June 30, 2023

IOB Medical Inc
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K231596
Trade/Device Name: IOB Temperature Management System Model IOB-507
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: Class II
Product Code: DWJ
Dated: May 29, 2023
Received: June 1, 2023

Dear Dave Yungvirt:

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

Digitally signed by Eric E. Richardson -S
Date: 2023.06.30 11:30:46 -04'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231596

Device Name
IOB Temperature Management System Model IOB-507

Indications for Use *(Describe)*
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.

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

I. SUBMITTER

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Fax: 1(301)916-6213

Contact Person: Joe Shia
Email: shiajl@yahoo.com

Date: 29 May, 2023

II. DEVICE

Name of Device: IOB Temperature Management System Model IOB-507
Common or Usual Name: Temperature Management System
Classification Name: Thermal Regulating System (21 CFR 870.5900)
Regulatory Class: II
Product Code: DWJ

III. PREDICATE DEVICE

K162679
IOB Temperature Management System
K190221
IOB Warming Blankets
K221669
IOB Warming Blankets

IV. DEVICE DESCRIPTION

The IOB Temperature Management System Model IOB-507 consists of the IOB Warming Unit and the IOB Warming Blankets. The IOB Warming Unit, model IOB-507, 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 the hose where the hose connects to the blanket. The unit can also deliver ambient-temperature air. The temperature indicated on the control panel is the temperature of air being delivered to the average contact surface temperature of the blanket. A control thermistor in the warming unit adjusts the power applied to the heater to maintain the selected temperature. This enables the unit to maintain the selected temperature under variations in ambient temperature. Besides, the warming unit has high and low air flow options.

A safety thermistor provides a signal to a separate high-temperature analog circuit. The safety thermistor activates and produces an alarm if the temperature exceeds the set point. The analog safety circuit provides an independent means of shutoff, which discontinues power to the heater and motor. This prevents patient exposure to excessive temperatures.

The IOB Warming Blankets in this submission are the following:
IOB-001/IOB-001S Torso Warming Blanket
IOB-002/IOB-002S Lower Body Warming Blanket
IOB-003/IOB-003S Upper Body Warming Blanket
IOB-004/IOB-004S Full Body Warming Blanket
IOB-005/IOB-005S Pediatric Under Body Warming Blanket
IOB-006/IOB-006S Adult Under Body Warming Blanket
IOB-007/IOB-007S Pediatric Full Body Warming Blanket
IOB-008/IOB-008S Full Body Surgical Warming Blanket
IOB-009/IOB-009S Large Pediatric Under Body Warming Blanket
IOB-010/IOB-010S Spinal Under Body Warming Blanket
IOB-011/IOB-011S Lithotomy Under Body Warming Blanket
IOB-012/IOB-012S Pediatric Lower Body Warming Blanket
IOB-014/IOB-014S Pediatric Long Warming Blanket
IOB-015/IOB-015S Cath Lab Warming Blanket
IOB-016/IOB-016S Surgical Access Warming Blanket
IOB-017/IOB-017S Chest Access Warming Blanket
IOB-018/IOB-018S Multi-Access Warming Blanket
IOB-019/IOB-019S Dual Port Torso Warming Blanket
IOB-020/IOB-020S Cardiac Access Warming Blanket
IOB-021/IOB-021S XL Upper Body Warming Blanket
IOB-022/IOB-022S Outpatient Care Warming Blanket
IOB-023/IOB-023S Cardiac Warming Blanket
IOB-024/IOB-024S Jackson Warming Blanket

IOB-025/IOB-025S Infant Full Body & Under Body Warming Blanket
IOB-026/IOB-026S Large Half Body Warming Blanket
IOB-027/IOB-027S Large Full Body Warming Blanket
IOB-028/IOB-028S Infant Under Body Warming Blanket
IOB-029/IOB-029S Lithotomy & Orthopedic Under Body Warming Blanket
IOB-030/IOB-030S Multi-position Upper Body Warming Blanket
IOB-034/IOB-034S Arms-in Upper Body Warming Blanket
IOB-301/IOB-301S Small Size Warming Suit
IOB-302/IOB-302S Medium Size Warming Suit
IOB-303/IOB-303S Large Size Warming Suit
IOB-304/IOB-304S Extra Large Size Warming Suit

IOB warming 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.

No product in the IOB Warming Blanket contains latex, DEHP or BPA.

V. INTENDED FOR USE

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.

VI. SUBSTANTIAL EQUIVALENCE INFORMATION

A summary comparison of features of the IOB Warming Unit Model IOB-507 and the predicate device is provided in following Table 1.

Table 1: Comparison between the IOB Warming Unit and the predicate device

Parameters	**Predicate Device K162679** IOB Warming Unit Model IOB-505	**Proposed Device** IOB Warming Unit Model IOB-507
Indications For Use	IOB Temperature Management system is indicated for hypothermic patients or normothermic patients for whom induced hyperthermia or localized increase in temperature is clinically indicated.	Same

Parameters	**Predicate Device K162679** IOB Warming Unit Model IOB-505	**Proposed Device** IOB Warming Unit Model IOB-507
Air Velocity	28-30cfm	30-45cfm
Temperature Settings	43°C+/-3°C 38°C+/-3°C 32°C+/-3°C Ambient	43°C+/-2°C 38°C+/-2°C 32°C+/-2°C Ambient
System Power	110-120 V, 60 Hz, 12 A 220-240 V, 50/60 Hz, 8 A	110-120 V, 60 Hz, 14 A
Heater Power	1000 W	950 W
Dimensions	28 X 22X 22cm	29.5 x 22 x 22 cm
Weight	4.5 kg	5.4 kg
EMI/EMC Compliant	IEC 60601-1, IEC 60601-1-2	Same
Forced Air Over Temperature	Auto-shuts heater off at 47°C+/-2°C	Same
Hose with Secure Locking	Yes	Same
Air Filter	Replaceable 0.2 micron	Same
Temperature Display	Front panel digital display	Front panel LCD display

A summary comparison of features of the IOB Warming Blankets and the predicate devices is provided in following Table 2.

Table 2: Comparison between the IOB Warming Blankets and the predicate devices.

Parameters	**Predicate Devices K162679** IOB Warming Blankets	**Predicate Devices K190221** IOB Warming Blankets	**Predicate Devices K221669** IOB Warming Blankets	**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-014, IOB-015, IOB-016, IOB-017, IOB-018, IOB-019, IOB-020, IOB-021, IOB-022, IOB-023	IOB-024, IOB-025, IOB-026, IOB-027, IOB-028, IOB-029, IOB-301, IOB-302, IOB-303, IOB-304	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, IOB-030/IOB-030S, IOB-034/IOB-034S	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-015, IOB-016, IOB-017, IOB-018, IOB-019, IOB-020, IOB-021, IOB-022, IOB-023, IOB-024, IOB-025, IOB-026, IOB-027, IOB-028, IOB-029, IOB-030, IOB-034, IOB-301, IOB-302, IOB-303, IOB-304, 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-014S, IOB-015S, IOB-016S, IOB-017S, IOB-018S, IOB-019S, IOB-020S, IOB-021S, IOB-022S, IOB-023S, IOB-024S, IOB-025S, IOB-026S, IOB-027S, IOB-028S, IOB-029S, IOB-030S, IOB-034S, IOB-301S, IOB-302S, IOB-303S, IOB-304S
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.	The IOB Warming Blankets are 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

Parameters	**Predicate Devices K162679** IOB Warming Blankets	**Predicate Devices K190221** IOB Warming Blankets	**Predicate Devices K221669** IOB Warming Blankets	**Proposed Devices** IOB Warming Blankets
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.	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.	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	3 years	3 years	Same
Sterility	Non-sterile except IOB-014, IOB-016, IOB-020 andIOB-023	Non-sterile and sterile	Non-sterile and sterile	Non-sterile and sterile

Parameters	Predicate Devices K162679 IOB Warming Blankets	Predicate Devices K190221 IOB Warming Blankets	Predicate Devices K221669 IOB Warming Blankets	Proposed Devices IOB Warming Blankets
Blanket Dimensions (approximate)	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 17×180cm 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 17×150cm IOB-023 142×120cm	IOB-024 240cm×150cm 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	IOB-001S 142×120cm IOB-002S 142×120cm IOB-003S 195×80cm IOB-004S 210×120cm IOB-006S 215×100cm IOB-008S 210×120cm IOB-010S 215×100cm IOB-011S 170×100cm IOB-015S 17×180cm IOB-017S 180×120cm IOB-018S 210×120cm IOB-019S 142×120cm IOB-021S 215×80cm IOB-022S 210×120cm IOB-007S 170×100cm IOB-005S 91×80cm IOB-009S 160×80cm IOB-012S 142×100cm IOB-030/IOB-030S 198cm×80cm IOB-034/IOB-034S 140cm×64cm	IOB-001/IOB-001S 142×120cm IOB-002/IOB-002S 142×120cm IOB-003/IOB-003S 202×64cm IOB-004/IOB-004S 210×120cm 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 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

VII. SAFETY AND PERFORMANCE CHARACTERISTICS

1. Nonclinical Tests
    a. Electrical safety, EMC testing, Usability and Alarm system testing according to IEC standards, air velocity testing and software validation report show that the device's safety and usability meet relevant applicable IEC standards, meets its design specifications, performs as intended.
    b. 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. Stability tests show 3 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 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.
2. Clinical Studies
    Not applicable.

VIII. CONCLUSION

Based on the information presented in this 510K premarket notification including nonclinical tests of Electrical safety/EMC testing, Usability and Alarm system testing, air velocity testing, software validation, temperature uniformity tests, stability tests, transport testing, bubble testing and biocompatibility testing, the IOB Temperature Management System Model IOB-507 is substantially equivalent to the predicates.