November 21, 2018

Draeger Medical Systems, Inc.
Karen Otrupchak
Project Manager, Regulatory Affairs
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K182977
Trade/Device Name: Isolette® 8000 Plus
Regulation Number: 21 CFR 880.5400
Regulation Name: Neonatal Incubator
Regulatory Class: Class II
Product Code: FMZ
Dated: October 25, 2018
Received: October 26, 2018

Dear Karen Otrupchak:

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,

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)*

Device Name
Isolette® 8000 plus

Indications for Use *(Describe)*

The Isolette® 8000 plus 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Special 510(k)
Premarket Notification Summary
K182977

Submitter: Draeger Medical Systems, Inc.
3135 Quarry Road
Telford, PA 18969 USA

Contact Person: Karen Otrupchak
Project Manager, Regulatory Affairs
Email: karen.otrupchak@draeger.com
Phone: 215-660-2292
Fax: 215-721-5424

Date prepared: 21 November 2018

Device Name:

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

Predicate Device: Isolette® 8000 plus, K172154

Draeger Medical Systems, Inc. is submitting a special 510(k) premarket notification for a modification to an existing device, the Isolette® 8000 Plus Neonatal Incubator, cleared under K172154.

Device Description

The Isolette® 8000 plus is a neonatal incubator that provides a controlled environment for both premature and full-term infants up to a maximum of 10 kg (22lbs). It controls temperature, oxygen and humidity (both are optional).

The predicate device as cleared in K172154 is offered with the hood and shell assembly of the incubator mounted on a variable high adjustable (VHA) trolley. All components and accessories for the device were cleared as part of the system.

The modification of the device is the replacement of the variable height adjustable (VHA) trolley with a fixed-height cabinet stand trolley. All other components and accessories of the device are identical to those cleared under K172154.

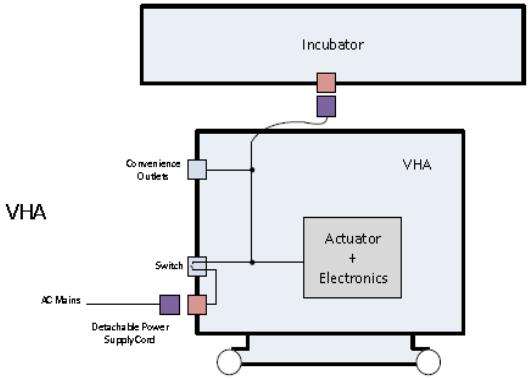
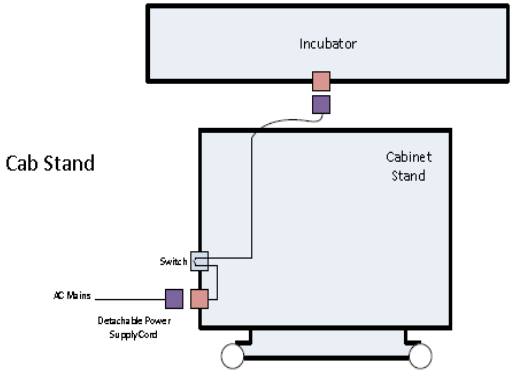
The modification does not change the intended use or alter the fundamental scientific technology of the currently approved predicate device.

Indications for Use

The Isolette® 8000 plus 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 (22 lbs). The Isolette® 8000 plus is not intended for home use.

Specification	Predicate Device **Isolette®8000 plus**	Modified Device **Isolette®8000 plus (with cabinet stand)**	Comments
Manufacturer	Draeger Medical Systems, Inc.	Draeger Medical Systems, Inc.	N/A
510(k)	K172154	K182977	N/A
Regulation #	880.5400	Same	N/A
Product Code	FMZ	Same	N/A
Classification	II	Same	N/A
UMDNS/GMDNS code	12-113/36025	Same	N/A
Standards	60601-1; 60601-1-2; 60601-2-19	Same	N/A
Part number	MU20602	Same	N/A
Model number	I8KP-1	I8KP-1C	**Different** – Identifier for modified device
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 (22 lbs). The Isolette® 8000 plus is not intended for home use.	Same	N/A
Target Population/ Patient Population	Newly born infants up to 10 kg. (22lbs)	Same	N/A
Environment of Use	For use 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.	Same	N/A

System Specifications			
Principle of Operation	Controller-based incubator that enables simultaneous control of temperature, oxygen, and humidity parameters affecting the infant	Same	N/A
Protection class	Class I, Type BF, continuous operation, not AP	Same	N/A
Ingress of liquids and particulate matter IEC60601-1	IPXO	Same	N/A
Physical Attributes			
Height	133.3 to 153.7 cm (52.5 to 60.5 in)	140 cm ± 1.2 cm (55 in ± 0.5 in)	**Different** – No impact on effect on safety and effectiveness.
Width	<104 cm (41 in)	Same	N/A
Depth	<76.2 cm (30 in)	Same	N/A
Weight	<98.5 kg (217.1 lb.) without options/accessories	<95.3 kg (210 lb.) without options/accessories	**Different** – No impact on effect on safety and effectiveness.
Mattress size	≥38 x 74 x3 cm (15 x 29.1 x 1.2 in)	Same	N/A
Trendelenburg/ Reverse Trendelenburg	Continuously variable to 12 deg. +1 deg.	Same	N/A
Infant Weight	10 kg (22 lbs.) maximum	Same	N/A
Appearance	Variable Height Stand (VHA) with Isolette 8000 plus incubator mounted on top	Fixed Height / Cabinet Stand with Isolette 8000 plus incubator mounted on top	**Different** – No impact on effect on safety and effectiveness.
Mobility	Support stand able to raise and lower the incubator on VHA. Storage with swivel drawer storage. Three (3) dual total lock castors, one (1) dual steering castor	Support stand without the ability to raise and lower incubator. Storage ability permitted within cabinet stand. Four (4) Single castors with total lock function	**Different** – No impact on effect on safety and effectiveness.

Power Routing and Convenience Outlets			**Different** – Convenience outlet and actuator/electronics controlling the VHA removed. No impact on effect on safety and effectiveness.
Environmental			
Operating temperature	Yes	Same	N/A
Operating humidity	5-95% RH non-condensing	Same	N/A
Operating altitude	Up to 3000 m (9800 ft.)	Same	N/A
Operating Ambient air pressure	110-70 kPa	Same	N/A
Storage temperature	-20 to 60 deg. C (-4 to 140 deg. F)	Same	N/A
Storage humidity	5-95% RH non-condensing	Same	N/A
Storage Ambient air pressure	110-50 kPa	Same	N/A
Electrical Requirements			
Power req. 100/120V	100/120V, 50/60 Hz, 1900 W max, 9.9 A max	Same	N/A
Auxiliary power sockets	All 50/60 Hz 100 V, 100W max 120 & 230 V 300W max	Same	N/A
Earth Leakage	$\leq$ 500 µA	Same	N/A

General Performance			
Air temperature mode			
Set point range	20 to 39 C (68-102.2 F)	Same	N/A
Control override range	37-39 C (98.6- 102.2 F)	Same	N/A
Set point display range	15 to 45 C (59-113 F)	Same	N/A
Upwards deviation limit	+1.5 to +2.5 C (+2.7 to 4.5 F)	Same	N/A
Upwards deviation limit default	+1.5 C (+2.7 F)	Same	N/A
Downwards deviation limit range	-1.5 to -2.5C (-2.7 to -4.5F)	Same	N/A
Downwards deviation limit default	-2.5C (-4.5F)	Same	N/A
Warm-up time at 22C (72F) ambient	<35min	Same	N/A
variability	<0.5C (<0.9F)	Same	N/A
overshoot	<0.5C (<0.9F)	Same	N/A
Uniformity with a level mattress	<0.8C (<1.4F)	Same	N/A
Skin Temperature Mode			
Set point range	34.0 to 37.0C (93.2 to 98.6F)	Same	N/A
Control override temp range	37.0 to 38.0C (98.6 to 100.4F)	Same	N/A
Set point display range	15.0 to 45.0C (59 to 113F)	Same	N/A

Accuracy of incubator temp indication	≤0.8C	Same	N/A
Deviation limit range	0.3 to 1.0C (0.5 to 1.8F)	Same	N/A
Deviation limit default	1.0C (1.8F)	Same	N/A
Kangaroo Mode			
Kangaroo Mode	Yes	Same	N/A
Thermomonitoring			
Thermomonitoring	Yes	Same	N/A
Misc. Specifications			
Noise level within the hood environment	≤47 dB(A) w/ 37 dB(A) or less ambient (w/out servo O2 control)	Same	N/A
Air velocity over the mattress	< 10 cm/second (4 in/second); average of 5 points at 10cm (4 in) above the mattress	Same	N/A
Carbon Dioxide (CO2) level (per IEC60601-2-19, clause 105)	<0.8%	Same	N/A
Oxygen deviation limit range	3% to 5%	Same	N/A
Oxygen deviation limit default	3%	Same	N/A
Set point data retention	Power failures lasting <10 min	Same	N/A
Device Support	Variable Height Adjustable (VHA) trolley	Cabinet Stand (fixed height) trolley	**Different** – No impact on safety and effectiveness

Acoustical level (all alarms on)	75 dB(A) maximum	Same	N/A
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	N/A
Type	9-pin Sub-D (female), electrically isolated Protocol	Same	N/A
Configurations	Serial Data Output (default) or MEDIBUS.X	Same	N/A
Serial data output			
Baud rate	2400	Same	N/A
Parity	None	Same	N/A
Data bits	8	Same	N/A
Stop bits	1	Same	N/A
Draeger MEDIBUS.X, version 6	By the RS-232 port only	Same	N/A
Baud rate	9600	Same	N/A
Parity	Even	Same	N/A
Data bits	8	Same	N/A
Stop bits	1	Same	N/A
Pin assignment			
Pin 2	RXD	Same	N/A
Pin 3	TXD	Same	N/A
Pin 5	GND	Same	N/A

Humidification system (optional)			
Automatic (Autohumidity)	Yes	Same	N/A
Humidity control duration of operation after refilling	>24 hours @ 85% RH and 37 deg. C, in air temp mode	Same	N/A
Humidity control reservoir capacity	1500 mL	Same	N/A
Humidity control range	30% to 95% in 1% increments (at high ambient humidity levels, low-level humidity settings may not be attainable)	Same	N/A
Humidity control accuracy between 10% and 90% @ 20 to 40C (68 to 104F)	±6% RH	Same	N/A
Humidity display range	10% to 100%	Same	N/A
Maximum humidity levels	>85% (incubator set temp at 39C with at least 30% RH at ambient)	Same	N/A
Oxygen control system (optional)			
Servo oxygen control system	Yes	Same	N/A
Oxygen inlet pressure	40 to 150 psi (2.8 kg/cm^2 to 10.5 kg/cm^2)	Same	N/A
Oxygen inlet flow rate	30 L/min	Same	N/A
Oxygen control range	21% to 65%	Same	N/A

Oxygen display resolution	1%	Same	N/A
Oxygen display accuracy (100% calibration)	±3%	Same	N/A
Oxygen display accuracy (21% calibration)	±5%	Same	N/A
Oxygen display range	18% to 100%	Same	N/A
Oxygen control accuracy	±2% of full scale	Same	N/A
Manual oxygen control system (optional)			
Oxygen inlet pressure	40psi to 150 psi (2.8 kg/cm^2 to 10.5 kg/cm^2)	Same	N/A
Oxygen inlet flow rate	30 L/min	Same	N/A
Weighing System			
Standard weighing system (accessory)			
Weight display range	0 kg (0 lb.) to 7 kg (15.4 lbs.)	Same	N/A
Weight display resolution	1 g or 1oz	Same	N/A
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	N/A
Tare weight	≤4.0 kg (8.82 lb.)	Same	N/A
OIML weighing system (accessory)	Yes	Same	OIML weighing system is only for EU countries requiring a scale that complies with the NAWI directive.

Material - no implants			
Material used for indirect patient contact	Metal (e.g. Aluminum) Synthetic material (e.g. TPE, Thermoplastics)	Same	N/A
Material used for direct patient contact	Textile Polyurethane, TPE, Hydrogel	Same	N/A
Biocompatibility	According to ISO 10993	Same	N/A
Components			
Hand ports	Yes	Same	N/A
Iris ports	Yes	Same	N/A
Access panel	Yes	Same	N/A
Serial port	Yes	Same	N/A
Skin temperature probes, probe covers	Yes	Same	N/A
Oxygen, & air filter inlets	Yes	Same	N/A
Sensor module	Yes	Same	N/A
Hose grommets	Yes	Same	N/A
Accessory rail and cable wrap	Yes	Same	N/A

Discussion of Non-clinical Testing

The modification to the predicate device is the replacement of the variable height adjustable (VHA) trolley with a fixed-height cabinet stand. A risk analysis for the modification to the Isolette 8000 plus was performed according to ISO 14971 Application of Risk Management to Medical Devices and Draeger's standard operating procedure on Product Risk Management. A review of the Product Risk Management Report (PRMR) revealed there were no new hazards or risk control measures (RCMs) associated with the modification of the device.

The following identified verification and validation activities necessary to establish substantial equivalence to the predicate device were carried out under well established methods and their results are summarized within the Design Control Activities Summary table within this submission.

- Instability (mechanical) per IEC60601-1
- Electrical Safety per IEC60601-1
- Electromagnetic Compatibility (EMC) per IEC60601-1-2

Conclusion

Based on the intended use, technological characteristics, performance/non-clinical testing, and comparison to the predicate device, the modified device is substantially equivalent to the predicate device K172154 and does not raise different questions of safety and effectiveness than the predicate device.