October 24, 2023

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

Re: K232638
Trade/Device Name: FilteredFlo Warming Blankets
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: Class II
Product Code: DWJ
Dated: October 10, 2023
Received: October 11, 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 (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.

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,

Nicole M. Gillette -S

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)*
K232638

Device Name
FilteredFlo Warming Blankets

Indications for Use *(Describe)*
The FilteredFlo Warming Blanket is intended to be used with the IOB-507 patient warming system. The IOB-507 Temperature Management system is indicated for hypothermic patients or normothermic patients for whom induced hyperthermia or localized increase in temperature is clinically indicated. These blankets are intended for adult and pediatric use.

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.

510(k) Summary

K232638

I. SUBMITTER

IOB Medical Inc.
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Cincinnati, OH 45241
IOB Medical is a part of Gentherm Medical.

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Date: October 21, 2023

II. DEVICE

Name of Device: FilteredFlo Warming Blankets
Common or Usual Name: Warming Blanket
Classification Name: Thermal Regulating System (21 CFR 870.5900)
Regulatory Class: II
Product Code: DWJ

III. PREDICATE DEVICE

K231596
IOB Temperature Management System Model IOB-507

IV. DEVICE DESCRIPTION

The FilteredFlo warming blankets are used with the IOB Temperature Management System (previously cleared k231596) 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 FilteredFlo 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 FilteredFlo warming blankets in the submission are the following:

FF-243 ADULT/PACU BLANKET
FF-244 PEDIATRIC BLANKET
FF-246 INFANT UNDERBODY BLANKET
FF-247 LARGE PEDIATRIC UNDERBODY BLANKET
FF-248 ADULT UNDERBODY BLANKET
FF-443 UPPER BODY BLANKET
FF-442 LOWER BODY BLANKET
FF-344 TORSO BLANKET
FF-145 WARMING TUBE BLANKET

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.

V. INTENDED FOR USE

The FilteredFlo Warming Blanket is intended to be used with the IOB-507 patient warming system. The IOB-507 Temperature Management system is indicated for hypothermic patients or normothermic patients for whom induced hyperthermia or localized increase in temperature is clinically indicated. These blankets are intended for adult and pediatric use.

VI. SUBSTANTIAL EQUIVALENCE INFORMATION

A summary comparison of features of the FilteredFlo Warming Blankets and the predicate device is provided in following Table 1.

Table 1: Comparison between the FilteredFlo Warming Blankets and the predicate device

Parameters	Predicate Device K231596	Proposed Device
	IOB Warming Blankets (models IOB-004, IOB-007, IOB-028, IOB-009, IOB-006, IOB-003, IOB-002, IOB-001, IOB-015)	FilteredFlo Warming Blankets (models FF-243, FF-244, FF-246, FF-247, FF-248, FF-443, FF-442, FF-344, FF-145)
Indications For Use	IOB Temperature Management system is indicated for hypothermic patients or normothermic patients for whom induced hyperthermia or	The FilteredFlo Warming Blanket is intended to be used with the IOB-507 patient warming system. The IOB-507 Temperature Management system is

	localized increase in temperature is clinically indicated.		indicated for hypothermic patients or normothermic patients for whom induced hyperthermia or localized increase in temperature is clinically indicated. These blankets are intended for adult and pediatric use.	
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	
Sterility	Sterile and Non-sterile		Non-sterile	
Blanket Dimensions	IOB-004	210 × 120 cm	FF-243	235 × 125 cm
	IOB-007	170 × 100 cm	FF-244	142 × 100 cm
	IOB-028	100 × 100 cm	FF-246	100 × 80 cm
	IOB-009	160 × 80 cm	FF-247	160 × 80 cm
	IOB-006	215 × 100 cm	FF-248	215 × 100 cm
	IOB-003	202 × 64 cm	FF-443	220 × 80 cm
	IOB-002	142 × 120 cm	FF-442	135 × 100 cm
	IOB-001	142 × 120 cm	FF-344	110 × 100 cm
	IOB-015	180 × 74 cm	FF-145	180 × 74 cm

VII. 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 FilteredFlo Warming Blankets and the predicate.

b. 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 k231596.

2. Clinical Studies

Not applicable.

VIII. CONCLUSION

Based on the information presented in this 510K premarket notification including nonclinical tests of temperature uniformity tests, transport testing, bubble testing and biocompatibility testing, the FilteredFlo Warming Blankets are substantially equivalent to the predicates.