Conmo Electronic Company Limited
% Charles Mack
Principal Engineer
Irc
2950 E Lindrick Drive
Chandler, Arizona 85249

Re: K202420
Trade/Device Name: Infrared Forehead Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: January 18, 2021
Received: January 26, 2021

Dear Charles Mack:

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 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

Enclosure

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)*

Device Name
Infrared Forehead Thermometer, DPT-IFT100

Indications for Use *(Describe)*
The infrared forehead Thermometer DPT-IFT100 is a non-contact thermometer intended for the intermittent measurement of human body temperature from forehead for people of one month old and above. The device is reusable for home use and clinical use.

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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K202420 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

Date: February 25, 2021

1. Company and Correspondent submitting:

Name – Conmo Electronic Company Limited
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FDA Establishment Registration No.: 3010968402

Designated Submission Correspondent and US Agent:
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2950 E Lindrick Dr., Chandler, Arizona 85249, USA
Mr. Charles Mack
Principal Engineer
Tel: 931-6254938
Email: charliemack@irc-us.com

2. Device :

Trade/proprietary name	Infrared Forehead Thermometer, Model DPT-IFT100
Common Name	Clinical Electronic Thermometer
Regulation Name	Clinical Electronic Thermometer
Classification Number	21 CFR 880.2910
Product Code	FLL
Regulatory Class	Class II
Device Panel	General Hospital

3. Predicate Device:

Manufacturer	Predicate Device	510(k) Number
Microlife Intellectual Property GmbH	Microlife Non-Contact Infrared Forehead Thermometer, Model FR1DG1 (NC200)	K191829

4. Device Description:

The infrared forehead thermometer, Model DPT-IFT100, is an electronic thermometer using an infrared temperature sensor to measure infrared energy radiated from the forehead. This energy is collected through the infrared temperature sensor convert to a voltage signal. The signal is measured by the main microcontroller, calculated by the internal algorithm, finally converted into a digital temperature value to display on the LCD.

The design consists of a lens to focus the infrared thermal radiation on to a detector, which converts the radiant power to an electrical signal displayed in units of temperature after being compensated for ambient temperature. This permits temperature measurement from a 3~5 cm distance without contact with the object to be measured.

The Infrared forehead thermometer, Model DPT-IFT100, consists of the following parts:

a) Thermopile Sensor
b) Application-Specific Integrated Circuit
c) Housing
d) LCD and Backlight
e) 1 button (Power on/Power off/Measurement)
f) Alkaline batteries; size AAA, 2 x 1.5 V
g) LCD cover

5. Indications for use:

The infrared forehead Thermometer DPT-IFT100 is a non-contact thermometer intended for the intermittent measurement of human body temperature from forehead for people of one month old and above. The device is reusable for home use and clinical use.

6. Comparison with the predicate device:

Conmo Electronic Company Limited believes that the Infrared Forehead Thermometer, DPT-IFT100 is substantially equivalent to the (K191829) Microlife Non-Contact Infrared Forehead Thermometer (Microlife Intellectual Property GmbH).

Comparison to Predicate Devices

Characteristics	**Subject Device Infrared Forehead Thermometer, DPT-IFT100 (K202420)**	**Predicate Device Microlife Non-Contact Infrared Forehead Thermometer, Model FR1DG1(NC200) (K191829)**	**Remark**
Manufacturer	CONMO ELECTRONIC COMPANY LIMITED	Microlife Intellectual Property GmbH, Switzerland	-
Indication for Use	The infrared forehead Thermometer DPT-IFT100 is a non-contact thermometer intended for the intermittent measurement of human body temperature from forehead for people of one month old and above. The device is reusable for home use and clinical use.	The Microlife Non-Contact Infrared 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.	Note 1
Measurement Method	Infrared radiation detection	Infrared radiation detection	Identical
Measurement range	34.0°C to 43.0°C (93.2°F to 109.4°F)	34.0°C to 43.0°C (93.2°F to 109.4°F)	Identical
Accuracy (Laboratory)	±0.2°C : 35.0°C ~ 42.0°C ±0.3°C : 34.0°C ~ 34.9°C , 42.1°C ~ 43°C ±0.4°F: 95°F ~ 107.6°F ±0.5°F: 93.2°F ~ 94.8°F, 107.8°F ~ 109.4°F	±0.2°C : 35.0°C ~ 42.0°C ±0.3°C : 34.0°C ~ 34.9°C , 42.1°C ~ 43°C ±0.4°F: 95°F ~ 107.6°F ±0.5°F: 93.2°F ~ 94.8°F, 107.8°F ~ 109.4°F	Identical
Accuracy(clinic repeatability)	0.1°C	Unknown	Note 2
Temperature Measurement distance	3~5cm	Appropriate within 5cm	*Note 3*
Measurement site	Forehead	Forehead	Identical
Sensor type	Thermopile	Thermopile	Identical
Temperature unit	℃ or ℉	℃ or ℉	Identical
Operating Environment	10°C to 40°C (50°F to 104°F) 15%~85%RH	15°C to 40°C (59°F to 104°F) 15%~95% RH	*Note 4*
Storage Environment	-25°C to 55°C (-13°F to 131°F) 90% RH or less	-25°C to 55°C (-13°F to 131°F) 15-95% RH	
Auto power-off while no operation	Yes	Yes	Identical
Memory capacity	1 measurement	30 measurements	*Note 5*
Battery type	3.0V DC with 2 AAA batteries	3.0V DC with 2 AAA batteries	Identical

Characteristics	Subject Device Infrared Forehead Thermometer, DPT-IFT100 (K202420)	Predicate Device Microlife Non-Contact Infrared Forehead Thermometer, Model FR1DG1(NC200) (K191829)	Remark
LCD Backlight feature	Available	Available	Identical
Display type & components	LCD	LCD	Identical
Display resolution	0.1˚C/0.1 ˚F	0.1˚C/0.1 ˚F	Identical
Reference site	Oral	Oral	Identical
Physical dimensions	145*38*35mm	156.7 x 43 x 47 mm	*Note 6*
Weight	78.2g (with batteries),56.6g (w/o batteries)	Unknown	
Skin contacting materials:	Housing and battery cover: ABS Key: ABS	Housing and battery cover: ABS Key: PMMA	*Note 7*
Response time	1s	Unknown	-
Measurement mode *(adjusted/direct mode)*	Adjusted	Unknown	*Note 8*
Algorithm	CM3.1 Algorithm	PH15.0 Algorithm	*Note 9*
Signal processing	24-bit analog-to-digital converter	24-bit analog-to-digital converter	Identical
Sensor model	MRT511	TPS336	*Note 10*
IC model	SN8P2977	HY11P14	*Note 11*
Touch IC	No	Yes	*Note 12*
Conformance standard	AAMI/ANSI ES60601-1 IEC60601-1-2 IEC 60601-1-11 ISO10993-1 ASTM E1965-98 (Performance) ISO 80601-2- 56(Performance)	AAMI/ANSI ES60601-1 IEC60601-1-2 IEC 60601-1-11 ISO10993-1 ASTM E1965-98 (Performance) ISO 80601-2- 56(Performance)	Identical

Note 1:

The wording for the subject device is slightly different from the predicate device but they are both non-contact thermometers for the intermittent measurement of human body temperature via forehead. The subject device addresses the target population based on the clinical study conducted, and they both conform to the same performance standard - ISO 80601-2-56, Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. The subject device added the device's description as reusable, the predicate device is also reusable based on the device manual. The subject device added the “clinical use” claim, they conform to the same safety and performance standards. The above wording differences between the subject device and predicate device will not affect the subject device's safety and effectiveness.

Note 2:

The result of clinical accuracy characteristics – clinic repeatability of subject device is 0.1℃. Although the predicate results are unknown, they conform to the same performance standard requirements of ASTM E1965-98. The differences between the predicate device and the subject device will not affect the subject device’s performance.

Note 3:

The subject device's measurement distance is included in the predicate device range. The subject device's clinical study report demonstrates the device meets the clinical accuracy requirements of the standards ISO 80601-2-56 and ASTM E1965-98 within the distance range. The differences between the subject device and predicate will not affect the subject device's safety and effectiveness.

Note 4:

Although the subject device's operating and storage conditions are slightly different from predicate device, they conform to the same standard requirements of ISO 80601-2-56 and IEC 60601-1-11. Therefore, operating and storage conditions do not influence product safety and effectiveness.

Note 5:

Memory function is only used to store data and has no effect on product safety and effectiveness.

Note 6:

The physical dimension & weight difference does not raise new safety and effectiveness issues. The subject device conforms to the applicable safety, EMC, and performance standards, including ANSI AAMI ES 60601-1, IEC 60601-1-2, IEC 60601-1-11, ISO 80601-2-56, ASTM E1965-98, etc. same as predicate device and reference device.

Note 7:

Although the skin-contacting materials are different, both conform to the same biocompatibility standard requirements of ISO 10993-1.

Note 8:

The subject device's measurement mode is adjusted mode only, and the measurement reference site is oral. The predicate device's information is unknown, but they both conform to the same performance standards requirements of ASTM E1965 and ISO 80601-2-56.

Note 9:

The subject device's algorithm is CM3.1, while the predicate device's is PH15.0. The difference is the algorithm version. It does not affect performance and accuracy, which was evaluated in the performance testing.

Note 10:

The subject device sensor model is MRT511, whereas the predicate device is TPS336. Both sensor models have the same operating principles. The difference does not affect the safety, EMC, and performance standards, including ANSI AAMI ES 60601-1, IEC 60601-1-2, IEC 60601-1-11, ISO 80601-2-56, ASTM E1965-98, etc. same as the predicate device.

Note 11:

The main IC of the subject device is SN8P2977, whereas the predicate device is HY11P14. Both main ICs have the same 24-bit analog to digital converter, just the model is different. The difference does not affect performance and accuracy, which was evaluated in the performance testing.

Note 12:

The subject device has no touch IC, whereas the predicate device has a touch IC. The function of the touch IC is to power the device ON. The difference does not affect the safety, EMC, and performance standards, including ANSI AAMI ES 60601-1, IEC 60601-1-2, IEC 60601-1-11, ISO 80601-2-56, ASTM E1965-98, etc. same as the predicate device.

7. **Testing Summary**:

The following performance data is provided in support of the substantial equivalence determination.

Comparative Clinical Study:

Clinical tests were conducted to verify that the proposed device meets the same design specifications as the Microlife Intellectual Property GmbH predicate. The testing was conducted according to the standard:

- ASTM E1965-98 (Reapproved 2016) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
-

This clinical study consists of 150 subjects, of which 1/3 (50 subjects) are infants, 1/3 (50 subjects) are children and the rest 1/3 (50 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 and clinical repeatability met the acceptance criteria of the clinical study protocol.

Safety and EMC

Testing was performed to verify the basic safety and essential performance of the Infrared Forehead Thermometer, DPT-IFT100. The following tests were performed:

- AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2:2014 Medical devices part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances –Requirements and tests

- IEC 60601-1-11 Edition 2.0 2015-01, Medical electrical equipment - part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

Performance Data:

The subject Infrared Forehead Thermometer, DPT-IFT100, was subjected to the following tests and passed all test criteria:

- ISO 80601-2-56 Second edition 2017-03 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. [Including Amendment 1 (2018)]
- ASTM E1965-98 (Reapproved 2016) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
- Premarket Notification [510(K)] Submissions For Clinical Electronic Thermometers

Software Verification and Validation

Software documentation, including verification & validation, was provided following FDA Guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices for software with a moderate level of concern.

Cleaning Validation

The device was cleaned following the procedure defined in the User's Manual. The device was checked for performance following the cleaning and met all performance requirements following the cleaning.

Biocompatibility

The subject Infrared Forehead Thermometer, DPT-IFT100, uses similar material to the predicate Microlife Intellectual Property GmbH device. Biocompatibility testing was performed to demonstrate compliance with the same biocompatibility standards as performed by the predicate device.

The Infrared Forehead Thermometer, DPT-IFT100 device is classified per ISO 10993-1: 2009 Annex 1 Biological evaluation tests as follows:
Surface Device – Intact skin– Contact Duration A – limited (≤24 h)

Based on this classification, the following cytotoxicity, skin irritation, and sensitization tests were conducted per the following standards:

- ISO 10993-5: 2009 Biological evaluation of medical devices – Part 5 Tests for In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological evaluation of Medical Devices – Part 10: Tests for Irritation- Skin Irritation
- ISO 10993-10: 2010 Biological evaluation of Medical Devices – Part 10: Tests for Irritation – Skin sensitization

The test results confirm compliance with the requirements of the standards.

All the labeling and characteristics of the submitted Infrared Forehead Thermometer, DPT-IFT100, is the same as the predicate device and most infrared forehead thermometers currently on the market. The proposed device and predicate use similar measuring methodologies and components to achieve the measurements.

The design of the submitted device specifications are similar to the predicate, with minor differences in the storage humidity range.

8. Conclusions:

   Based on the performance testing, comparison and analysis provided it was concluded that the subject device, Infrared Forehead Thermometer, DPT-IFT100 is substantially equivalent to predicate device, Microlife Non-Contact Infrared Forehead Thermometer, Model FR1DG1(NC200) cleared under K191829.