November 25, 2019

Ningbo David Medical Device Co., Ltd
Lin Dingyu
Vice General Manager
No.2, Keyuan Road, Shipu Technology Park,
Xiangshan
Ningbo, 15731
China

Re: K190494
Trade/Device Name: Infant Incubator
Regulation Number: 21 CFR 880.5400
Regulation Name: Neonatal incubator
Regulatory Class: Class II
Product Code: FMZ, FMT
Dated: October 23, 2019
Received: October 25, 2019

Dear Lin Dingyu:

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,

for Geeta Pamidimukkala
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K190494

Device Name
YP-3000 Infant Incubator

Indications for Use *(Describe)*
The device is an infant incubator and an infant warmer. The two functions can be converted through the canopy lifting system. The incubator provides an enclosed, temperature-controlled environment and the warmer provides infrared heat in an open environment. The warmer provides heat in a controlled manner to neonates who are unable to thermoregulate based on their own physiology. The incubator and warmer may also be used for short periods of time to facilitate a neonate's transition from the uterus to the external environment.

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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K190494 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

(As Required by 21 CFR 807.92)

1. **Date Prepared [21 CFR 807.92(a)(1)]**

   November 22, 2019

2. **Submitter's Information [21 CFR 807.92(a)(1)]**

Company Name:	Ningbo David Medical Device Co., Ltd.
Company Address:	NO. 2, KEYUAN ROAD, SHIPU TECHNOLOGY PARK, XIANGSHAN, NINGBO, ZHEJIANG PROVINCE, P.R. CHINA
Fax:	+86-574-87800008

3. **Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]**

Trade Name:	Infant Incubator
Models:	YP-3000
Product Codes:	FMZ, FMT
Regulation Number:	21 CFR 880.5400
Regulation Name:	Neonatal incubator
Device Class:	Class II

4. **Identification of Predicate Devices(s) [21 CFR 807.92(a)(3)]**

   The identification of the predicate device within this submission is as follows:

Manufacturer:	OHMEDA MEDICAL.
Trade Name:	OmniBed
Product Codes:	FMZ, FMT
Regulation Name:	Neonatal incubator
Regulation Number:	21 CFR 880.5400
FDA 510 (k) #:	K993407

5. **Description of the Device [21 CFR 807.92(a)(4)]**

[510(k)] Summary

The YP-3000 has the functions of an infant incubator and an infant radiant warmer. The infant radiant warmer is optional, the two functions can be converted through the canopy lifting system. For the infant incubator, the temperature control system implements servo control on the temperature in the incubator (air temperature / skin temperature) and the device performs proportional heating control based on the setting of the temperature and the actual measured temperature. The internal air is adjusted through thermal convection to create an environment with proper temperature and humidity for infant incubation. It is intended to be used for constant temperature incubation of low birth weight infants, critically sick babies and neonates, as well as neonatal body temperature resuscitation, transfusion, oxygen therapy, emergency treatment, and hospitalization for neonates. The Infant radiant warmer transfers heat to the patient from the infrared radiation heating source through the parabolic reflecting hood transmitting heat to the patient on the mattress. proportional heating is controlled based on actual skin temperature. The device is equipped with a mattress, an electronic scale, and an oxygen control system. Other accessories include an observation lamp, tray, and an IV pole.

6. Indications for Use [21 CFR 807.92(a)(5)]

The device is an infant incubator and an infant warmer. The two functions can be converted through the canopy lifting system. The incubator provides an enclosed, temperature-controlled environment and the warmer provides infrared heat in an open environment. The warmer provides heat in a controlled manner to neonates who are unable to thermoregulate based on their own physiology. The incubator and warmer may also be used for short periods of time to facilitate a neonate's transition from the uterus to the external environment.

7. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92(b)(2)]

	YP-3000 Infant Incubator	**OmniBed**	**Differences Discussion**
State	Subject Device	Predicate Device	N/A

[510(k)] Summary

Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-19 IEC 60601-2-21 ISO 10993-5 ISO 10993-10	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-19 IEC 60601-2-21 ISO 10993-5 ISO 10993-10	Same
Indications for Use	The device is an infant incubator and an infant warmer. The two functions can be converted through the canopy lifting system. The incubator provides an enclosed, temperature-controlled environment and the warmer provides infrared heat in an open environment. The warmer provides heat in a controlled manner to neonates who are unable to thermoregulate based on their own physiology. The incubator and warmer may also be used for short periods of time to facilitate a neonate's transition from the uterus to the external environment.	The OmniBed is a combination of an infant incubator (incubator) and an infant warmer (warmer). Incubators and warmers provide heat in a controlled manner to neonates who are unable to thermo-regulate based on their own physiology. Incubators provide an enclosed, temperature-controlled environment and warmers provide infrared heat in an open environment. They may also be used for short periods of time to facilitate the neonate's transition from the uterus to the external environment.	Similar – same intended use, users, and use environment; minor grammatical differences and device trade name is not mentioned.
Electrical Description			
Power supply	AC 220-230V/50Hz; AC 110-120V/60Hz	100V, 115V, 220V, 230V, 240V, 50/60Hz	Similar-1. We performed safety tests and performance tests based on IEC 60601-1，IEC 60601-2-19 and IEC

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			60601-2-21 standards to cover both voltage ranges. The test results demonstrate that the subject device YP-3000 met the standard requirements, so this difference does not raise new questions of safety and effectiveness.
Maximum current/ power consumption	1300VA	≈1100VA	Similar-2. We conducted safety tests and performance tests based on the IEC 60601-1 standard. The test results demonstrate that the subject device YP-3000 met the standard requirements, so this difference does not raise new questions of safety and effectiveness.
Electrical safety	According to IEC 60601-1	According to IEC 60601-1	Same
Principles of Operation			
General	Radiant Warmer and Infant Incubator	Radiant Warmer and Infant Incubator	Same
Control Modes	Incubator mode; Warmer mode	Incubator mode; Warmer mode	Same
Probe Type & Connectors	Air temperature sensor	Air temperature sensor	Same
	Skin temperature sensor	Skin temperature sensor	Same
	air flow temp. sensor	air flow temp. sensor	Same
	O_2 Sensors	O_2 Sensors	Same
	Humidity Sensor	Humidity Sensor	Same
	Isolated air temperature sensor	Isolated air temperature sensor	Same
	Multi-port connector connects 2	Multi-port connector connects 2	Same

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	transducers	transducers	
	RS232 connector	RS232 connector	Same
Warmer Operation			
Warmer	Radiant Warmer	Radiant Warmer	Same
Temperature Control Modes	Pre-warm mode; Manual mode; Baby mode (Baby temperature control)	Manual mode; Baby mode; (Pre-warm mode);	Same
Temperature Control Range Under the Skin temp. Mode	34.5℃~37.5℃ in 0.1 increments	35～37.5℃ in 0.1 increments	Similar-3. Compared with the predicate device, the temperature control range of the subject device YP-3000 is slightly wider, and under this temperature control range, the temperature control accuracy of the device, the consistency of the bed temperature and the predicate device are equivalent. This control range satisfies the requirements of 201.15.4.2.2.101 of IEC60601-2-21. This difference does not raise new questions of safety and effectiveness.
Difference Between Skin Temperature Sensor and Control Temperature	≤0.5℃	≤0.5℃	Same
Temperature Uniformity of Bed Surface	≤2℃	≤2℃	Same

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Incubator Operation			
Heater	Convective heater	Convective heater	Same
Modes under the incubator mode	Air mode; Baby mode	Air mode; Baby mode	Same
Air Temperature Control range	25～39℃ in 0.1increments	20～39℃ in 0.1 increments	Similar-4. Neonatal patients in the ambient temperature should not be less than 25 ℃, so YP-3000 product air control temperature range is designed to 25℃～39℃. Under this temperature control range, the temperature control accuracy, temperature stability and predicate equipment of the equipment are equivalent. This control range satisfies the requirements of 201.15.4.2.2.101 in IEC60601-2-19. Therefore, this difference does not raise new questions of safety and effectiveness.
Skin Temperature Control range	34～38℃ in 0.1 increments	35～37.5℃ in 0.1 increments	Similar-5. The comparison with the predicate device, YP-3000's temperature control range is slightly wider, and under this temperature control range, the temperature control accuracy, temperature stability and predicate equipment of the device are all equivalent. This control range satisfies the requirements of 201.15.4.2.2.102 in

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			IEC60601-2-19. Therefore, this difference does not raise new questions of safety and effectiveness.
Temperature Rise Time	≤40min	<50min	Similar-6. Compared with the predicate device, the temperature rise time of the YP-3000 is faster, and the product can be warmed up to the predetermined temperature and put into use. The performance of this article meets the requirements of 201.12.1.107 in IEC60601-2-19, so this difference does not raise new questions of safety and effectiveness.
Difference Between Average Incubator Temperature and Control Temperature	≤1.0℃	≤1.0℃	Same
Difference Between Incubator Temperature and Average Incubator Temperature	≤0.5℃	≤0.5℃	Same
Skin Temperature Sensor Precision	±0.2℃	±0.3℃	Similar-7. Compared with the predicate device, the skin temperature display of YP-3000 is more accurate. The performance of this article satisfies the requirements of 201.12.1.103 in IEC60601-

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			2-19, so this difference does not raise new questions of safety and effectiveness.
Humidity Control	30% - 90% in 1% increments	30% - 95% in 5% increments	Similar-8. Compared with the predicate device, the humidity control range of the YP-3000 is included in the humidity control range of the predicate device, so this difference does not raise new questions of safety and effectiveness.
Humidity Control Precision	±5% RH	±10% for settings up to 85%; minimum 75% for settings >85%	Similar-9. Based on the analysis of the humidity control range, this indicator indicates the deviation range between the actual humidity and the control value in the incubator during humidity control, the humidity control precision of subject device YP-3000 is better than the predicate device, so this difference does not raise new questions of safety and effectiveness

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Oxygen Concentration Control Range	20% O_2～60% O_2	21% O_2～65% O_2	Similar-10. In general, the concentration of oxygen in the nature atmosphere is about 20.9%. Compared with the predicate device, the oxygen concentration control range of YP-3000 is included in the oxygen concentration control range of the predicate device, the oxygen concentration range is verified to meet the design requirement, so this difference does not raise new questions of safety and effectiveness.
Oxygen Concentration Control Precision	±4% O_2	±:5% O_2	Similar-11. Based on the analysis of the oxygen concentration control range, this index indicates the deviation range between the actual oxygen concentration in the incubator and the control value during oxygen concentration control. The oxygen concentration precision is verified to meet the design requirement and is slightly different to predicate device. This difference does not raise new questions of safety and effectiveness.

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Carbon dioxide (CO_2) Concentration Inside the Hood Under Incubator Mode	<0.5%	0.2%	Similar-12. Both the subject device and predicate device conform to IEC 60601-2-19 clause 201.12.4.2.101, so this difference does not raise new questions of safety and effectiveness.
Weight Scale			
Function Range	100mg to 8kg	300mg to 8kg	Similar-13. Both the subject device and predicate device comply with the requirements of 201.12.1.112 of IEC 60601-2-19, and the difference of this indicator does not affect the temperature control performance of the product. It is an auxiliary function, so this difference does not raise new questions of safety and effectiveness.
Accuracy	± 10 mg	± 10 mg	Same
Integrated X-Ray Cassette / Tray	Yes	Yes	Same
Drawer	Yes	Yes	Same
Bed-tilt Mechanism	Yes	Yes	Same
Operating Noise			
Operating Noise Volume in Patient Compartment	≤50dB（Under the steady temperature condition）	<49dB	Similar-14. Both the subject device and predicate device meet the requirements of clause 201.9.6.2.1.101 of IEC60601-2-19, so this difference does not raise new questions of safety and effectiveness.

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Alarm Volume	According to IEC 60601-2-19 and IEC 60601-1-8	According to IEC 60601-2-19 and IEC 60601-1-8	Same
Alarms			
Power Failure Alarm	Yes	Yes	Same
Non-recoverable system failure	Yes	Yes	Same
Failure of Fan system	Fan Motor Alarm	Fan Failure Alarm	Same
High Air Temp	Display temperature is 3℃ higher than set temperature	1.5℃ over SET	Similar-15. Both the subject device and predicate device meet the requirements of 201.15.4.2.1 dd) of IEC 60601-2-19, so this difference does not raise new questions of safety and effectiveness.
Low Air Temp	Display temperature is 3℃ lower than set temperature	3.0℃ under SET	Same
Baby Cold	Display temperature of sensor 1 is 1℃ lower than set temperature	1.0℃ under SET	Same
Baby Hot	Display temperature of sensor 1 is 1℃ higher than set temperature	1.0℃ over SET	Same
Air Overheat	Temperature of incubator is not over 38℃ (set value is less than 37℃), or not over 39.5℃ (set value is over than 37℃)	>38℃ (SET≤37℃) >40℃ (SET>37℃)	Similar-16. Both the subject device and predicate device meet the requirements of 201.15.4.2.1 aa) of IEC 60601-2-19, so this difference does not raise new questions of safety and effectiveness.
Skin Overheat Alarm	The temperature measured by skin temperature sensor	Not provided	Similar-17. Both the subject device and predicate device meet

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	under the warmer mode is over 38.5℃		the requirements of 201.15.4.2.1 bb) of IEC 60601-2-19, so this difference does not raise new questions of safety and effectiveness.
Water Shortage	Water tank is lacking water	Water tank is lacking water	Same
Operating Condition Description			
Temperature	+20～+30℃	+20～+30℃	Same
Humidity	30%～75%RH	10% to 95% RH	Similar-18. Under the specified working conditions, whether the safety and effectiveness of the product can be guaranteed depends on the product itself and cannot be concluded through data comparison. Therefore, we provide an environmental test report to prove that the subject device YP-3000 can work normally under this operation condition, so this difference does not raise new questions of safety and effectiveness.
Storage Condition Description			

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Temperature	-20～+55℃	-25～+60℃	Similar-19. Under the specified working conditions, whether the safety and effectiveness of the product can be guaranteed depends on the product itself and cannot be concluded through data comparison. Environmental testing supports that the subject device YP-3000 performs as intended under this operation condition, so this difference does not raise new questions of safety and effectiveness.
Relative humidity	≤93%RH	≤95%RH	Similar-20. Under the specified working conditions, whether the safety and effectiveness of the product can be guaranteed depends on the product itself and cannot be concluded through data comparison. Therefore, we provided environmental testing report to support that the subject device YP-3000 works normally under this operation condition, so this difference does not raise new questions of safety and effectiveness.

Discussion of Substantial Equivalence:

Comparison of Product performance, Power Supply, Operating Conditions, and Storage Conditions between the predicate device and the proposed device, YP-3000, identified minor differences with the Predicate Device OmniBed; the differences were supported with performance testing, as appropriate, and do not raise new questions of device safety and effectiveness. The proposed device YP-3000 has similar indications for use; the technological characteristics differences listed in the above table between

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the proposed device YP-3000 and the predicate device OmniBed do not raise any new questions of safety and effectiveness.

Non-Clinical Testing:
The following bench testing was conducted in order to support substantial equivalence:

- ES 60601-1:2006+A1:2012 Medical electrical equipment -- part 1: general requirements for basic safety and essential performance.
- IEC 60601-1-2:2014 Medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests.
- IEC 6060-1-8 General requirements for basic safety and essential performance - collateral standard: general requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
- IEC 60601-2-19 Particular requirements for the basic safety and essential performance of infant incubators.
- IEC 60601-2-21 Particular requirements for the basic safety and essential performance of infant radiant warmers.
- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.
- Guidance for Industry and FDA Staff, titled “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,” issued on: May 11, 2005.
- Guidance for Industry and Food and Drug Administration Staff titled “Applying Human Factors and Usability Engineering to Medical Devices,” issued on: February 3, 2016.
- Guidance for Industry and Food and Drug Administration Staff titled “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling,” issued on March 17, 2015.

Clinical Testing:
Clinical evaluation is not applicable for the proposed device.

8. Conclusion [21 CFR 807.92(b)(3)]

Based on the performed testing per the standards above and comparison of technological characteristics with the predicate device, the YP-3000 Infant

Incubator is substantially equivalent to the predicate device. It does not introduce a new intended use and has equivalent technological characteristics. The differences from the predicate do not introduce any new potential hazards or safety risks.

[510(k)] Summary