August 17, 2018

International Biomedical
Amy Pieper
Director of Regulatory Affairs
8206 Cross Park Drive
Austin, Texas 78754

Re: K173516
Trade/Device Name: NuBorne Infant Warmer
Regulation Number: 21 CFR 880.5130
Regulation Name: Infant Radiant Warmer
Regulatory Class: Class II
Product Code: FMT
Dated: July 16, 2018
Received: July 16, 2018

Dear Amy Pieper:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

FDA
Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173516

Device Name
NuBorne Infant Warmer

Indications for Use *(Describe)*

The NuBorne 500 Infant Warmer is an open care environment used for providing controlled infrared heat to neonates who are physiologically unable to maintain their body temperature or may require external heat to ease the transition from the mother's womb to the external environment.

The device is intended to be used in a Labor & Delivery environment for warming the infants immediately after birth, or in a Neonatal Intensive Care Unit for providing premature infants long duration thermoregulation therapy, or in newborn care areas, for providing external heat to low-birth weight infants, and for cases where clinical indications require short/ long duration warming therapy.

The device allows access to the infants for various procedures, tilting of the mattress, weighing the infant and x-ray diagnostics. The device provides three modes of warming: Manual, Skin, and Standby mode for varying care requirements. Also, allows attaching optional accessories on the rail for therapy and monitoring of the infant.

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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K173516

510(k) SUMMARY

Submitter Information:

International Biomedical
8206 Cross Park Drive
Austin, TX 78754
U.S.A.

Regulatory Affairs Contact:

Amy Pieper
Director of Regulatory Affairs
(512) 873-0033 - phone
(512) 873-9090 - fax

Date Summary Prepared: October 27, 2017

Device Identification:

Trade Name: NuBorne Infant Warmer
Common Name: Radiant Warmer
Regulatory Class: II
Regulation: 880.5130
Product Code: FMT
Panel: General Hospital

Predicate Device:

GE Medical – Lullaby Warmer – k121625 (Primary Predicate)
Drager Medical Systems – Babyleo TN500 – k162821 (Supplemental Predicate)

Device Description:

The NuBorne Infant Warmer is an open care environment used for providing controlled infrared heat to neonates who are physiologically unable to maintain their body temperature or who need external heat to smoothen the transition from the mother's womb to the external environment.

The NuBorne Infant Warmer has three modes of temperature control available – manual temperature mode, skin temperature control mode and standby mode. The device includes a bed that tilts, has height adjustment, side panels, APGAR timer, x-ray tray and an optional in-bed scale.

Indications for Use:

The NuBorne 500 Infant Warmer is an open care environment used for providing controlled infrared heat to neonates who are physiologically unable to maintain their body temperature

or may require external heat to ease the transition from the mother's womb to the external environment.

The device is intended to be used in a Labor & Delivery environment for warming the infants immediately after birth, or in a Neonatal Intensive Care Unit for providing premature infants long duration thermoregulation therapy, or in newborn care areas, for providing external heat to low-birth weight infants, and for cases where clinical indications require short/long duration warming therapy.

The device allows access to the infants for various procedures, tilting of the mattress, weighing the infant and x-ray diagnostics. The device provides three modes of warming: Manual, Skin, and Standby mode for varying care requirements. Also, allows attaching optional accessories on the rail for therapy and monitoring of the infant.

Substantial Equivalence:

The NuBorne Infant Warmer described in this submission is, in our opinion, substantially equivalent to the predicate devices, in regards to intended use and safety and effectiveness.

The intended use of the NuBorne Infant Warmer is equivalent to the intended use of the primary predicate k121625. The differences in the indications for use between the predicate devices (k121625 and k162821) and the subject device do not constitute a new intended use. The NuBorne Warmer does not incorporate any incubator indications or functions that are referenced in the supplemental predicate (k162821) – the comparison to the Babyleo predicate is soley based on the infant warmer functionality and indications related to the incubator function are not considered in the substantial equivalence determination.

The Lullaby Warmer (k121625) is identified as the primary predicate because it has comparable indications, functionality and features. The Babyleo (k162821) is identified as a supplemental predicate because it has comparable indications and a comparable standby mode. The differences in technological features between the NuBorne Warmer and Babyleo do not raise new questions of safety and effectiveness.

	Proposed NuBorne Infant Warmer	Predicate K121625 Lullaby Warmer (GE)	Predicate K162821 Babyleo TN500 (Drager)
Indications for Use	The NuBorne 500 Infant Warmer is an open care environment used for providing controlled infrared heat to neonates who are physiologically unable to maintain their body temperature or may require external heat to ease the transition from the mother's womb to the external environment. The device is intended to be used in a Labor & Delivery environment for warming the infants	The Lullaby Warmer is a radiant warmer which provides a microenvironment for a premature, new born baby which otherwise might have very little chance of survival as it will not be able to maintain, by itself, its core body temperature. The Lullaby Warmer provides a means for the care giver to monitor the baby continuously by giving	The Babyleo TN500 is intended for use with premature babies and neonates and can be used as both an incubator and a radiant warmer. When the product is switched between incubator and radiant warmer operation, patients continue to be kept warm during the transition. The device provides a thermally regulated environment for patients with a body

	immediately after birth, or in a Neonatal Intensive Care Unit for providing premature infants long duration thermoregulation therapy, or in newborn care areas, for providing external heat to low-birth weight infants, and for cases where clinical indications require short/long duration warming therapy. The device allows access to the infants for various procedures, tilting of the mattress, weighing the infant and x-ray diagnostics. The device provides three modes of warming: Manual, Skin, and Standby mode for varying care requirements. Also, allows attaching optional accessories on the rail for therapy and monitoring of the infant.	timely feedback via the different alarm systems and servo controlled thermal feedback mechanism while maintaining a pre-set temperature and thus ensures that the neonate slowly develops the internal organs to enable it to maintain its body temperature.	weight of up to 5kg(11lbs) and a height of up to 55cm (22in). The device can be operated as either a closed care unit or an open care unit. As a closed care unit, Babyleo TN500 is an incubator. Neonates are kept warm in the patient compartment with humidifiable air, which can be enriched with oxygen (option). As an open care unit, Babyleo TN500 is a radiant warmer. Babyleo TN500 provides controlled ambient conditions for premature babies and neonates. The following parameters are regulated, according to the intended use: Temperature; Humidity; Oxygen (option).
Environment for Use	Hospital or institution	Hospital or institution	Hospital or institution
Patient Population	Neonatal	Neonatal	Neonatal
Prescriptive	Yes	Yes	Yes
Operating Modes			
Skin Temp Mode	Yes	Yes	Yes
Servo Controlled Temperature Monitoring	Yes	Yes	Yes
Manual Temperature Mode	Yes	Yes	Yes
Standby Mode	Yes (Standard)	No	Yes (AutoThermo Option)
PreWarm Mode	Yes	Yes	Yes
Operation Parameters and Functions			
Operating Volume measured in patient bed	36.2 dB(A)	38.2 dB(A)	40 dB(A)
Alarm Volume	Adjustable from: 54-69 dB(A)	Adjustable from: 52-65 dB(A)	Adjustable from: 50-70 dB(A)
Power Failure Alarm	Continuous audible alarm when power switch is “On” and mains power is disconnected. Cannot be silenced	Continuous audible alarm when switch is “On” and power is disconnected. Cannot be silenced.	Continuous audible alarm when switch is “On” and power is disconnected. Cannot be silenced
Air Temperature Measurement Range	This device is an open air radiant warmer. Newborns are warmed by the radiation of the heater head. Air temperature is NOT measured in this type of device.	This device is an open air radiant warmer. Newborns are warmed by the radiation of the heater head. Air temperature is NOT measured in this type of device.	Because this device can be used as both an open radiant warmer and closed convective incubator the air temperature range is during incubator operations is: 13-45°C
Air Temperature settings and Override	This device is an open air radiant warmer. Newborns are warmed by the radiation of the heater head. Air temperature is NOT measured in this type of device.	This device is an open air radiant warmer. Newborns are warmed by the radiation of the heater head. Air temperature is NOT measured in this type of device.	Because this device can be used as both an open radiant warmer and closed convective incubator the air temperature range that can be set during normal operations is: 20-39°C with a confirmation override at <28°C and >37°C

Oxygen Regulation	This device is an open air radiant warmer. Oxygen delivery can be accomplished by ventilator, nasal prongs or by mask. The warmer does NOT regulate oxygen delivery to the patient, regulation requires different device(s)	This device is an open air radiant warmer. Oxygen delivery can be accomplished by ventilator, nasal prongs or by mask. The warmer does NOT regulate oxygen delivery to the patient, regulation requires different device(s)	An optional accessory to this combination warmer incubator allows oxygen delivery into the closed compartment. Measurement range: Normal range: 18-65 % Extended range: 66-99% Accuracy ± 2.5% When used as an open air radiant warmer, oxygen delivery can be accomplished by ventilator, nasal prongs or by mask. Oxygen delivery to the patient when used as an open air warmer will requires different device(s) NOT controlled by the warmer
Radiant Warmer Settings Range in Manual Mode	Single heating element with setting range of: Off-100% in 5% increments Pre-Warm Mode: 100% for 10 minutes 50% until setting is changed	Single heating element with setting range of: Off-100% in 5% increments Pre-Warm Mode: 100% for 12 minutes 25% until setting is changed	Two heating elements Setting range: Off, 10% to 100% Pre-Warm Mode: 100% for 3 minutes 60% for 11.5 minutes 30% until setting is changed
Radiant Warmer Skin Temperature Regulation Range	34-38°C A visual symbol appears warning the user if temperature setting >37° C	30-38°C No visual or confirmation override	34-38°C A confirmation override required if setting is >37° C
Skin Temperature Monitoring Range	25-40°C	25-40°C	13-43°C
Warmer Features			
Maximum Irradiance of Warmer	25 mW/cm2 (at 100% power)	22 mW/cm2 (at 100% power)	32 mW/cm2 (at 100% power)
APGAR Timer	Yes (0-60 minutes)	Yes (0-60 minutes)	Yes (0-10 minutes)
Trending	Temperature and Weight	No	Temperature and Weight
Manual Mode Setting Range	0 to 100% in 5% increments	0 to 100% in 5% increments	Off, 10% - 100%
Set Temperature Range	33 to 38 °C (in 0.1 increments)	30 to 38 °C (in 0.1 increments)	34 to 38 °C (in 0.1 increments)
Heater Hood Swivel	Two Sides	Two Sides	N/A
Integrated X-Ray Cassette Tray	Yes	Yes	Yes
Bed Tilt Mechanism	Continuous up to 12°	Continuous up to 15°	Continuous up to 13°
Storage Drawer Available	Yes	Yes	Yes
Access Panels	All side panels are hinged for patient access to support medical procedures and interventions	All side panels are hinged for patient access to support medical procedures and interventions	All side panels are hinged for patient access to support medical procedures and interventions
Castors	4 double castors with locking brakes.	4 single castors with locking brakes.	4 double castors with locking brakes.
Weighing Scale	250g – 10kg	N/A	200g – 10kg
Alarms			

High Priority Alarms	1. High skin temp 2. Low skin temp 3. Check Baby 4. Max temp 5. Skin temp probe disconnected 6. Skin temp probe failure	1. High skin temp 2. Low skin temp 3. Check Baby 4. max Temp 5. Temp probe failure	1. Check Baby 2. Max temp 3. Scale defective
Medium Priority Alarms	N/A	N/A	1. Skin mode not confirmed 2. Skin temp not confirmed 3. Kangaroo mode not confirmed 4. Air mode not confirmed 5. Manual mode not confirmed 6. Radiant Power not confirmed 7. Skin temp probe defective 8. Skin temp probe disconnected 9. High skin temp 10. Low skin temp
Low Priority Alarms	N/A	N/A	N/A
Electrical Description			
Power Supply	115V – 230V, 50/60 Hz	115V – 230V, 50/60 Hz	100V to 240V, 50/60 Hz
Power Consumption	750W	600W	1000W
Physical Description			
Weight (without options and accessories)	105kg	72kg	<140kg
Height (mm)	1800 – 2000	1800	1850 - 2250
Width (mm)	850	655	690
Length (mm)	1170	1120	1154
Mattress Height from Floor (mm)	900-1100	880 - 1020	700 – 1100
Mattress Size (mm)	450 x 650	462 x 640	450 x 690
Material			
Material Used for Indirect Patient Contact	Metal (e.g. Aluminum); Molded Plastic	Metal (e.g. Aluminum); Molded Plastic	Metal (e.g. Aluminum); Synthetic material (e.g. TPE)
Material used for direct patient contact	Cell Cast Acrylic; Textile (Wiman)	Textile; Acrylic	Textile (Vowalon Medilind)
Bisphenol A (BPA)	BPA free in-patient compartment	Unknown or not stated in literature	BPA free in-patient compartment
Latex	Latex Free	Unknown or not stated in literature	Latex Free
Performance Testing			
IEC 60601-1	Pass	Pass	Pass
IEC 60601-1-2	Pass	Pass	Pass
IEC 60601-2-21	Pass	Pass	Pass

Performance Testing:

Testing was performed to confirm compliance to the following standards:

- IEC 60601-1, Medical Electrical Equipment, Part 1: General Requirements for Safety
- IEC 60601-1-2, Medical Electrical Equipment, Part 1-2: General Requirements for Safety Collateral Standard: Electromagnetic Compatibility
- IEC 60601-1-10, Medical Electrical Equipment, Part 1-10: Requirements for the Development of Physiological Closed-Loop Controllers
- IEC 60601-1-8, Medical Electrical Equipment, Part 1-8: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-1-6, Medical Electrical Equipment, Part 1-6: General Requirements for Safety – Collateral Standard: Usability
- IEC 60601-2-21, Medical Electrical Equipment, Part 2-21: Particular Requirements for the Basic Safety and Essential Performance of Infant Radiant Warmers

Bench Testing:

The following additional tests were performed

- Software Verification & Validation Testing
  - Software verification and validation testing was conducted and documentation was provided as recommended by FDA.
- Device Validation
  - The device was functionally tested to confirm the performance to the essential requirements of the device, including warming, skin temperature monitoring and alarms.
- Biocompatibility Testing
  - The biocompatibility evaluation for the NuBorne Infant Warmer was conducted in accordance with the FDA guidance on Biocompatibility on the International Standard ISO-10993, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing”. The testing included Cytotoxicity, Irritation and Sensitization.
- Human Factor Evaluation
  - The usability evaluation for the NuBorne Infant Warmer was conducted in accordance with the FDA guidance: Applying Human Factors and Usability Engineering to Medical Devices Guidance for Industry and Food and Drug Administration Staff.
- Reprocessing Evaluation
  - The reprocessing validation for the NuBorne Infant Warmer was conducted in accordance with the FDA guidance: Reprocessing Medical Devices in Health

Care Settings: Validation Methods and Labeling; Guidance for Industry and Food and Drug Administration Staff.

Conclusion:

In regards to intended use and technology the Nuborne Infant Warmer is substantially equivalent to the listed predicates.

Any differences between the NuBorne Infant Warmer and the predicates do not raise any new questions of safety and effectiveness.