Hangzhou Tappa Medical Technology Co., Ltd.
Dan Cao
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Hangzhou,
China

Re: K262089
Trade/Device Name: Disposable Warming Blanket
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: June 21, 2026
Received: June 22, 2026

Dear Dan Cao:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

KATHLEEN M. GRUNDER -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262089	?
Please provide the device trade name(s).		?

Disposable Warming Blanket

Please provide your Indications for Use below.		?

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

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?
Please select the age group(s) for which the device(s) is to be used.	☒ Neonates/Newborns (Birth to < 29 days old) ☒ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)	?

510(k) Summary

I. Submitter

Hangzhou Tappa Medical Technology Co., Ltd.
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Preparation date: June 11, 2026

II. Proposed Device

Device Trade Name:	Disposable Warming Blanket
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:	K190221
Trade name:	IOB Warming Blankets
Common name:	System, thermal regulating
Classification:	Class II
Product Code:	DWJ
Manufacturer	IOB Medical Inc

IV. Device description

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

Combined with Medical Warming Unit (K252861), the disposable warming blanket provides physical warming to the patient by controlling the temperature of the blanket, thereby assisting in regulating the patient's body temperature.

V. Indications for use

The Disposable Warming Blanket 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.

Table1 General Comparison between Disposable Warming Blanket and the predicate device

Characteristics	**Proposed device**	**Predicate device (K190221)**	**Discussion**
Indications For Use	The Disposable Warming Blanket 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 increase in temperature is clinically indicated.	Same
Material Design	Consists of Non-woven fabric and PE film	Each blanket consists of two layers of non-woven polypropylene fabric coated with a layer of polyethylene.	Same
Shelf Life	5 years	3 years	Difference 1
Sterility	Non-sterile and sterile	Non-sterile and sterile	Same
Blanket	WB-1101-R/WB-1101-N	IOB-024 240cm×150cm	Similar

Dimensions (approximate)	210×100cm WB-1102-R/WB-1102-N 190X70cm WB-1103-R/WB-1103-N 200X100cm WB-1104-R/WB-1104-N 150X100cm WB-1105-R/WB-1105-N 130X100cm WB-1106-R/WB-1106-N 130X100cm WB-1105-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	IOB-025 120cm× 80cm IOB-026 150cm×120cm IOB-027 220cm×120cm IOB-028 100cm×100cm IOB-029 200cm×100cm IOB-301 170cm×100cm IOB-302 170cm×100cm IOB-303 180cm×120cm IOB-304 182cm×120cm	

	210X100cm WB-1202-R/WB-1202-N 210X100cm WB-1203-R/WB-1203-N 180X100cm 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		

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 in accordance with applicable standards and internal performance specifications. The following tests were conducted, and the results met the acceptance criteria:

Performance testing：

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

VIII. Clinical Testing
No clinical study is included in this submission.

IX. Conclusion
The proposed device shares the same indications for use as the predicate device and has similar design features and technological characteristics. Performance testing data have demonstrated that the proposed device is as safe and as effective as the predicate device. Therefore, the proposed device is determined to be substantially equivalent to the predicate device.