April 7, 2026

Hangzhou Tappa Medical Technology Co., Ltd.
Na Ban
Registration Specialist
No. 225#, Chutian Road, Binjiang District, Hangzhou
Hangzhou,
China

Re: K252861
Trade/Device Name: Warming System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: March 6, 2026
Received: March 6, 2026

Dear Na Ban:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Meaghan Erlewein -S

For Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural, and Vascular Devices
OHT2: Office of Cardiovascular 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252861

Device Name
Warming System

Indications for Use *(Describe)*
The Warming System is indicated for hypothermic patients or normothermic patients for whom induced hyperthermia or localized increase in temperature is clinically indicated.

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."

510(k) Summary

I. Submitter

Hangzhou Tappa Medical Technology Co., Ltd.
No. 225#, Chutian Road, Binjiang District, Hangzhou, China
Contact person: Ms. Banna
Tel.:+86-13985728517
E-mail: bann@tongpumed.com

Preparation date: September 8th, 2025

II. Proposed Device

Device Trade Name:	Warming System
Common name:	system, thermal regulating
Regulation Number:	21 CFR 870.5900
Regulatory Class:	Class II
Product code:	DWJ
Review Panel:	Cardiovascular

III. Predicate Devices

510(k) Number:	K231596
Trade name:	IOB Temperature Management System
Common name:	System, thermal regulating
Classification:	Class II
Product Code:	DWJ
Manufacturer	IOB Medical Inc

IV. General description

The Warming System is a forced air warming system which is comprise of a Medical Warming Unit and variety models of Disposable Warming Blankets. It is indicated for hypothermic patients or normothermic patients for whom induced hyperthermia or localized increase in temperature is clinically indicated.

Medical Warming Unit (TMS - W101)

The Medical Warming Unit is composed of a Medical Warming Unit and a mobile trolley (optional accessory).

The Medical Warming Unit has the function of physically warming the human body in vitro, achieving the goal of assisting in regulating human body temperature. It can also be used to provide patients thermal comfort when the conditions exist that may cause patients to become too cold. The Medical Warming Unit are suitable for both adult and pediatric patients. Its application part is a Disposable Warming Blanket.

The operation panel of Medical Warming Unit fully considers human-computer interaction. It is located on the inclined surface of the device and is simply operated by buttons. The desired temperature can be selected by pressing different temperature buttons.

In an emergency, the alarm will sound and the screen will flash and display a fault code. In the standby interface, the total running time of the device can be checked by pressing the call mode button (hidden button, under the product model character) and the 43℃ button.

Disposable Warming Blanket (Sterile or Non Sterile)

The Warming System is indicated for hypothermic patients or normothermic patients for whom induced hyperthermia or localized increase in temperature is clinically indicated.

V. Indications for use

The Warming System is indicated for hypothermic patients or normothermic patients for whom induced hyperthermia or localized increase in temperature is clinically indicated.

VI. Comparison of technological characteristics with the predicate devices

The comparison and discussion between the subject device and the predicate devices are listed in below table:

Table 1 General Comparison

Characteristics	**Proposed device**	**Predicate device (K231596)**	**Discussion**
Trade name	Warming System	IOB Temperature Management System	/
Classification Name	system, thermal regulating	system, thermal regulating	Same
Product Code	DWJ	DWJ	Same
Regulation Number	21 CFR 870.5900	21 CFR 870.5900	Same
Indications for use	The Warming System is indicated for hypothermic patients or normothermic patients for whom induced hyperthermia or localized increase in temperature is clinically indicated.	The IOB Temperature Management System Model IOB-507 is indicated for hypothermic patients or normothermic patients for whom induced hyperthermia or localized increase in temperature is clinically indicated.	Same
Temperature Settings	Average temperature at the end of the gas pipe: High temperature:43℃±1℃ Medium temperature:38℃±1℃ Low temperature:32℃±1℃	43°C+/-2°C 38°C+/-2°C 32°C+/-2°C Ambient	Same
System Power	100VAC 50Hz/60Hz 12A 110VAC 50Hz/60Hz 13.5A 120VAC 50Hz/60Hz 14A 127VAC 50Hz/60Hz 15A	110-120 V, 60 Hz, 14 A	Similar
Heater Power	1000VA(Nominal value)	950 W	Similar
Dimensions	33cm Length *27.5cm width *33cm height	29.5 x 22 x 22 cm	Similar

Weight	6.5kg	5.4 kg	Similar
EMI/EMC Compliant	IEC 60601-1, IEC 60601-1-2	IEC 60601-1, IEC 60601-1-2	Same
Forced Air Over Temperature	When the temperature of the outlet of the air pipe exceeds 50℃, the sound and light alarm will be turned on and the heating will stop.	Auto-shuts heater off at 47°C+/-2°C	Similar
Hose with Secure Locking	Yes	Yes	Same
Air Filter	Replaceable 0.2 micron	Replaceable 0.2 micron	Same
Temperature Display	Front panel LCD display	Front panel LCD display	Same

Analysis 1 System Power
Clinical warming performance remains consistent across all supported voltages. This difference does not impact safety or effectiveness.

Analysis 2 Heater Power
The device meet EC 60601-1 requirements, this minor difference does not affect safety or effectiveness.

Analysis 3 Forced Air Over Temperature
Testing demonstrates equivalent patient protection. This difference does not compromise safety or effectiveness.

Table 2 General Comparison between Disposable Warming Blanket and the predicate device

Characteristics	**Proposed device**	**Predicate device (K231596)**	**Discussion**
Indications For Use	The Warming System is indicated for hypothermic patients or normothermic patients for whom induced hyperthermia or localized increase in temperature is clinically indicated.	The IOB Warming Blankets are indicated for hypothermic patients or normothermic patients for whom induced hyperthermia or localized	Same

		increase in temperature is clinically indicated.	
Material Design	Consists of Non-woven fabric and PE film	Consists of two layers of nonwoven polypropylene fabric bonded to a fusion layer of polyethylene. The layers are bonded together to form a distribution network of air delivery channels. The warm air is distributed around the patient's body through the delivery channels and exits the blanket through a specially designed series of perforations in the patient side layer of the blanket. The distribution of air is designed to minimize temperature differences of delivered air at different blanket locations.	Same
Shelf Life	5 years	3 years	Difference 1
Sterility	Non-sterile and sterile	Non-sterile and sterile	Same
Blanket Dimensios (approximate)	WB-1101-R/WB-1101-N 210×100cm WB-1102-R/WB-1102-N 190X70cm WB-1103-R/WB-1103-N 200X100cm	IOB-001/IOB-001S 142×120cm IOB-002/IOB-002S 142×120cm IOB-003/IOB-003S 202×64cm IOB-004/IOB-004S 210×120cm	Similar

	WB-1104-R/WB-1104-N 150X100cm WB-1105-R/WB-1105-N 130X100cm WB-1106-R/WB-1106-N 130X100cm WB-1107-R/WB-1107-N 190X100cm WB-1109-R/WB-1109-N 210X100cm WB-1110-R/WB-1110-N 210X100cm WB-1111-R/WB-1111-N 210X100cm WB-1113-R/WB-1113-N 210X100cm WB-1114-R/WB-1114-N 210X100cm WB-1115-R/WB-1115-N 210X100cm WB-2101-R/WB-2101-N 160X100cm WB-2102-R/WB-2102-N 100X70cm WB-1201-R/WB-1201-N 210X100cm WB-1202-R/WB-1202-N 210X100cm WB-1203-R/WB-1203-N 180X100cm	IOB-005/IOB-005S 100×80cm IOB-006/IOB-006S 215×100cm IOB-007/IOB-007S 170×100cm IOB-008/IOB-008S 210×120cm IOB-009/IOB-009S 160×80cm IOB-010/IOB-010S 215×100cm IOB-011/IOB-011S 200×100cm IOB-012/IOB-012S 142×100cm IOB-014/IOB-014S 122×64cm IOB-015/IOB-015S 192×74cm IOB-016/IOB-016S 210×120cm IOB-017/IOB-017S 215×100cm IOB-018/IOB-018S 210×120cm IOB-019/IOB-019S 109×102cm IOB-020/IOB-020S 142×120cm IOB-021/IOB-021S 230×100cm IOB-022/IOB-022S 210×120cm IOB-023/IOB-023S 162×74cm IOB-024/IOB-024S 180×100cm	

	WB-1204-R/WB-1204-N 180X70cm WB-1205-R/WB-1205-N 210X100cm WB-1206-R/WB-1206-N 210X100cm WB-2201-R/WB-2201-N 100X90cm WB-2202-R/WB-2202-N 140X90cm	IOB-025/IOB-025S 120×80cm IOB-026/IOB-026S 120×80cm IOB-027/IOB-027S 220×120cm IOB-028/IOB-028S 100×100cm IOB-029/IOB-029S 200×100cm IOB-030/IOB-030S 198×80cm IOB-034/IOB-034S 140×64cm IOB-301/IOB-301S 230×100cm IOB-302/IOB-302S 280×100cm IOB-303/IOB-303S 330×120cm IOB-304/IOB-304S 384×120cm	

Analysis 1
The shelf life has been verified. This difference does not compromise safety or effectiveness.

VII. Non-Clinical Testing
The device described in this summary, was tested and demonstrated to be in conformance with the following standards:

Performance testing：
The following tests were conducted on the Medical Warming Unit:
Appearance
Output temperature control
Temperature control accuracy
Nozzle temperature protection
Temperature protection of air duct compartment
Output pipeline length
Noise

Time to reach the set temperature
Safety
Software function
Labels and accompanying materials

The following tests were conducted on the Disposable Warming Blanket:
Appearance
Dimensions
Sterility
Welding Strength

In addition, combined use testing of the Medical Warming Unit and Disposable Warming Blanket was performed.

Reprocessing, Sterility, and Shelf-Life
ASTM F1886/F1886M-16
ASTM F2096-11
ASTM F1929-23
ASTM F88/F88-23
USP<71>
ASTM F 1980

Biocompatibility testing
Biocompatibility of the device was evaluated in accordance with the FDA guidance “Use of International Standard ISO 10993-1” The following testing was conducted:

- ISO 10993-1
- ISO 10993-5
- ISO 10993-10
- ISO 10993-23

Software
Guidance for Industry and Food and Drug Administration Staff-Content of Premarket Submissions for Device Software Functions.

Electrical Safety and EMC

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-4-2

- IEC 60601-1-6
- IEC 60601-1-8
- IEC 60601-2-35
- IEC 61000-4-3

VIII. Clinical Testing

No clinical study is included in this submission.

IX. Conclusion

The proposed device has the same indication for use and has similar design features and technological characteristic as the predicate device. Performance testing data demonstrates that the proposed device is as safe and as effective as the predicated device. Accordingly, the proposed device is substantially equivalent to the predicate device.