November 20, 2018

Shenzhen AOJ Medical Technology Co., Ltd.
Qihuan Zhao
General Manager
Room 202, HaoGu Industry Park, 2037 Guanguang Road,
Guangming District, Shenzhen
Guangdong, 518105
China

Re: K182133
Trade/Device Name: Infrared Thermometer, models AOJ-20A and AOJ-20B
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: October 12, 2018
Received: October 22, 2018

Dear Qihuan Zhao:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 K. Pamidimukkala -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182133

Device Name
Infrared thermometer, models AOJ-20A and AOJ-20B

Indications for Use *(Describe)*
The Infrared thermometers (AOJ-20A and AOJ-20B) take human body temperature via the eardrum or forehead. They apply to all age groups except for babies under three months. Both devices apply to both professional use and home 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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510(k) Summary

K182133

Prepared in accordance with the requirements of 21 CFR Part 807.92

1. Submitter:

Shenzhen AOJ Medical Technology Co., Ltd.

Room 202, HaoGu industry park, 2037 Guanguang road, Guangming district, 518105, Shenzhen, P.R. China

Tel.: +86 18603031299

Contact Person: Qihuan Zhao

Prepare date: 2018-11-15

2. Device name and classification:

Device Name: Infrared Thermometer

Models: AOJ-20A, AOJ-20B

Regulation Number: 21 CFR 880.2910

Regulation Name: Clinical Electronic Thermometer

Product code: FLL

Regulatory Class: Class II

3. Predicate Device(s):

Shenzhen Brav Electronic Technologies Co., Ltd., EFT-165 Infrared Thermometer /K171214

4. Device Description:

The infrared thermometers (AOJ-20A and AOJ-20B) are handheld instruments, which can measure human body's temperature either via the eardrum or the forehead for clinical or home use. The intended patient population is all age groups except for babies under three months.

The thermometers are powered by AAA 1.5V×2 alkaline batteries. The results can be displayed on LCD.

A thermopile sensor is employed to detect or monitor the infrared thermal energy emitted from the eardrum or the surface of the skin of the forehead, which is converted into temperature measurement with the unit of ℃ or ℉.

5. Indications for Use:

The Infrared thermometers (AOJ-20Aand AOJ-20B) take human body temperature via the eardrum or forehead. They apply to all age groups except for babies under three months. Both devices apply to both professional use and home use.

6.**Predicate Device Comparison**

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

ITEM	**Proposed Device AOJ-20A&AOJ-20B**	**Predicate Device EFT-165/K171214**	**Comparison Result**
Manufacture	Shenzhen AOJ Medical Technology Co., Ltd.	Brav Electronic Technologies Co., Ltd.	---
Indications for Use	The Infrared thermometers (AOJ-20Aand AOJ-20B) take human body temperature via the eardrum or forehead. They apply to all age groups except for babies under three months. Both devices apply to both professional use and home use.	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	32.0°C～42.9°C （89.6°F~109.2°F)	32.0°C～42.9°C （89.6°F~109.2°F)	Same
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 20 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
Applicable Standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, and ASTM E1965-98	AAMI ANSI ES60601-1, IEC 60601-1-2, IEC 60601-1-11, and ASTM E1965-98	Same
Display	0.1°C/°F, LCD	0.1°C/°F, LCD	Same
Operating Environment	Temperature: 10°C~ 40°C (50°F–104°F) Humidity: 15%–95% RH, non-condensing Atmospheric pressure: 70–106 kPa	15°C ~ 35°C (59°F to 95 °F) ≤85% moisture condensation	Different [2]
Storage Environment	Ambient Temperature: -20°C to 55°C （-4°F–131°F） Relative Humidity: 0-95% RH, non-condensing Atmospheric pressure: 50kPa to 106kPa	-20°C~55°C（-4°F~131°F）≤90% moisture condensation	
Power supply	2 X 1.5V AAA	2 X 1.5V AAA	Same

Physical Specifications			
Weight	90g (battery included)	72 g (without battery)	Different [3]
Dimensions	146mm *52 mm *40 mm	152mm * 44 mm *30mm	
Biological Specifications			
Patient Contacting Materials	PC+ABS	PC+ABS	Same
Patient Contacting	Surface-contacting, Less than 24 h	Surface-contacting, Less than 24 h	Same
Biocompatibility Standard	ISO 10993-5, ISO 10993-10	ISO 10993-5, ISO 10993-10	Same
Biocompatibility Testing Items	In vitro Cytotoxicity Skin Sensitization Irritation	In vitro Cytotoxicity Skin Sensitization Irritation	Same

Justification for the differences:

1) Different Indications for Use

   As indicated in the comparison table, the subject device and the predicate device have similar indications for use, the subject device includes the patient population and areas to take temperature. The intended use is the same.

2) Different Operation&Storage&Transport Environments

   Minor difference to operation environments (including Temperature and Relative Humidity) for the subject device, but the system has demonstrated to be as safe and effective as the predicate device since the safety testing was conducted under the suggested environment; Moreover, environment testing data shows the device can work as intended under the suggested conditions. So those changes do not raise any safety and effectiveness concerns.

3) Different Physical Specifications

   The subject and the predicate are of different size but proximity. Moreover, such engineering design has been verified during development by compliance with the applicable international standards, so such minor different will not raise any new problems.

As seen in the comparison tables, the subject and predicate devices have almost the same design features and performance specifications. Moreover, as demonstrated in the non-clinical and clinical testing, AOJ-20A&AOJ-20B Infrared thermometer system can perform as intended.

7.**Performance Testing**

7.1 Non-Clinical Data

The following safety standards are conducted on the subject device support of the substantial equivalence determination, including performance testing and bench testing.

Performance Testing Information:

(1) ISO 10993-5 *Biological evaluation for medical device Part 5 - Test for In Vitro Cytotoxicity*
(2) ISO 10993-10 *Biological evaluation for medical device Part 10 - Test for irritation and skin sensitization*
(3) AAMI TIR12:2004 *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers, Approved 23 December 2004.*

Bench Testing Information:

(1) ANSI/AAMI 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.*
(2) IEC 60601-1-11: 2010 *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.*
(3) IEC 60601-1-11: 2010 *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.*
(4) 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.*
(5) 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.*
(6) Software verification and validation testing per FDA's Guidance for Industry and FDA Staff, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued on May 11, 2005.*

7.2 Clinical Data

Clinical testing is conducted per *ASTM E 1965-98 (Reapproved 2009) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature.*

This clinical study is a randomization, simple blind homologous control, pairing design of clinical investigation, consists of a minimum of 90 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.). with no single measurement error exceeding the allowable limit, provides a 99% confidence. A reference device is introduced as required by the standard, and the acceptance criteria is that clinical accuracy of the subject device is at least the same as that of the reference, and the accuracy is ±0.2°C during the claimed measurement range 32°C - 42.9°C.

8.**Conclusion**

Verification and validation testing was conducted on the subject device and all testing passed pre-specified criteria. This premarket notification submission demonstrates that the AOJ-20A & AOJ-20B Infrared Thermometer is substantially equivalent to the predicate device.