



October 14, 2023

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

Re: K232128

Trade/Device Name: Infrared Thermometer (AOJ-20A); Infrared Thermometer (AOJ-20Y)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: July 13, 2023
Received: July 17, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

A handwritten signature in black ink that reads "David Wolloscheck". The signature is written in a cursive style and is positioned over a large, light blue, semi-transparent watermark of the letters "FDA".

David Wolloscheck, Ph.D.
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

Indications for Use

Submission Number (if known)

K232128

Device Name

Infrared Thermometer (AOJ-20A);
Infrared Thermometer (AOJ-20Y)

Indications for Use (Describe)

The Infrared thermometer is intended to measure human body temperature of people over three months old from the eardrum or forehead. 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.

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510(k) Summary

Prepared on: 2023-07-17

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Shenzhen AOJ Medical Technology Co., Ltd
Applicant Address	Room 301&4F, Block A, Building A, Jingfa Intelligent Manufacturing Park, Xiaweyuan, Gushu Community, Xixiang Street, Bao'an District, Shenzhen Guangdong 518126 China
Applicant Contact Telephone	86 755-27786026
Applicant Contact	Mr. Jack Wang
Applicant Contact Email	regulation@aojmedical.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Infrared Thermometer (AOJ-20A); Infrared Thermometer (AOJ-20Y)
Common Name	Clinical electronic thermometer
Classification Name	Thermometer, Electronic, Clinical
Regulation Number	880.2910
Product Code	FLL

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221039	Infrared Thermometer, models AOJ-20A, AOJ-20Y	FLL
K220276	Infrared Thermometer TET-351 (Reference Device)	FLL

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The Infrared thermometer is a handheld device, which can measure human body's temperature either via the eardrum or the forehead for clinical or home use. The results can be displayed on LCD and can also be transmitted to a non-device APP to record and display through Bluetooth.

There are two models AOJ-20A and AOJ-20Y. Both models share the same construction except differences on product enclosure, PCB layout and button designs.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The Infrared thermometer is intended to measure human body temperature of people over three months old from the eardrum or forehead. It is indicated to be used in homecare and healthcare environments.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indication for use of the subject device is the same as the predicate devices.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The subject device is a modification device to the device cleared by K221039. The only modification is software change to allow Bluetooth communication to a non-device APP. K220276 was used as a reference device to support the evaluation of the Bluetooth feature.

Non-Clinical and/or Clinical Tests Summary & Conclusions [21 CFR 807.92\(b\)](#)

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

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 includes the following tests:

- - Cytotoxicity
- - Skin Sensitization
- - Skin Irritation

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the thermometer devices. 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 documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions" The software for this device was considered as a "Basic" Documentation level.

Not Applicable.

Based on the non-clinical performance data as documented in the device development, the subject devices were found to be as safe, as effective, and perform as well as the legally marketed devices identified above.