April 19, 2018

Dräger Medical Systems, Inc.
Gale Winarsky
Manager, Regulatory Affairs
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K172154
Trade/Device Name: Isolette® 8000 plus
Regulation Number: 21 CFR 880.5400
Regulation Name: Neonatal Incubator
Regulatory Class: Class II
Product Code: FMZ
Dated: March 16, 2018
Received: March 19, 2018

Dear Gale Winarsky:

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.

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.

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,

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)*
K172154

Device Name
Isolette® 8000 plus

Indications for Use *(Describe)*

The Isolette® 8000 plus incubator is indicated for thermoregulation and controlling oxygen (optional), and humidity (optional) for both premature and full-term infants up to a maximum of 10 kg (22lbs).

The Isolette® 8000 plus is not intended for home 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.

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510(k) Summary

K172154

Manufacturer Name and Address: Dräger Medical Systems, Inc.
3135 Quarry Road
Telford, PA 18969

Contact Person: Gale Winarsky
Manager, Regulatory Affairs

Phone: 215-660-2239
Fax: 215-721-5424

Date summary was prepared: 2018-04-19

Device Name:

Trade Name:	Isolette® 8000 plus
Classification Name:	Neonatal Incubator
Regulation Number:	21 CRF 880.5400
Product Code:	FMZ
Class:	II

Legally Marketed Device Identification: Substantial equivalence is claimed to the legally marketed predicate; Isolette Infant Incubator, Model C2HS, K001242.

Device Description:

The Isolette 8000 plus is a device used to maintain environmental conditions suitable for neonates. The Isolette 8000 plus incubator provides a controlled environment for both premature and full-term infants up to a maximum of 10 kg (22lbs). It controls temperature, oxygen (optional) and humidity (optional). It is a controller-based incubator featuring the ability to enable simultaneous control of temperature, and optional oxygen and humidity. The system operates on AC power. Data is provided on a liquid crystal display. It is operated in closed care therapy as an incubator according to IEC60601-2-19.

Components include hand ports or iris ports, access panel, serial port, trolley with height adjustment, castor wheels with brakes, power receptacle, a Trendelenburg bed-tilt mechanism (0° to 12°), softbed mattress, skin temperature probes, probe covers, oxygen inlet, air filter inlet, sensor module, hose grommets, accessory rail and cable wrap. Optional components include IV pole, drawers, water reservoir, collection bottle, cylinder mount litter bag holder, basket for gloves, breathing hose holder kit, tray, high frequency ventilation (HFV) door with grommets, positioning aids, incubator cover, and monitor shelf.

Indications for Use:

The Isolette® 8000 plus incubator is indicated for thermoregulation and controlling oxygen (optional), and humidity (optional) for both premature and full-term infants up to a maximum of 10 kg (22lbs).

The Isolette® 8000 plus is not intended for home use.

Comparison of Technological Characteristics with Predicate Device:

Specification	Predicate	Device Under Review	Comments
Device Name	**Isolette® Infant Incubator, Model C2HS**	**Isolette®8000 plus (I8000 plus)**	
Manufacturer	Hill-Rom Air-Shields	Draeger Medical Systems, Inc.	
510(k)	K001242	K172154	
Regulation #	880.5400	880.5400	**Same** - Neonatal Incubator
Product Code	FMZ	FMZ	**Same**
Classification	II	II	**Same**
UMDNS/GMDNS code	12-113/36025	12-113/36025	**Same**
Standards	60601-1; 60601-1-2; 60601-2-19	60601-1; 60601-1-2; 60601-2-19	**Same**
Intended Use	Designed to care for the smaller premature baby as well as the healthier full term baby. It does this by providing a controlled environment, one in which the baby can be provided with the necessary care as well as being left undisturbed in the security of the incubator. It is to this end that the product can be used in any department of the hospital that provides neonatal and infant care. One would typically expect the Isolette to be used in the NICU/Special Care Baby Unit. The design lends itself to all levels of care in the NICU making it suitable for use in level I, II, III, and IV where applicable. Other departments would include the Step Down Nursery, Newborn Nursery and pediatrics.	The Isolette® 8000 plus incubator provides a controlled environment for both premature and full-term infants up to a maximum of 10 kg (22lbs). It controls temperature, oxygen (optional) and humidity (optional).	**Same –** While the wording is different, the intended use of the I8000 plus has not changed from the predicate C2HS. Both devices are incubators, both provide a controlled environment, both are used for the same patient population. The patient population has not changed from the predicate. The weight is now provided in as additional information for the user.

Specification	Predicate	Device Under Review	Comments
Device Name	**Isolette® Infant Incubator, Model C2HS**	**Isolette®8000 plus (I8000 plus)**	
Indications for Use	Effective temperature management is Imperative to the development of the premature baby. The Isolette® Infant Incubator incorporates a unique bidirectional air flow to help reduce radiant heat loses from the infant by warming the inner hood surface. The Hill-Rom Air-Shields patented Air Curtain has been incorporated into the Isolette Infant Incubator to reduce temperature fluctuations within the incubator when the access panels are opened. With the Humidity module installed, operational evaporative heat losses are minimized. With the installation of the optional Oxygen control system, the Oxygen level within the infant compartment can be monitored and maintained.	The Isolette® 8000 plus incubator is indicated for thermoregulation and controlling oxygen (optional), and humidity (optional) for both premature and full-term infants up to a maximum of 10 kg (22lbs). The Isolette® 8000 plus is not intended for home use.	**Similar -** While the indications statement has been simplified, substantial equivalence is supported by the following: The functional indications for use for the I8000 plus have not changed from the C2HS. Both devices provide temperature management. This wording has been simplified in the I8000 plus Indications by using the term "thermoregulation", which by definition means temperature control. Both devices use the same air flow and "Air Curtain' technology for thermoregulation. Both devices offer humidity, and oxygen control used for the same applications. Both devices have the same environment of use. Neither device is intended for home use.
Target Population/Patient Population	Premature and full term infants	Newly born infants up to 10 kg. (22lbs)	**Same -** The patient population has not changed from the predicate. The weight of the patient is now provided as additional information for the user.
Environment of Use	Isolette to be used in the NICU/Special Care Baby Unit and the Step Down Nursery, Newborn Nursery and pediatrics.	The I8000 plus can be used in any department of the hospital that provides neonatal and infant care, including NICU/Special Care Baby Unit and the Step Down Nursery, Newborn Nursery and pediatrics.	**Similar –** Some hospitals may refer to their neonatal and infant care areas by other terms than NICU, Step Down Nursery, Newborn Nursery and pediatrics.
System Specifications			
Principle of Operation	Controller-based incubator that enables simultaneous control of temperature, oxygen, and humidity parameters affecting the infant	Same as C2HS	**Same**

Specification	Predicate	Device Under Review	Comments
Device Name	**Isolette® Infant Incubator, Model C2HS**	**Isolette®8000 plus (I8000 plus)**	
Protection class	Class I, Type BF, continuous operation, not AP	Same as C2HS	**Same**
Ingress of liquids and particulate matter (IEC 60601-1)	IPXO	Same as C2HS	**Same**
Physical Attributes			
Height	133.4-152.4 cm (52.5-60 in)	133.3 to 153.7 cm (52.5 to 60.5 in)	**Similar** – No effect on function
Width	99 cm (38.0 in)	<104 cm (41 in)	**Similar** – No effect on function
Depth	59.7 cm (23.5in)	<76.2 cm (30 in)	**Similar** – No effect on function
Weight	99 kg (198 lb.)	<98.5 kg (217.1 lb.) without options/accessories	**Similar** – No effect on function
Mattress size	40.6 x 78.7cm(16 x 31.5 in)	≥38 x 74 x3 cm (15 x 29.1 x 1.2 in)	**Similar** – No effect on function
Trendelenburg/Reverse Trendelenburg	Continuously variable to 12 deg. ±1 deg.	Same as C2HS	**Same**
Infant Weight	Not published	10 kg (22 lbs.) maximum	**Same** - Specification not previously published.
Environmental			
Operating temperature	20-30C (68-86 F)	Same as C2HS	**Same**
Operating humidity	5-99% RH non-condensing	5-95% RH non-condensing	**Similar**
Operating altitude	3048m (10,000 ft.)	Up to 3000 m (9800 ft.)	**Similar** – 3000 m meets the criteria from IEC 60601-1 and internal requirements.
Operating Ambient air pressure	Not available	110-70 kPa	**Same** - Operating ambient air pressure is not documented for the predicate. The incubator design elements related to the ambient air pressure have not changed from C2HS predicate to the I8000 plus.
Storage temperature	-30 to 70 deg. C (-22 to 158 deg. F)	-20 to 60 deg. C (-4 to 140 deg. F)	**Similar** - Device packaging is marked with storage temperature requirements
Storage humidity	0-99% RH, non-condensing	5-95% RH non-condensing	**Similar**
Storage Ambient air pressure	Not available	110-50 kPa	**Same -** Only the operating altitude is available for the predicate. The incubator design elements related to the ambient air pressure have not changed from C2HS predicate to the I8000 plus.

Specification	Predicate	Device Under Review	Comments
Device Name	**Isolette® Infant Incubator, Model C2HS**	**Isolette®8000 plus (I8000 plus)**	
Electrical Requirements			
Power req. 100/120V	100/120V± 10%, 50/60 Hz, 1900 W max.	100/120V, 50/60 Hz, 1900 W max, 9.9 A max	**Similar** - Amperage was not applicable to the C2HS as it had a circuit breaker instead of fuse. Not clinically relevant.
Auxiliary power sockets	All 50/60 Hz 100, 120, 220, & 240V ± 10% 500W max.	All 50/60 Hz 100 V, 100W max 120 & 230 V 300W max	**Similar -** Both meet current safety standards.
Earth Leakage	≤ 300µA 100 & 120V ≤ 500µA 220 & 240V	≤ 500 µA	**Similar -** Both meet current safety standards.
General Performance			
Air temperature mode			
Set point range	20-37 C (68-98.6 F)	20 to 39 C (68-102.2 F)	**Same -** Both devices have a range of 20-39 C (68-102.2 F). The I8000 plus publishes the entire range including the Control Override Range from 37-39 C, rather than just the general range as published by the C2HS 20-37C.
Control override range	37-39 C (98.6- 102.2 F)	Same as C2HS	**Same**
Set point display range	15 to 45 C (59-113 F)	Same as C2HS	**Same**
Upwards deviation limit	Fixed +1.5	+1.5 to +2.5 C (+2.7 to 4.5 F)	**Similar** - Both devices have an air temperature deviation limit. The I8000 plus allows the user to adjust the deviation range for the set point at which an alarm will activate.
Upwards deviation limit default	Fixed +1.5	+1.5 C (+2.7 F)	**Similar –** Default value is the same
Downwards deviation limit range	Fixed -2.5C	-1.5 to -2.5C (-2.7 to-4.5F)	**Similar** - Both devices have an air temperature deviation limit. The I8000 plus allows the user to adjust the deviation range for the set point at which an alarm will activate.
Downwards deviation limit default	Fixed -2.5	-2.5C (-4.5F)	**Similar -** Default value is the same
Warm-up time at 22C (72F) ambient	<35min	Same as C2HS	**Same**
variability	<0.5C (<0.9F)	Same as C2HS	**Same**

Specification	Predicate	Device Under Review	Comments
Device Name	**Isolette® Infant Incubator, Model C2HS**	**Isolette®8000 plus (I8000 plus)**	
overshoot	<0.5C (<0.9F)	Same as C2HS	**Same**
Uniformity with a level mattress	<0.8C (<1.4F)	Same as C2HS	**Same**
Skin Temperature Mode			
Set point range	34.0 to 37.0C (93.2 to 98.6F)	Same as C2HS	**Same**
Control override temp range	37.0 to 38.0C (98.6 to 100.4F)	Same as C2HS	**Same**
Set point display range	15.0 to 45.0C (59 to 113F)	Same as C2HS	**Same**
Accuracy of incubator temp indication	≤0.8C	Same as C2HS	**Same**
Deviation limit range	0.5 to 1.0C	0.3 to 1.0C (0.5 to 1.8F)	**Similar -** the I8000 plus has a tighter limit
Deviation limit default	1.0C (1.8F)	Same as C2HS	**Same**

Specification	Predicate	Device Under Review	Comments
Device Name	**Isolette® Infant Incubator, Model C2HS**	**Isolette®8000 plus (I8000 plus)**	
Kangaroo Mode	No	Yes	**Different -** The C2HS does not include Kangaroo Mode. Kangaroo Care is commonly used in neonatal care to allow skin to skin contact between the patient and parent/caregiver. The features of Kangaroo Mode are provided under the Discussion of Non-Clinical Testing.
Misc. Specifications			
Noise level within the hood environment	≤47 dB(A) w/ 37 dB(A) or less ambient (w/out servo O2 control)	Same as C2HS	**Same**
Air velocity over the mattress	<10 cm/second (4 in/second); average of 5 points at 10cm (4 in) above the mattress	Same as C2HS	**Same**
Carbon Dioxide (CO2) level (per IEC60601-2-19, clause 105)	<0.8%	Same as C2HS	**Same**
Oxygen deviation limit range	3% fixed	3% to 5%	**Similar -** In the I8000 plus the alarm limit deviation can be adjusted by the user to minimize nuisance alarms.
Oxygen deviation limit default	3%	Same as C2HS	**Same**
Set point data retention	Power failures lasting <10 min	Same as C2HS	**Same**
Acoustical level (all alarms on)	75 dB(A) maximum	Same as C2HS	**Same**
External Communication			
COM port (output only)	Only connects to devices that fulfill the requirements of the standard IEC 60950-1 on unearthed SELV circuits or the requirements of the standard IEC 60601-1 on accessible secondary circuits with max. 60 V DC nominal voltage.	Same as C2HS	**Same**

Specification	Predicate	Device Under Review	Comments
Device Name	**Isolette® Infant Incubator, Model C2HS**	**Isolette®8000 plus (I8000 plus)**	
Type	9-pin Sub-D (female), electrically isolated Protocol	Same as C2HS	**Same**
Configurations	Serial Data Output	Serial Data Output (default) or MEDIBUS.X	**Similar** - The addition of Medibus.X as an alternate for the output of data is not clinically relevant to the function of the incubator.
Serial data output			
Baud rate	2400	Same as C2HS	**Same**
Parity	None	Same as C2HS	**Same**
Data bits	8	Same as C2HS	**Same**
Stop bits	1	Same as C2HS	**Same**
Draeger MEDIBUS.X, version 6	By the RS-232 port only	Same as C2HS	**Same**
Baud rate	9600	Same as C2HS	**Same**
Parity	Even	Same as C2HS	**Same**
Data bits	8	Same as C2HS	**Same**
Stop bits	1	Same as C2HS	**Same**
Pin assignment			**Same**
Pin 2	RXD	Same as C2HS	**Same**
Pin 3	TXD	Same as C2HS	**Same**
Pin 5	GND	Same as C2HS	**Same**
Humidification system (option)	Manual adjustment of humidity setpoints	Automatic based on user setpoint (Autohumidity)	**Similar** - Both provide humidity control
Humidity control duration of operation after refilling	>24 hours @ 85% RH and 37 deg. C, in air temp mode	Same as C2HS	**Same**
Humidity control reservoir capacity	1000 mL	1500 mL	**Similar** - The difference in reservoir capacity is not clinically relevant.
Humidity control range	30% to 95% in 1% increments (at high ambient humidity levels, low-level humidity settings may not be attainable)	Same as C2HS	**Same**
Humidity control accuracy between 10% and 90% @ 20 to 40C (68 to 104F)	±5% RH	±6% RH	**Similar** - The difference in the humidity control of 1% is not clinically relevant
Humidity display range	10% to 100%	Same C2HS	**Same**
Maximum humidity levels	>85% (incubator set temp at 39C with at	Same C2HS	**Same**

Specification	Predicate	Device Under Review	Comments
Device Name	**Isolette® Infant Incubator, Model C2HS**	**Isolette®8000 plus (I8000 plus)**	
	least 30% RH at ambient)		
Oxygen control system (option)			
Servo oxygen control system (option)	Yes	Same C2HS	**Same**
Oxygen inlet pressure	40 to 150 psi (2.8 kg/cm^2 to 10.5 kg/cm^2)	Same as C2HS	**Same**
Oxygen inlet flow rate	30 L/min	Same as C2HS	**Same**
Oxygen control range	21% to 65%	Same as C2HS	**Same**
Oxygen display resolution	1%	Same as C2HS	**Same**
Oxygen display accuracy (100% calibration)	±3%	Same as C2HS	**Same**
Oxygen display accuracy (21% calibration)	±5%	Same as C2HS	**Same**
Oxygen display range	18% to 100%	Same as C2HS	**Same**
Oxygen control accuracy	±2% of full scale	Same as C2HS	**Same**
Manual oxygen control system (option)			
Oxygen inlet pressure	40psi to 150 psi (2.8 kg/cm^2 to 10.5 kg/cm^2)	Same as C2HS	**Same**
Oxygen inlet flow rate	30 L/min	Same as C2HS	**Same**
Weighing System			
Standard weighing system (accessory)			
Weight display range	0 kg (0 lb.) to 7 kg (15.4 lbs.)	Same as C2HS	**Same**
Weight display resolution	1 g or 1oz	Same as C2HS	**Same**
Weight display accuracy	0 to 2 kg: ±2 g (0 to 4.4 lb.: ±0.07 oz.) > 2 kg: ±5 g (>4.4 lb.: ±0. 18 oz.)	Same as C2HS	**Same**
Tare weight	4±0.5kg	≤4.0 kg (8.82 lb.)	**Same**
OIML weighing system (accessory)			OIML weighing system is only for EU countries requiring a scale that complies with the NAWI directive.
Material - no implants			

Specification	Predicate	Device Under Review	Comments
Device Name	**Isolette® Infant Incubator, Model C2HS**	**Isolette®8000 plus (I8000 plus)**	
Material used for indirect patient contact	Metal (e.g. Aluminum) Synthetic material (e.g. TPE, Thermoplastics)	Metal (e.g. Aluminum) Synthetic material (e.g. TPE, Thermoplastics)	**Same**
Material used for direct patient contact	Textile Polyurethane, PVC, Hydrogel	Textile Polyurethane, TPE, Hydrogel	**Similar** - the materials used for direct patient contact are the same as the C2HS with the exception of the TPE material used in the I8000 plus temperature probes. This material was tested and found to be biocompatible for the intended use.
Biocompatibility	According to ISO 10993	Same as C2HS	**Same**
Components			
hand ports	Yes	Yes	
iris ports,	Yes	Yes	
access panel,	Yes	Yes	
serial port,	Yes	Yes	
trolley with height adjustment, castor wheels with brakes & power receptacle	Yes	Yes	
skin temperature probes, probe covers	Yes	Yes	
Oxygen, & air filter inlets	Yes	Yes	
sensor module	Yes	Yes	
hose grommets	Yes	Yes	
accessory rail and cable wrap	Yes	Yes	
Thermonitoring	N/A - only displays skin temperature	Trend display of difference between central and peripheral skin temperatures	**Similar** Skin temperature is displayed for user in both systems. Isolette 8000 plus provides additional temperature trend information.

Discussion of Non-clinical Testing

The Isolette 8000 plus was tested in accordance with applicable standards, guidance and internal design control procedures including performance testing, functional/operation testing, verification and validation, biocompatibility, human factors, risk analysis and verification of risk control measures. Testing included accessories and optional components.

The following performance data were provided in accordance with standards or technical system requirements and as identified in the IFU Technical Data Section:

Electrical safety and electromagnetic compatibility (EMC), incl. performance testing
Electrical safety and EMC testing were conducted on the Isolette 8000 plus. The device complies with the IEC 60601-1, IEC 60601-2-19, standards for safety and performance and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing
Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."2005. The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Biocompatibility testing
The biocompatibility evaluation for the Isolette 8000 plus 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,', and International Standard ISO 10993-1 Biological Evaluation of edical evices Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. Testing included the following tests:
_ Integral Test for volatile organic compounds
_ Photogenic bacteria test
_ Emission of particles
_ Material characterization according to ISO 10993-18
_ Toxicological Evaluation according to ISO 10993-17
_ Cytotoxicity
_ Irritation
_ Sensitization

Human Factor
The usability evaluation for the Isolette 8000 plus 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, 2016.

Reprocessing
The Isolette 8000 plus was assessed 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, 2015.

Cleaning/Disinfection
Macroscopic and microbiological validation with Oxycide was performed by an accredited laboratory pursuant to DIN EN ISO/IEC 17025 and provided in the submission.

Kangaroo Mode
Kangaroo Care is commonly used in neonatal care to allow skin to skin contact between the patient and parent caregiver. In kangaroo mode, the patient is warmed by the parents or caregivers body heat instead of the device. The patient is removed from the incubator and placed on the caregivers naked breast. To prevent heat loss, the patient may also be covered with a blanket. Skin temperature probes remain on the patient during Kangaroo Mode and function the same as if the patient were inside the incubator. Numerous studies have documented the clear benefits of this simple technique on the physiologic and emotional well-being of infants and mothers, especially for preterm babies. Kangaroo Mode performance testing was performed according to the technical requirements of the Isolette 8000 Plus incubator and provided in the submission.

Animal Study
No animal study has been conducted.

Clinical Studies
None

Sterilization
Not applicable

Humidification System (Optional)
Autohumidity performance testing was performed according to the technical requirements of the Isolette 8000 Plus incubator and provided in the submission.

Thermomonitoring
Thermomonitoring performance testing was performed according to the technical requirements of the Isolette 8000 Plus incubator and provided in the submission.

External Communication
Serial data output or Medibus X performance testing was performed according to the technical requirements of the Isolette 8000 Plus incubator and provided in the submission.

Trendelenburg (Tilt Mechanism)
Regression testing was performed for a mechanical change to the tilt mechanism from the predicate to the Isolette 8000 plus according to the technical requirements and provide in the submission.

Conclusion Drawn from Non-Clinical Studies
The results of the non-clinical bench testing, and comparison to the predicate device show that the Isolette® 8000 plus meets the performance requirements of the standards and guidance mentioned above and is substantially equivalent to the predicate device K001242.