October 7, 2022

Shenzhen AOJ Medical Technology Co., Ltd.
Jack Wang
Deputy Chief
Room 301&4F, Blk A, Building A, Jingfa IM Park
Xiaweiyuan, Gushu Community, Xixiang, Baoan
Shenzhen, Guangdong 518126
China

Re: K221170
Trade/Device Name: Forehead Thermometer, models AOJ-F101, AOJ-F102, AOJ-F103, AOJ-F104 AOJ-F105, AOJ-F106, AOJ-F107
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: September 1, 2022
Received: September 6, 2022

Dear Jack Wang:

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,

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)*
K221170

Device Name
Forehead Thermometer, models AOJ-F101, AOJ-F102, AOJ-F103, AOJ-F104, AOJ-F105, AOJ-F106 and AOJ-F107

Indications for Use *(Describe)*
The thermometer is intended to measure human body temperature of people over one month from surface of forehead. It is a non-sterile, reusable, non-contact and hand-held device. It is indicated to be used in homecare and healthcare environments.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

K221170

510(k) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

1. Submitter:	Shenzhen AOJ Medical Technology Co., Ltd. Room 301&4F, Block A, Building A, Jingfa Intelligent Manufacturing Park, Xiaweiyuan, Gushu Community, Xixiang Street, Bao'an District, 518126, Shenzhen, China TEL: 86 755-27786026
Contact Person:	Jack Wang
Prepare date:	September 14, 2022
2. Device name and classification:	**Device Name:** Forehead Thermometer **Models:** AOJ-F101, AOJ-F102, AOJ-F103, AOJ-F104, AOJ-F105, AOJ-F106 and AOJ-F107 **Classification Name:** 21 CFR 880.2910 Clinical Electronic Thermometers-Temperature Monitor with Probe **Product code:** FLL **Regulatory Class:** Class II
4. Predicate Device(s):	Shenzhen Changkun Technology Co., Ltd. CK-T1503 Infrared thermometer cleared under K193253.
5. Device Description:	The Forehead thermometer is a handheld device, which can measure human body's temperature from the forehead for clinical or home use. The results can be displayed on LCD. The measurement is non-contact with a distance of 3-5 cm to measure the temperature. The thermometers are powered by AAA 1.5V×2 alkaline batteries, which can be used for people over one month. A thermopile sensor is employed to detect or monitor the infrared thermal energy emitted from the surface skin of the forehead, which is converted to a body temperature with the unit of ℃ or °F. The reference body site of the output temperature is oral. All the models share the similar design and the same critical components, and compose of a sensor, PCB, buttons, LCD display and housing. Functions include temperature measurement, memory reading recall, voice mute/unmute and unit/mode switch, low battery detection and high temperature indicator.
6. Indications for Use:	The thermometer is intended to measure human body temperature of people over one month from surface of forehead. It is a non-sterile, reusable, non-contact and hand-held device. It is indicated to be used in homecare and healthcare environments.

7. Predicate Device Comparison

Comparison to the predicate devices, the subject device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate device.

Please refer to following table to find 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. And no question is raised regarding to effectiveness and safety.

Table 1 Comparison between the predicate CK-T1503 and the subject devices

ITEM	**Proposed Device K221170 AOJ-F101/AOJ-F102/AOJ-F103/AOJ-F104/AOJ-F105/AOJ-F106/AOJ-F107**	**Predicate Device CK-T1503/K193253**	**Comparison Result**
Manufacture	Shenzhen AOJ Medical Technology Co., Ltd.	Shenzhen Changkun Technology Co., Ltd.	----
Indications for Use	The thermometer is intended to measure human body temperature of people over one month from surface of forehead. It is a non-sterile, reusable, non-contact and hand-held device. It is indicated to be used in homecare and healthcare environments.	Infrared Thermometer (model: CK-T1501, CK-T1502, CK-T1503) is a non-sterile, reusable, non-contact and handheld device. It can be used by consumers in homecare environment and doctors in clinic as reference. It is intended for measuring human body temperature of people over one month old by detecting infrared heat from the forehead.	Different [1]
Operational Specifications			
Operational Principle	Infrared radiation detection	Infrared radiation detection	Same
Measuring Mode	Forehead	Forehead	Same
Measurement Distance	3~5 cm for forehead mode	3~5 cm for forehead mode	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
Measurement Range	32.0°C～42.9°C	32.0°C～42.5°C	Different [2]
Accuracy	±0.2°C	32°C~34.9°C: ± 0.3°C 35°C~42°C: ±0.2°C 42.1°C~42.5°C: ±0.3°C	
Memory Data Limit	40 values	32 values	Different [3]
Temperature unit and conversion	YES, ℃/℉ switchable	YES, ℃/℉ switchable	Same
Applicable Standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, and ISO 80601-2-56	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, and ISO 80601-2-56	Same
Display	0.1°C/°F, LCD	0.1°C/°F, LCD	Same
Operating Environments	Temperature: 15°C~ 40°C Humidity: 10% - 85% (Non-Condensing) Atmospheric pressure: 70–106 kPa	Temperature: 10°C~ 40°C Humidity: 15%–85% (Non-Condensing) Atmospheric pressure: 80–106 kPa	Different [4]
Transport and Storage Environments	Temperature: 0°C~ 40°C Humidity: no more than 90% (Non-Condensing)	Temperature: 0°C~ 50°C Humidity: ≤90% (Non-Condensing)	

	Atmospheric pressure: 70–106 kPa	Atmospheric pressure: 80–106 kPa	
Power supply	2 X 1.5V AAA Alkaline battery	2 X 1.5V AAA Alkaline battery	Same
Physical Specifications			
Weight	AOJ-F101: 100 g (W/O battery) AOJ-F102: 100 g (W/O battery) AOJ-F103: 102 g (W/O battery) AOJ-F104/AOJ-F105/ AOJ-F106 /AOJ-F107: 100 g (W/O battery)	172 g (battery included)	Different [5]
Dimensions (mm×mm×mm)	AOJ-F101: 158×102×41 AOJ-F102: 158×83×45 AOJ-F103: 158×95×43 AOJ-F104/AOJ-F105/ AOJ-F106 /AOJ-F107: 158×83×45	149×77×43	
Biological Specifications			
Patient Contacting Materials	ABS, PC	ABS	Different [6]
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 application scenario of the subject device and the predicate device can be used both in hospital and home, they have same intended use, they are just some language description differences. The difference does not raise new safety and effectiveness issues.

2) Different measurement range and accuracy

   The measurement range and accuracy of subject device have minor difference from that of the predicate device, which are software-controlled function, and the measurement range and accuracy has been evaluated per the internal standards ISO 80601-2-56. The test results met the requirements.

   The differences do not raise new safety and effectiveness issues.

3) Different memory capacity

   The predicate device can store up to 32 values, while the subject device has the capacity to store 40 memories, this memory function has been verified during the design and development process. The test results met the requirements.

   The differences do not raise new safety and effectiveness issues.

4) Different Operation Environments

   Minor difference to operation environments between the subject device and the predicate device, but the system has been proved to be safe and effective since the performance testing was conducted under the suggested environment and the results met the requirements. The difference does not raise

new safety and effectiveness issues.

5) Different Physical Specifications

   The weight and size of the subject device and predicate are different. The performance testing was conducted in accordance with standards. The test results met requirements. The differences do not raise new safety and effectiveness issues.

6) Different Patient Contacting Materials

   Different materials used in the subject device and the predicate.

   Biocompatibility testing was conducted for the subject device. The test results demonstrate the subject device comply with standard ISO 10993-5 and ISO 10993-10. The difference does not raise any new safety and effective issues.

8. Performance Testing:

Performance data includes "Non-Clinical Data" and "Clinical Data", brief description of which are shown as below.

Non-Clinical Data:

Biocompatibility testing

The biocompatibility evaluation for the thermometer were 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 surface-contacting, limited exposure (-less than 24 hours). And the evaluation of testing is summarized as below.

Test name	Test standard	Evaluation endpoint	Summary results
In vitro Cytotoxicity	ISO 10993-5	No potential cytotoxicity is allowed	No potential cytotoxicity
Skin Sensitization	ISO 10993-10	No sensitization should be observed	No sensitization observed (test sample score 0)
Skin Irritation	ISO 10993-10	No irritation should be observed	Negligible (no observed primary irritation, test sample score 0).

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the thermometer device. The device complies with the IEC 60601-1 *Medical electrical equipment Part 1: General requirements for basic safety and essential performance* for safety, IEC 60601-1-11 *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 *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 thermometer device, consisting of all the accessories in the system. The system complies with the ISO 80601-2-56 *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 verification and validation testing were conducted and the test results demonstrated the software function met the requirements. The 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 software for this device was considered as a "moderate" level of concern.

Clinical data:

The clinical testing was conducted per Section 201.102 of ISO 80601-2-56 on the subject device. Clinical accuracy validation was carried out on people over one month indicated in the instructions for use. The number of subjects in each age group met the minimum number requirements. The specific number of tested subjects, age groups and test results are described as below.

Item / Model	Age group	Subject number in total
AOJ-F101	A1, A2, B, C	153
AOJ-F102	A1, A2, B, C	142
AOJ-F103	A1, A2, B, C	132

Age group is defined as below:

- A1 1 month up to 3 months
- A2 3 months up to one year
- B older than one and younger than five years
- C older than five years

9. Conclusion:

Verification and validation testing was conducted on the subject device and all testing passed pre-specified criteria. Based on the performance testing, comparison and analysis above, the subject AOJ Forehead Thermometer is substantially equivalent to the predicate device.