December 27, 2022

IOB Medical Inc
% Joe Shia
Director
LSI International Inc
504E Diamond Ave., Suite J
Gaithersburg, Maryland 20877

Re: K221669
Trade/Device Name: IOB Warming Blankets
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: November 27, 2022
Received: November 28, 2022

Dear Joe Shia:

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,

Eric E. Richardson -S 2022.12.27 09:05:58 -05'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K221669

Device Name
IOB Warming Blankets

Indications for Use *(Describe)*
The IOB Warming Blankets are 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.

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510(k) SUMMARY
K221669

1. Date: November 27, 2022

2. Submitter:
IOB Medical Inc
504E Diamond Ave., Suite I
Gaithersburg, MD 20877

3. Contact person:
Joe Shia
LSI International Inc.
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Gaithersburg, MD 20877
Telephone: 240-505-7880
Fax: 301-916-6213
Email:shiajl@yahoo.com

4. Device Name: IOB Warming Blankets

5. Classification:
Class: Class II

Product Code	CFR #	Product Name
DWJ	870.5900	Thermal Regulating System

6. Predicate Devices:
K162679
IOB Temperature Management System

7. Indications for Use
The IOB Warming Blankets are indicated for hypothermic patients or normothermic patients for whom induced hyperthermia or localized increase in temperature is clinically indicated.

8. Device Description
The IOB warming blankets are used with the IOB Temperature Management System (previously cleared k162679) that draws ambient- temperature air through a 0.2 micron particulate air filter. The filtered air is warmed to a selected temperature. The warmed air enters the IOB Warming Blanket through the hose and is distributed through delivery channels. Perforations on the patient side of the air delivery channels in the warming blanket gently disperse the warmed air over and around the patient..

The IOB Warming Blankets in this submission are the following:

Torso IOB-001S
Lower Body IOB-002S
Upper Body IOB-003S
Full Body IOB-004S

Pediatric Underbody IOB-005S
Adult Underbody IOB-006S
Pediatric Full Body IOB-007S
Full Body Surgical IOB-008S
Large Pediatric Underbody IOB-009S
Spinal Underbody IOB-010S
Lithotomy Underbody IOB-011S
Pediatric Lower Body IOB-012S
Cath Lab IOB-015S
Chest Access IOB-017S
Multi-Access IOB-018S
Dual Port Torso IOB-019S
XL Upper Body IOB-021S
Outpatient Care IOB-022S
Multi-position Upper Body Warming Blanket IOB-030/IOB-030S
Arms-in Upper Body Warming Blanket IOB-034/IOB-034S

These blankets are single-use and disposable. Each blanket consists of two layers of non-woven polypropylene fabric coated with a layer of polyethylene. The layers are bonded together to form a distribution network of air delivery channels. The warm air is distributed around the blanket through the delivery channels and exits the blanket through a specially designed series of perforations in the patient side of the blanket.

9. Substantial Equivalence Information

A summary comparison of features of the IOB Warming Blankets and the predicate devices is provided in following Tables.

Table 1: Comparison between IOB Warming Blankets and predicate devices.

Parameters	**Predicate devices K162679**	**Proposed devices**
	IOB Warming Blankets (models IOB-001, IOB-002, IOB-003, IOB-004, IOB-005, IOB-006, IOB-007, IOB-008, IOB-009, IOB-010, IOB-011, IOB-012, IOB-015, IOB-017, IOB-018, IOB-019, IOB-021, IOB-022)	IOB Warming Blankets (models IOB-001S, IOB-002S, IOB-003S, IOB-004S, IOB-005S, IOB-006S, IOB-007S, IOB-008S, IOB-009S, IOB-010S, IOB-011S, IOB-012S, IOB-015S, IOB-017S, IOB-018S, IOB-019S, IOB-021S, IOB-022S)
INDICATIONS FOR USE	The IOB Temperature Management 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 increase in temperature is clinically indicated.
MATERIAL DESIGN	Consists of two layers of non- woven polypropylene fabric bonded to a fusion layer of polyethylene. The layers are bonded together to form a	SAME

	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.	
Shelf Life	3 years	SAME
Sterility	Non-sterile	Sterile

Parameters	**Predicate devices K162679**	**Proposed devices**
	IOB Warming Blankets (models IOB-021, IOB-003)	IOB Warming Blankets (models IOB-030/IOB-030S, IOB-034/IOB-034S)
INDICATIONS FOR USE	The IOB Temperature Management 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 increase in temperature is clinically indicated.
MATERIAL DESIGN	Consists of two layers of non- woven 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	3 years	SAME
Sterility	Sterile and Non-sterile	SAME
Blanket Dimensions (approximate)	IOB-021 230cm×100cm IOB-003 202cm×64cm	IOB-30/IOB-30S 198cm×80cm IOB-34/IOB-34S 140cm×64cm

10. Safety and Performance Characteristics
    1. Nonclinical Tests

a. Temperature uniformity tests were performed by measuring five testing points on blanket surface at different IOB Warmer settings. All test results show temperature uniformity equivalence between the IOB warming blankets and the predicate.
b. Real time stability tests show three years shelf-life of the IOB warming blankets.
c. Simulated transport testing was performed according to ASTM D4169. No package damage was observed. All product hold integrity after the transport testing.
d. Bubble testing was carried out according to the ASTM F2096. No leakage was found.
e. Biocompatibility tests were reported in the previously cleared k162679.

2. Clinical Studies

   Not applicable

11. Conclusion

Based on the information presented in this 510K premarket notification including nonclinical tests of temperature uniformity, real time stability, transport testing, Bubble testing and biocompatibility, the IOB Warming Blanket is substantially equivalent to the predicate.