001)	ABS707	Different (6) See below
Probe cover	Rigid cover (PP)	Soft cover (PE)	Different (7) See below
Positioning indication	Yes	No	Different (8) See below
IC(Integrated Circuitry)	HY11P14	SN8P1919	Different (9) See below
Offset	With	With	Same
Clinical Study Support	Yes. Clinical test report	Yes. Clinical test report	Same
“Start ”/ “Power” button material	PMMA	ABS707	Different (10) See below
Housing and battery cover material	ABS707	ABS707	Same

Patient contact Materials			
Probe Cover	Rigid cover (Polypropylene (PP))	Soft cover (Polyethylene (PE))	Different **(7) See below**
Measuring probe material	PCTG(TX2001)	ABS707	Different **(6) See below**
"Start "/ "Power" button material	PMMA	ABS707	Different **(10) See below**
Housing and battery cover material	ABS707	ABS707	Same

The major differences between the subject modified device IR1DN1 (IR210), and the predicate device IR1DB 1 are the measurement range, probe cover, position indicator, measuring probe and buttons material.

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

1. Measurement range (body mode)

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.

2. Accuracy (blackbody mode)

The modified device's accuracy: ±0.2 °C: 35.0 ~ 42.0 °C,
±0.3 °C: 32.0 ~ 34.9 °C&42.1 ~ 43.0 °C,
±0.4 °F: 95.0 ~ 107.6 °F
±0.5 °F: 89.6 ~94.8 °F & 107.8~109.4 °F

The predicate device's accuracy: ±0.2°C: 32.0~42.2°C, ±0.4°F, 89.6~108.0°F.

The modified device's measurement range and accuracy are wider than the predicate device. ; these are based on device's performance standards and patient's requirement. These differences do not affect the performance and accuracy according to our Reliability Test Report (ASTM E1965- 98), ISO 80601-2-56 Test Report, and our Clinical Test Report of IR1DN1 (IR210).

3. Memory

The modified device IR1DN1 (IR210) can recall the last 30 readings, whereas the predicate device IR1DB1 can only recall the last reading. Only storage reading quantity is different which does not affect the device's performance or safety and effectiveness.

4. Error

Both modified device IR1DN1 (IR210) and the predicate device IR1DB1 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. IR1DN1 (IR210) device will display icon "Er6", IR1DB1 will display icon "Err". Although the icons are different, the purpose is the same. This does not affect the device's performance or safety and effectiveness.

5. Sensor Type

The sensor type of the modified device is TPS23B, whereas the sensor type of the predicate device is OTP-668D2. The difference does not affect the performance and accuracy according to Reliability Test Report (ASTM E1965-98), ISO 80601-2-56 Test Report and Clinical Test Report of IR1DN1 (IR210).

6. Measuring probe material

The measuring probe material of the subject device is PCTG, whereas the measuring probe material of the predicate device is ABS707. The probe is not the patient contacting material. Biocompatibility testing was performed on the PCTG material in accordance with ISO 10993 standard and testing results proved the subject probe material to be biocompatible.

7. Probe cover

The subject device measures with rigid cover (PP), whereas the predicate device measures with a soft cover (PE). Biocompatibility testing was performed on the finished subject probe cover according to the ISO10993 standard. Our Biocompatibility Test Report of the PP material (Rigid Probe Cover) proves the subject probe cover material to be biocompatible. Our Clinical Test Report of IR1DN1 (IR210), showed that the subject probe cover did not affect the subject modified device's accuracy and performance.

8. Position indication

The subject device includes a position indication feature which was not included with the predicate device. This feature has been validated and verified through performance testing and clinical testing.

9. IC (Integrated Circuitry)

The integrated circuit model and its features have changed. These changes have been verified through performance testing.

10. "Start"/ "Power" button

The button material of the subject device is PMMA, whereas the button material of the predicate device is ABS707. The PMMA material's biocompatibility testing was performed according to ISO10993 standard. Biocompatibility Test Report of PMMA testing proved that the subject button material to be biocompatible.

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.

Performance Testing

Testing information demonstrating performance of the Microlife Digital Infrared Ear Thermometer, Model IR1DN1 (IR210) 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	AAMI/ANSI ES60601-1:2005/(R2012) and A1:2012, C1:2009/(R)2012 and A2:2010/(R2012)	Passed all testing requirements
2	AAMI/ANSI/IEC 60601-1-2:2014	Passed all testing requirements
3	ASTM E1965-98 (2016)	Passed all testing requirements
4	AAMI/ANS/ ISO 14971:2007/(R)2010	Passed all testing requirements
5	AAMI/ANSI/ISO 10993-1: 2009/(R)2013	Passed all testing requirements
6	AAMI/ANSI/ISO 10993-5:2009/(R)2014	Passed all testing requirements
7	AAMI/ANSI/ISO 10993-10: 2010/(R)2014	Passed all testing requirements
8	AAMI/ANSI/ISO 10993-12: 2012	Passed all testing requirements
9	ISO 80601-2-56: 2017	Passed all testing requirements
10	AAMI/ANSI HA60601-1-11:2015	Passed all testing requirements

Performance Testing Summary

A risk assessment was conducted in accordance is ISO 14971:2007/EN ISO 14971:2012 to assess risk management activities due to modifications to our predicate device. Verification activities that were performed included modifications, associated risk, validation method, and results revealed that all acceptance criteria passed.

Clinical Tests Conducted

Clinical testing was conducted according to ASTM E1965-98 and ISO 80601-2-56. This clinical study is a randomization, simple blind homologous control, pairing design of clinical investigation, consists of 114 subjects, of which 1/3 are infants, 1/3 are children and the rest 1/3 are adults (NOTE: Infants---newborn to one year; Children--- greater than one to five years; Adults---greater than five years old.). The test reports demonstrated that the clinical data, represented by clinical bias, with uncertainty of bias, and clinical repeatability, met the acceptance criteria of the clinical study protocol.

Conclusions

Based on the performance testing, comparison, analysis, and risk assessment, it demonstrated that the Microlife Digital Infrared Ear Thermometer IR1DN1 (IR210) is substantially equivalent to the Microlife Digital Infrared Ear Thermometer IR1DB1, cleared under K003308.