DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 28, 2017

IOB Medical, Inc.
% Joe Shia
Regulatory Consultant
LSI International, Inc.
504 East Diamond Ave., Suite F
Gaithersburg, Maryland 20877

Re: K162679
Trade/Device Name: IOB Temperature Management System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: March 10, 2017
Received: March 20, 2017

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Fernando Aguel -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162679

Device Name
IOB Temperature Management System

Indications for Use *(Describe)*
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.

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

1. Date: April 28, 2017

2. Submitter:
IOB Medical Inc
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Gaithersburg, MD 20877

3. Contact person:
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LSI International Inc.
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Telephone: 240-505-7880
Fax: 301-916-6213
Email:shiajl@yahoo.com

4. Device Name: IOB Temperature Management System

5. Classification:
Class: **Class II**

Product Code	CFR #	Product Name
DWJ	870.5900	Thermal Regulating System

6. Predicate Devices:
K021473
Bair Hugger Temperature Management System

7. Intended 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.

8. Device Description
The IOB Temperature Management System consists of the IOB warming unit and the IOB warming blankets. The IOB warming unit draws ambient- temperature air through a 0.2 micron 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 warming unit has three temperature settings of 32°C, 38°C, and 43°C. These temperature settings are servo-controlled by a thermistor placed at the end of hose where the hose connects to the blanket. The unit can also delivers ambient-temperature air. The temperature indicated on the control panel is the temperature of air being delivered to the blanket at the end of the hose. A control thermistor in the warming unit adjusts the power applied to the heater to maintain the selected temperature. This enables the system to maintain the selected temperature under variations in ambient temperature. Besides, the warming unit has high and low air flow for choose.

The IOB Warming Blankets in this submission are the following:

Torso IOB-001
Lower Body IOB-002
Upper Body IOB-003
Full Body IOB-004
Pediatric Underbody IOB-005
Adult Underbody IOB-006
Pediatric Full Body IOB-007
Full Body Surgical IOB-008
Large Pediatric Underbody IOB-009
Spinal Underbody IOB-010
Lithotomy Underbody IOB-011
Pediatric Lower Body IOB-012
Pediatric Long IOB-014
Cath Lab IOB-015
Surgical Access IOB-016
Chest Access IOB-017
Multi-Access IOB-018
Dual Port Torso IOB-019
Cardiac Access IOB-020
XL Upper Body IOB-021
Outpatient Care IOB-022
Cardiac IOB-023

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 Temperature Management system and the predicate devices is provided in following Tables.

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

Parameters	**Predicate devices K021473**	**Proposed devices**
	Bair Hugger blankets (models 540,525,522,300,555,635,310,610,550,575, 585,537,530,560,570,305,315,542,645,523, 110,630)	IOB Warming Blankets (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-014,IOB-15,IOB-16 IOB-17, IOB-18, IOB-019,IOB-020,IOB-021, IOB-022,IOB-023)

INDICATIONS FOR USE	The Bair Hugger temperature management system is indicated for hyper- or hypothermic patients or normothermic patients for whom induced hyper- or hypothermia or localized temperature therapy is clinically indicated. In addition, the Bair Hugger temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. The Bair Hugger temperature management system can be used with adult and pediatric patients.	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.
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	Non-sterile except 645 and 630	Non-sterile except IOB-14, IOB-16, IOB-020 and IOB-023

Blanket Dimensions (approximate)	540 107×91cm 525 152×91cm 522 188×61cm 300 213×91cm 635 221×91cm 610 183×91cm 575 188×91cm 585 188×91cm 560 23×335cm 570 213×91cm 305 183×91cm 315 213×91cm 542 107×91cm 523 213×91cm 110 213×91cm 310 152×91cm 555 91×84cm 550 152×81cm 537 89×61cm 530 188×21cm 645 23x274cm 630 152x91cm	IOB-001 142×120cm IOB-002 142×120cm IOB-003 195×80cm IOB-004 210×120cm IOB-006 215×100cm IOB-008 210×120cm IOB-010 215×100cm IOB-011 170×100cm IOB-015 17x180cm IOB-016 210×120cm IOB-017 180×120cm IOB-018 210×120cm IOB-019 142×120cm IOB-021 215×80cm IOB-022 210×120cm IOB-007 170×100cm IOB-005 91×80cm IOB-009 160×80cm IOB-012 142×100cm IOB-014 110×17cm IOB-020 17x150cm IOB-023 142x120cm
Air Velocity	28-30cfm	Same
Air Temperature	Hose End Temperature 43°C +/- 3.0°C 38°C +/- 3.0°C 32°C +/- 3.0°C Ambient	Hose End Temperature 43°C +/- 3.0°C 38°C +/- 3.0°C 32°C +/- 3.0°C Ambient
System Power	110-120VAC,60Hz,10A 220-240VAC,50Hz,4.5A	110-120V, 60 Hz, 12A 230V, 50/60 Hz, 8A
Heater Power	850 Watts	1000 W
Dimensions	33X 25 X 28cm	28 X 22X 22cm
Weight	5.2kg	4.5kg
EMI/EMC Compliant	IEC60601-1, IEC 60601-1-2	IEC60601-1, IEC 60601-1-2
Forced air Over Temperature	Auto-shuts heater off at 47°C +/- 2°C	Auto-shuts heater off at 47°C +/- 2℃.

Hose with Secure Locking	Yes	Yes
Air Filter	Replaceable 0.2 micron	Replaceable 0.2 micron
Temperature Display	Front panel LCD display	Front panel digital display

10. Safety and Performance Characteristics
    1. Temperature uniformity tests show equivalence between the IOB warming blankets and the predicate.
    2. Accelerated stability tests show three years shelf-life of the IOB warming blankets.
    3. Electrical safety/EMC testing, and software validation show that the device meets its design specifications, performs as intended.
    4. Biocompatibility testing (cytotoxicity, irritation and sensitivity) according to ISO 10993 for a limited contact device was demonstrated to be suitable for the intended use of the product.
    5. Clinical Studies

       Not applicable

11. Conclusion

Based on the information presented in this 510K premarket notification, the IOB Temperature Management System is substantially equivalent to the predicate.