DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 6, 2017

Intelliworks, LLC
Dr. Jessica Leonardi
R&D Director
4910 Wright Road, Suite 120
Stafford, Texas 77477

Re: K163256
Trade/Device Name: Dual Mode Infrared Thermometer, Model DM-IR200
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: March 2, 2017
Received: March 8, 2017

Dear Dr. Jessica Leonardi:

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)*
K163256

Device Name
Dual Mode Infrared Thermometer, Model DM-IR200

Indications for Use *(Describe)*
The Dual Mode Infrared Thermometer (Model DM-IR200) is intended for the intermittent measurement and monitoring of human body temperatures. It is for non-professional use by consumers at home. The ear canal mode is indicated for use by people above one year old and the skin/forehead mode is indicated for use by people of all ages.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 2. 510(k) Summary
K163256

1. Submitter's Information

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Contact: Dr. Jessica Leonardi, R&D Director
Phone: 832-715-9539
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Date Summary Prepared: November 15, 2016

2. Proposed Device

Name: Dual Mode Infrared Thermometer, Model DM-IR200
Common Name: Ear Canal IR Thermometer; Skin IR Thermometer
Classification Name: Clinical Electronic Thermometer
Review Panel: General Hospital
Product Code: FLL
Device Class: II
Regulation Number: 21 CFR 880.2910

3. Predicate Devices

Predicate device #1: Microlife Dual Mode Thermometer, Model IFR1MJ1
510(k) Number: K113141

Predicate device #2: easystem duo, Dual Thermometer, Forehead/Ear, Model BT-021
510(k) Number: K033077

4. Device Description

The Dual Mode Infrared Thermometer (Model DM-IR200) is a hand-held, non-sterile, reusable, battery powered device designed to measure human body temperature via one of two body sites: the ear canal or skin of the forehead.

The DM-IR200 thermometer utilizes infrared technology to measure the natural thermal infrared energy emitted from the surface of the skin of the forehead or from the eardrum tissue.

5. Indications for Use

The Dual Mode Infrared Thermometer (Model DM-IR200) is intended for the intermittent measurement and monitoring of human body temperatures. It is for non-

professional use by consumers at home. The ear canal mode is indicated for use by people above one year old and the skin/forehead mode is indicated for use by people of all ages.

6. Comparison to Predicate Devices and Substantial Equivalence

The Dual Mode Infrared Thermometer (Model DM-IR200) is substantially equivalent to the predicate devices, which uses the same fundamental technology, is similar in design and has the same intended use.

The proposed device and predicate devices all utilize an infrared technology to measure natural infrared energy emitted from the skin surface of the forehead or from the eardrum tissue.

The proposed device and predicate devices are intended for the intermittent measurement and monitoring of human body temperatures by detecting body temperatures from the forehead or auditory canal. The proposed and predicate devices are designed for non-professional use by consumers at home. The intended population of the proposed device is all ages for the forehead mode and above one year old for the ear mode. There is a minor difference with the predicate devices with intended population of all ages.

The proposed and predicate devices mainly differ by the measurement range, memory sets, power supply and storage condition. A side-by-side comparison of the proposed device and the predicate device is included in the 510(k) submission.

Comparison of basic technological characteristics

Characteristics	Predicate Device #1	Predicate Device #2	Proposed Device
510(k) Number	K113141	K033077	K163256
Device name	Microlife Dual Mode Thermometer, Model IFR1MJ1	Easystem duo, Dual Thermometer, Forehead/Ear, Model BT-021	Dual Mode Infrared Thermometer, Model DM-IR200
Indications for use	The device is intended for the intermittent measurement and monitoring of human body temperatures. The device is indicated for use by people	The device is intended for the intermittent measurement and monitoring of human body temperature in the home. It is intended for use on people of all ages.	The device is intended for the intermittent measurement and monitoring of human body temperatures. It is for non-professional use by consumers at home. The ear mode is indicated for use by

	above 12 years old to geriatric for ear mode and from newborn to geriatric for forehead mode in the home.		people above one year old and the forehead mode is indicated for use by people of all ages.
Measurement method	Infrared radiation detection	Infrared radiation detection	Infrared radiation detection
Measurement mode	Dual mode – Ear and Forehead mode	Dual mode – Ear and Forehead mode	Dual mode – Ear and Forehead mode
Measurement range	Ear mode: 32.0°F-212.0°F (0.0°C-100.0°C) Forehead mode: 93.2°F-107.9°F (34.0°C-42.2°C)	Ear mode: 32.0°F-212.0°F (0.0°C-100.0°C) Forehead mode: 71.6°F-109.4°F (22.0°C-43.0°C)	Ear mode: 32.0°F-212.0°F (0.0°C-100.0°C) Forehead mode: 64.4°F-107.6°F (18.0°C-42.0°C)
Measurement accuracy	± 0.4°F /± 0.2°C	± 0.4°F /± 0.2°C	± 0.4°F / ± 0.2°C
Display resolution	0.1°F / 0.1°C	0.1°F / 0.1°C	0.1°F / 0.1°C
Signal output and display	LCD, Buzzer	LCD	LCD, Buzzer
°F/°C switchable	Yes	Yes	Yes
Memory	12 sets	10 sets	20 sets
Power supply	One 3V CR2032 battery	One 3V CR2032 battery	Two 1.5V AAA batteries
Operating conditions	Temperature: 50.0°F-104.0°F (10.0°C-40.0°C) Humidity: 15%-95% RH	Temperature: 60.8°F-104.0°F (16.0°C-40.0°C) Humidity: 15%-95% RH	Temperature: 50.0°F-104.0°F (10.0°C-40.0°C) Humidity: 15%-95% RH
Storage conditions	Temperature: -13.0°F to +131.0°F (-25.0°C to +55.0°C) Humidity: 15%-95% RH	Temperature: -4.0°F to +122.0°F (-20.0°C to +50.0°C) Humidity: 15%-95% RH	Temperature: -4.0°F to +122.0°F (-20.0°C to +50.0°C) Humidity: 15%-95% RH

7. Performance Summary

The Dual Mode Infrared Thermometer (Model DM-IR200) conforms to applicable standards that include:

ASTM E1965 Standard specification for infrared thermometers for intermittent determination of patient temperature

IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility

ISO 10993-1 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process

ISO 10993-5 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity

ISO 10993-10 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization

IEC 62304 Medical device software – Software life cycle processes

ISO 14971 Medical devices – Application of risk management to medical devices

Guidance document includes the FDA Guidance on the Content of Premarket Notification 510(k) Submissions for Clinical Electronic Thermometers.

8. Clinical Testing

A clinical study was performed to determine the clinical accuracy and to provide comparison with predicate device. The three groups of subjects being tested were: 1) infants under 1 year old, 2) children between 1 and 5 years old, and 3) patients over 5 years old.

The study included 105 subjects, with 33.3% febrile subjects. For each age group, the ratio of febrile subjects was more than 30%. The study excluded subjects with medical conditions such as inflammation at the measuring sites and subjects using medications known to affect body temperature. From each test site, a total of 105 data sets were collected.

The clinical accuracy of the proposed device was evaluated by determining two kinds of errors in accordance with requirements of ASTM E1965 – clinical bias with stated uncertainty and clinical repeatability. The clinical test results showed that there is substantial clinical agreement and repeatability between the proposed device and

predicate devices. The calculated clinical bias did not exceed 0.06°C, with uncertainty that did not exceed 0.02°C. The clinical repeatability was 0.1°C.

9. Conclusion

The Dual Mode Infrared Thermometer (Model DM-IR200) has the same intended use and similar technological characteristics as the predicate devices. In addition, compliance with applicable voluntary standards, as well as performance testing demonstrate that any differences in technological characteristics do not raise any new questions of safety and/or effectiveness. Therefore, we conclude that the Dual Mode Infrared Thermometer (Model DM-IR200) is substantially equivalent to the predicate devices.