



October 18, 2019

Suzhou Melodicare Medical Technology Co.,Ltd.
Xiaoqian Zou
General Manager
Building Room 301, No 32 Hongxi Road, Suzhou High-Tech Zone
Suzhou, 215163
China

Re: K191283

Trade/Device Name: Infrared Thermometer, Breeze model
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: September 11, 2019
Received: September 20, 2019

Dear Xiaoqian Zou:

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,

Geeta Pamidimukkala
Acting 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

Indications for Use

510(k) Number (if known)

K191283

Device Name

Infrared thermometer, model Breeze

Indications for Use (Describe)

The infrared thermometer is intended for the measurement and monitoring of human body temperature by physician or lay person. The device is not intended for infants less than three months.

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

Prepared in accordance with the requirements of 21 CFR Part 807.92

- 1. Submitter:** Suzhou Melodicare Medical Technology Co., Ltd.
Building Room 301, no. 32 Hongxi road, Suzhou high-tech zone, Jiangsu province, China
Tel.: +86 -791-85216384
- Contact Person:** Xiaoqian Zou
- Prepare date:** October 17, 2019
- 2. Device name and classification:** **Device Name:** Infrared Thermometer
Models: Breeze
Classification Name:
21 CFR 880.2910
Clinical Electronic Thermometers
Product code: FLL
Regulatory Class: Class II
- 3. Reason for Submission** New Application.
- 4. Predicate Device(s):** Shenzhen Brav Electronic Technologies Co., Ltd., EFT-165 Infrared Thermometer /K171214
- 5. Device Description:** Breeze Infrared Thermometer measure the body temperature through receiving infrared energy radiation via the ear or forehead. These thermometers have the capability to measure temperature via forehead temperature mode or ear temperature mode, and the temperature is directly shown on the LCD display.
- The device is intended to be used in the home setting and medical institutes.
 - The product is mainly composed of infrared temperature sensors, signal receiving processor, buttons, buzzer, LCD display. It is powered by 2 X 1.5 AAA batteries.
 - It focuses the infrared energy received from the human's forehead or ear by using the Fresnel lens of the thermometer.
- When measuring the ear temperature, the ear cover provided by the manufacturer must be used.
- 6. Indications for Use:** The infrared thermometer is intended for the measurement and monitoring of human body temperature by physician or lay person. The device is not intended for infants less than three months.

7. Predicate Device Comparison

In comparison to the predicate device, the subject device has the same intended use, similar product design, same performance effectiveness, and performance safety as the predicate device.

Please refer to the following table that notes differences between the subject device and predicate device. All the differences do not affect the basic design principle, usage, effectiveness and safety of the subject device. No new questions are raised regarding effectiveness and safety.

Table 1 Comparison between the main predicate device EFT-165 and the subject device

ITEM	Proposed Device Breeze	Predicate Device EFT-165/ K171214	Comparison Result
Manufacture	Suzhou Melodicare Medical Technology Co., Ltd.	Brav Electronic Technologies Co., Ltd.	---
Indications for Use	The infrared thermometer is intended for the measurement and monitoring of human body temperature by physician or lay person. The device is not intended for infants less than three months.	The infrared thermometer is intended for the measurement and monitoring of human body temperature by doctor or customers in the hospital or home.	Different ¹
Operational Specifications			
Operational Principle	Infrared radiation detection	Infrared radiation detection	Same
Measuring Mode	Forehead and ear	Forehead and ear	Same
Measurement Range	34.0°C~42.4°C (93.2°F~108.3°F)	32.0°C~42.9°C (89.6°F~109.2°F)	Different ²
Measurement Distance	0 cm	0 cm	Same
Accuracy	±0.2°C(0.4°F)	±0.2°C(0.4°F)	Same
Memory Data Limit	memorize 32 measurements automatically	memorize 20 measurements automatically	Same
Product configuration	It is mainly composed with infrared sensor, signal receiving processor, buttons, buzzer, LCD display, battery and etc.	It is mainly composed with infrared sensor, signal receiving processor, buttons, buzzer, LCD display, battery and etc.	Same
Temperature unit and conversion	Dual temperature units “°C” and “°F” optional, and the two units can convert by the conversion key automatically	Dual temperature units “°C” and “°F” optional, and the two units can convert by the conversion key automatically	Same
Bluetooth Compatible	NO	YES	Different ³
Applicable Standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, and ASTM E1965-98, ISO 10993-5, ISO 10993-10, ISO 80601-2-56	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, and ASTM E1965-98, ISO 10993-5, ISO 10993-10, ISO 80601-2-56	Same
Display	0.1°C/°F, LCD	0.1°C/°F, LCD	Same

Operating Environment	15°C ~ 35°C (59°F to 95 °F) ≤85% moisture condensation	15°C ~ 35°C (59°F to 95 °F) ≤85% moisture condensation	Same
Storage Environment	-20°C~55°C (-4°F~131°F) ≤90% moisture condensation	-20°C~55°C (-4°F~131°F) ≤90% moisture condensation	Same
Power supply	2 X 1.5V AAA	2 X 1.5V AAA	Same
Physical Specifications			
Weight	62 g (without battery)	72 g (without battery)	Different ⁴
Dimensions (length x width x height)	161.5mm *35.8mm *55.9mm	152mm * 44 mm *30mm	
Biological Specifications			
Patient Contacting Materials	ABS, PE	ABS, PE	Same
Patient Contacting	Surface-contacting, less than 24 h	Surface-contacting, less than 24 h	Same

Justification for the differences:

1) Different Indications for Use

As indicated in the comparison table, the subject device can be used both in hospital and home, which the predicate can be used in both scenarios. The difference is just the different language, so the difference will not introduce any new questions of safety and effectiveness. The age range of the patients for the subject device is based on the conducted clinical testing.

2) Different Measurement Range

The measurement range of the subject device is 34.0°C~42.4°C, minor different from that of the predicate device 32.0°C~42.9°C. The difference will not affect the clinical safety and effectiveness since the range can cover the temperature range during intended application scenarios, and the subject device has been verified to meet the accuracy requirements defined in the standards ASTM E 1965-98 and ISO 80601-2-56.

3) Different Bluetooth function

The subject device is not equipped with the Bluetooth function while the predicate does, but absence of this function will not raise new safety and effectiveness.

4) Different Physical Specifications

The subject and the predicate are of different size but proximity. Moreover, such engineering design has been verified during the international standards, so such minor difference will not raise any safety and effectiveness questions.

As seen in the comparison tables, the subject and predicate devices have almost the same design features and performance specifications. The only differences between the subject and predicate devices are the indications for use (which link specific age groups with specific modes of temperature reading) and the appearance and operating/storage environment, which do not raise different questions of safety or effectiveness. Moreover, as demonstrated in the non-clinical and clinical testing, the different indications and technological characteristics do not affect the safety and effectiveness of the Breeze Infrared thermometer system.

8. Performance Testing:

Performance data includes “Non-Clinical Data” and “Clinical Data”. Summary of the data provided is below:

Non-Clinical Data:

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

Biocompatibility testing

The biocompatibility evaluation for the Breeze Infrared thermometer was conducted in accordance with the International Standard ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. The worst case of the whole system is considered tissue-contacting for a duration of less than 24 hours. And Cytotoxicity, Skin Sensitization and Skin Irritation tests were conducted.

Reprocessing: Cleaning and Disinfection

The sterilization and shelf life information provided are acceptable because the subject devices are non-sterile devices. The validation testing results for cleaning and disinfection of the subject devices are adequate and acceptable.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Breeze Infrared thermometer device, consisting of all the modules and accessories in the system. The system complies with IEC60601-1: 2012, *Medical electrical equipment Part 1: General requirements for basic safety and essential performance* for safety, IEC 60601-1-11: 2015 *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*, and the IEC 60601-1-2: 2014 *Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests* standard for EMC.

Bench Testing

Bench testing was conducted on the Breeze Infrared thermometer device, consisting of all the accessories in the system. The system complies with ISO 80601-2-56: 2009 *Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement* for performance effectiveness.

Software Verification and Validation Testing

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

Risk Analysis

A risk analysis was conducted in accordance with ISO 14971: 2007 – Medical devices - Application of risk management to medical devices.

Clinical data:

Clinical testing was conducted per ASTM E 1965-98 (2009) *Standard Specification for Infrared Thermometers For Intermittent Determination Of Patient Temperature*. This clinical study was randomized, with a simple blind homologous control, which consisted of a minimum of 144 subjects with the various age groups as referenced in Section 201.102 of ISO 80601-2-56.

9. Substantial Equivalence Conclusion:

Differences between the indications for use and technological characteristics of the subject device compared to the predicate do not raise different questions of safety and effectiveness. The performance of the device is supported by non-clinical testing, clinical testing, and risk management activities. The Suzhou Melodicare Medical Technology Co., Ltd. Breeze Infrared Thermometer is Substantially Equivalent (SE) to the Shenzhen Brav Electronic Technologies Co., Ltd., EFT-165 Infrared Thermometer, cleared under K171214.