February 12, 2021

Shandong Bittel Intelligent Technology Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co.,Ltd
Contact AddressP.O. Box 120-119
Shanghai, 200120
China

Re: K202368
Trade/Device Name: Infrared Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: January 14, 2021
Received: January 15, 2021

Dear Diana Hong:

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
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

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)*
K202368

Device Name
Infrared thermometer

Indications for Use *(Describe)*
The Infrared thermometer is non-contact infrared thermometer intended for the intermittent measurement of human body temperature from forehead for people of all age. 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Exhibit # 2 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K202368

1. Date of Preparation: 02/12/2021

2. Sponsor Identification

Shandong Bittel Intelligent Technology Co., Ltd.
No.1 Rizhao North Road, Rizhao, Shandong China 276800

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

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P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Infrared thermometer
Common Name: Clinical electronic thermometer

Regulatory Information

Classification Name: Clinical electronic thermometer;
Classification: II;
Product Code: FLL;
Regulation Number: 21CFR 880.2910
Review Panel: General Hospital;

Indication for Use Statement:
The Infrared thermometer is non-contact infrared thermometer intended for the intermittent measurement of human body temperature from forehead for people of all age. The device is reusable for home use and clinical use

Device Description
The proposed device, infrared thermometer, is hand-held, reusable, battery powered device, which is intended to measure human body temperature by measuring forehead. The distance of the measurement is 1~5cm. The device is non-contacting infrared thermometer and intended for people of all age.

5. Identification of Predicate Device

510(k) Number: K191251
Device Name: Infrared Thermometer
Product Code: FLL;
Regulation Number: 21CFR 880.2910

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test performed on the proposed device include

Biocompatibility testing
The biocompatibility test for the proposed device was conducted in accordance with the FDA guidance "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The biocompatibility testing items include cytotoxicity, Sensitization and Irritation test, the test result demonstrated that there was no adverse

effects, thereby, it can be determined that the device can comply with 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 and skin sensitization

Electrical safety and EMC

Electrical safety and EMC testing were conducted on the proposed device and the test result demonstrated that the device can operate normally and did not raise any performance degradation and safety issue, thereby, it can be determined that the device can comply with the following standards

- IEC 60601-1: 2005+CORR.1(2006)+CORR.2(2007)+AMI(2012) Medical electrical equipment-Part 1: general requirement for basic safety and essential performance
- IEC 60601-1-2:2014 Medical Electrical Equipment- Part 1-2: General Requirements for Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility-Requirements And Tests.
- ISO 80601-2-56: 2017+A1: 2018 Medical Electrical Equipment- Part 1-2: Particular Requirements for Basic Safety And Essential Performance of Clinical thermometers for body temperature measurement

Software Verification and Validation Testing

Software verification and validation testing were conducted on the Infrared thermometer and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The test result demonstrated that the software can achieve its performance.

7. Clinical Test Conclusion

A controlled human clinical study was conducted on proposed device by comparing against with predicate device in accordance with ASTM E1965-98 (2016). The test result demonstrated that accuracy and repeatability can meet the acceptance criteria. Therefore, it can be considered that the device conforms with ASTM E1965-98 (2016).

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device K202368	Predicate Device K191251	Remark
Product Code	FLL	FLL	Same
Regulation Number	21 CFR 880.2910	21 CFR 880.2910	Same
Indication for Use	The Infrared thermometer is non-contact infrared thermometer intended for the intermittent measurement of human body temperature from forehead for people of all age. The device is reusable for home use and clinical use	The Infrared thermometer is non-contact infrared thermometer intended for the intermittent measurement of human body temperature from forehead for people of all age. The device is reusable for home use and clinical use	Same
Measurement Method	Infrared radiation detection	Infrared radiation detection	Same
Components	Side button and main button Left/Right shell Spear shell Display screen case Battery cover	Button Shell LCD display case Battery cover	Different 1
Measurement Range	32.5℃ ~42.5℃ (90.5 ~ 108.5 °F)	32.0℃ ~ 42.5℃ (89.6 ~ 108.5 °F)	Different 2
Accuracy	±0.2℃ (0.4°F) at 35.0℃～42.0℃ (95.0°F ~ 107.6 °F) Others ±0.3℃ (0.5 °F)	±0.2℃ (0.4°F) at 35.0℃～42.0℃ (95.0°F ~ 107.6 °F) Others ±0.3℃ (0.5 °F)	Same
Display	0.1℃(0.1℉)	0.1℃(0.1℉)	Same
Memory	NA	60 sets	Different 3
Measurement mode	Direct mode	Direct mode	Same
Display type	LCD	LCD	Same
Measurement Place	Forehead	Forehead	Same
Measurement distance	1~5cm	≤3cm	Different 4
Response time	1s	1s	Same
Sensor type	Thermopile	Thermopile	Same
Scale Selection	℃/℉	℃/℉	Same
Auto power-off while no operation	Yes	Yes	Same
Operation	15℃～40℃ (59 ~ 104 °F)	10℃~40℃ (50°F ~ 104 °F)	Different 5

environment	15%～85% RH	15%～95% RH	
Storage environment	-25℃～+50℃ (-13 ~ +122°F) 15%～90% RH	-25℃～+55℃ (-13 ~ +131°F) 15%～95% RH	
Power requirements	Two pieces of 1.5V AAA batteries	Two pieces of 1.5V AAA batteries	Same
Safety	Complied with IEC 60601-1	Complied with IEC 60601-1	Same
EMC	Complied with IEC 60601-1-2	Complied with IEC 60601-1-2	Same
Performance	Complied with ISO 80601-2-56	Complied with ISO 80601-2-56	Same
Service life	3 years	Unknown	Different 6
Patient-contact Materials	ABS PC Silicone rubber	ABS	Different 7
Biocompatibility	No Cytotoxicity	No Cytotoxicity	Same
	No Sensitization	No Sensitization	
	No Irritation	No Irritation	

Different 1 – Components

The components of the proposed device is different with the predicate device. However, the components don't affect the intended use. Therefore, the different will not affect the substantially equivalency.

Different 2 - Measurement Range

The measurement range of the proposed device is different with the predicate device, but the measurement range of the proposed device is within the measurement range of predicate device and the measurement range can meet the requirement of ISO 80601-2-56. In addition, the clinical investigation has been conducted on the proposed device and the test result demonstrated that the accuracy can meet the requirement. Therefore, this difference is not considered to affect the substantially equivalency.

Different 3 - Memory

The proposed device does not have the memory function. However, this function does not affect the intended use. Therefore, the different will not affect the substantially equivalency.

Different 4 - Measurement distance

The measurement distance of the proposed device is different from the predicate device. However, the clinical investigation has been conducted on the proposed device within the intended measurement range (1~5cm) and the test result demonstrated that the accuracy can meet the requirement. Therefore, this difference is not considered to affect the substantially equivalency.

Different 5 - Operation environment & Storage environment

The operation environment and storage environment of the proposed device is different with the

predicate device. However, the operation environment and storage environment is similar with predicate device. Therefore, this difference is not considered to affect the substantially equivalency.

Different 6 - Service life

The service life for the predicate device is unknown. However, the service life test has been conducted on the proposed device and the results show that the proposed device can still maintain its function as intended at the end of the proposed service life. Therefore, this difference is not considered to affect the substantially equivalency.

Different 7 - Materials

The material of the proposed device is different with the predicate device, however, the biocompatibility test has been conducted on the proposed device and the test result does not show any adverse effects. Therefore, this difference is not considered to affect the substantially equivalency.

9. Substantially Equivalent (SE) Conclusion

From the bench test conducted on the proposed device provided in above, the test result showed that the proposed device can meet the requirements of related standards. Therefore, it can be determined that the proposed devices are Substantially Equivalent (SE) to the predicate device, K191251.