August 14, 2025

Mom Incubators Limited
Rosalyn Archer
Director of Clinical Affairs
Newstead House
Pelham Road
Nottingham, Nottinghamshire NG5 1AP
United Kingdom

Re: K243437
Trade/Device Name: mOm Essential Incubator (ME1)
Regulation Number: 21 CFR 880.5400
Regulation Name: Neonatal incubator
Regulatory Class: Class II
Product Code: FMZ
Dated: July 16, 2025
Received: July 16, 2025

Dear Rosalyn Archer:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

David Wolloscheck -S

David Wolloscheck, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K243437

Device Name
mOm Essential Incubator (ME1)

Indications for Use *(Describe)*
The mOm Essential Incubator is indicated for thermoregulation for both premature and full-term infants up to a maximum of 6 kg (13 lbs).
The mOm Essential Incubator 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

[as required by 21 CFR §807.92(c)]

mOm Essential Incubator (ME1)

510(k) Number	K243437
DATE PREPARED:	August 15, 2025
APPLICANT:	Mom Incubators Ltd Newstead House Pelham Road Nottingham NG5 1AP United Kingdom
CONTACT:	Rosalyn Archer Director of Clinical Affairs Newstead House Pelham Road Nottingham NG5 1AP United Kingdom Telephone: +44 7853 633 079 Email: rarcher@momincubators.com
TRADE NAME:	mOm Essential Incubator (ME1)
COMMON NAME:	Neonatal incubator
CLASSIFICATION **REGULATION:**	Neonatal incubator 21 CFR §880.5400, Product Code FMZ
DEVICE CLASS:	II
PANEL CODE:	General hospital / 880
PREDICATE DEVICE:	Isolette® 8000 plus, K172154

INTENDED USE/INDICATIONS FOR USE:

The mOm Essential Incubator is indicated for thermoregulation for both premature and full-term infants up to a maximum of 6 kg (13 lbs).

The mOm Essential Incubator is not intended for home use.

DEVICE DESCRIPTION:

The mOm Essential Incubator, ME1, is a neonatal incubator used for thermoregulation for both premature and full-term infants up to a maximum of 6 kg (13 lbs). Power is sourced either from an external AC supply or an internal rechargeable battery.

The mOm Essential Incubator (ME1) is intended to provide a heated environment with a stable temperature for infants who require assistance with thermoregulation but do not require a humidity-controlled environment. The ME1 should only be used within healthcare settings providing neonatal and infant care, by properly trained personnel, as directed by an appropriately qualified attending physician familiar with current known risks and benefits of infant incubator use.

The mOm Essential Incubator provides a filtered air system creating a thermally controlled environment based on air temperature control. It provides incubation as well as a degree of isolation for infants who may be near others or being cared for in clinical areas. The incubator is designed to allow adequate visibility and access to the infant to deliver care.

The Infant Compartment is designed to be disassembled and packed into a compact unit for storage and transportation and must be assembled before use. It has been designed as a cost-effective alternative to traditional incubators.

The mOm Essential Incubator is made up of several key components and sub- assemblies, which are assembled by the user prior to use:

- The incubator base unit, which includes the device's electronics, fan, heating system, display and controls.
- A rigid front panel which contains a door and two portholes.
- A flexible panel that makes up the top and rear of the infant compartment – this includes an inflatable section and is supplied with a manual inflation bulb.
- A rigid top and back U-shaped panel which provide the structure for the top and rear of the infant compartment.
- Two side panels which form the ends of the infant compartment.

An infant mattress is supplied, which is inserted into the infant compartment. A skin temperature probe is also supplied. An optional cart (trolley) is available.

COMPARISON WITH PREDICATE DEVICE:

	mOm Essential Incubator (ME1)	Isolette® 8000 plus	Comparison	Impact of Differences on patient population, clinical use environment and testing to support differences
	Subject	**Predicate**		
510(k)	K243437	K172154	-	-
Manufacturer	Mom Incubators Ltd	Draeger Medical Systems Inc	-	-
Regulation number	880.5400	880.5400	Identical	N/A
Product Code	FMZ	FMZ	Identical	N/A
Classification	Class II	Class II	Identical	N/A
Intended Use	Neonatal incubator	Neonatal incubator	Identical	N/A
Indication for Use	The mOm Essential Incubator is indicated for thermoregulation for both premature and full-term infants up to a maximum of 6 kg (13 lbs). The mOm Essential Incubator is not intended for home 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.	Similar – while the wording is different, the intended use of the ME1 has not changed from that of the predicate. Both devices are incubators, both provide a controlled environment, both are used for the same patient population, and both devices are not intended for home use.	The subset of infants the ME1 is intended for are those who are more well and who are near-term rather than the most premature infants who require humidity, which is not provided or facilitated by the ME1. For infants who are ≤60cm long and fit in our device, the maximum weight of 6 kg was considered to be a more accurate indication of the maximum weight of intended users, which would be the 98.9th percentile for a 30 day old infant (the maximum length of 60cm would be the 99.7th percentile for a 30 day old infant according to WHO growth charts.)[1,2,3] There is no negatice impact to the
Target population	Pre-term and term infants up to 6kg (13lbs) in weight, who do not require a humidity-controlled environment	Newly born infants up to 10 kg. (22 lbs)	Similar – the subject has a lower allowable infant weight; both devices can provided a non-humidity controlled environment	

[1] WHO Weight for boys 0-13 weeks age. https://cdn.who.int/media/docs/default-source/child-growth/child-growth-standards/indicators/weight- for- age/wfa-boys-0-13-percentiles.pdf?sfvrsn=292d03f1_11
[2] WHO Infant Growth Chart Calculator: Weight Age WHO 0-2 Year. https://www.infantchart.com/infantweightage.php
[3] WHO Infant Growth Chart Calculator: Length Age WHO 0-2 Year. https://www.infantchart.com/infantlengthage.php

	mOm Essential Incubator (ME1)	Isolette® 8000 plus	Comparison	Impact of Differences on patient population, clinical use environment and testing to support differences
	Subject	**Predicate**		
				safety or effectiveness of the device
Environment of Use	Within healthcare setting providing neonatal and infant care	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.	Identical	N/A
System Specifications				
Principle of Operation	Controller-based incubator that enables control of temperature affecting the infant	Controller-based incubator that enables simultaneous control of temperature, oxygen, and humidity parameters affecting the infant	Similar	The intended population of the ME1 are pre-term and term infants who do not require a humidity-controlled environment. There is no negative impact to the safety or effectiveness of the device.
Protection class	Class I, Type BF, continuous operation	Class I, Type BF, continuous operation, not AP	Identical	N/A
Ingress of liquids and particulate matter (IEC 60601-1)	IPX0	IPX0	Identical	N/A
Intended for use in Transport vehicles	No	No	Identical	N/A

	mOm Essential Incubator (ME1)	Isolette® 8000 plus	Comparison	Impact of Differences on patient population, clinical use environment and testing to support differences
	Subject	**Predicate**		
Electrical Safety and Performance	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-19	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-19	Identical	N/A
Physical Attributes				
Height	44.2 cm (17.4 inches) 129 cm (51 inches) with cart	133.3 to 153.7 cm (52.5 to 60.5 inches)	Different	The difference in height has no impact on the patient population to be treated or the environment in which it is to be used; difference also has no impact on overall safety and effectiveness based on non-clinical testing performed
Width	44.5 cm (17.5 in)	< 104cm (41 in)	Different	The difference in width has no impact on the patient population to be treated based on WHO data;[1,2,3] there is no clinical relevance for the overall width of the device
Weight	20 kg (44 lb) without options/accessories 73 kg (161lb) with cart	<98.5 kg (217 lb.) without options/accessories	Different	The difference in weight has no clinical relevance to the patient population to be treated or to the clinical environment where it will be used
Depth	76.4 cm (30.1 inches)	< 76.2 cm (30 inches)	Same	N/A
Mattress size	30 x 62 x 2.5 cm	≥ 38 x 74 x 3 cm (15 x 29.1 x 1.2 inches)	Similar	The difference in the mattress size has no impact on the patient population to be treated as it is sized to fit the device; the mattress size has no relevance on the clinical environment. For infants who are ≤60cm long and

	mOm Essential Incubator (ME1)	Isolette® 8000 plus	Comparison	Impact of Differences on patient population, clinical use environment and testing to support differences
	Subject	**Predicate**		
				fit in our device, the maximum weight of 6 kg was considered to be a more accurate indication of the maximum weight of intended users, which would be the 98.9th percentile for a 30 day old infant (the maximum length of 60cm would be the 99.7th percentile for a 30 day old infant according to WHO growth charts.)[1,2,3]
Tilt	None	Continuously variable to 12 deg. +1 deg.	Different	The absence of tilt has no impact on the patient population to be treated or relevance to the clinical environment where the device is to be used
Infant weight	Maximum 6 kg (13.2 lbs)	Maximum 10 kg (22 lbs)	Similar	The subset of infants the ME1 is intended for are those who are more well and who are near-term. For infants who are ≤60cm long and fit in our device, the maximum weight of 6 kg was considered to be a more accurate indication of the maximum weight of intended users
Environment				
Operating temperature	20-30°C (68-86 °F)	20-30°C (68-86 °F)	Identical	N/A

	mOm Essential Incubator (ME1)	Isolette® 8000 plus	Comparison	Impact of Differences on patient population, clinical use environment and testing to support differences
	Subject	Predicate		
Operating humidity	10-80% RH non-condensing	5-95% RH non-condensing	Similar	The incubator is for use within a hospital setting. As standard NICU healthcare facilities require a minimum of 30% humidity and a maximum of 60%.[4] The operating range of the ME1 fall within this range and non-clinical testing supports that the device can function in this range as intended. This operating range has no impact on the patient population to be treated.
Operating ambient air pressure	520-760 mmHg (70-101 kPa)	70-110 kPa	Similar	The ME1 can operate at normal ambient conditions; the minimal difference does not impact the patient population to be treated nor the environment in which the incubator is to be used
Storage temperature	0 to 40°C (32 – 104°F)	-20 to 60°C (-4 to 140°F)	Different	The storage conditions for the ME1 are within the range cleared for the predicate device; thus the conditions are suitable for a hospital/healthcare setting; non-clnical testing supports the device functions as intended when stored under these conditions; the difference in storage temperature has no impact on the

[4] NICU Standard 11: Ambient Temperature and Ventilation. https://nicudesign.nd.edu/nicu-standards/nicu-standard-12-ambient-temperature-and-ventilation/#:~:text=The%20NICU%20shall%20be%20designed,two%20changes%20being%20outside%20air.

	mOm Essential Incubator (ME1)	Isolette® 8000 plus	Comparison	Impact of Differences on patient population, clinical use environment and testing to support differences
	Subject	**Predicate**		
				patient population to be treated
Electrical Requirements				
Power requirements	100-240V, 50-60 Hz at 2.5-9.0A	100/120V, 50/60 Hz, 1900 W max, 9.9 A max	Similar	The ME1 can operate in a larger voltage range, which is supported by the non-clinical testing performed; the broadened range affords more flexibility when operating the unit; the difference in allowable voltage has no impact on the patient population to be treated
Auxiliary power sockets	n/a	All 50/60 Hz 100 V, 100W max 120 & 230 V 300W max	Different	The absence of auxiliary power sockets does not affect the function of the subject device as a neonatal incubator, nor the patient population to be treated
In-Use Battery Life	On Battery Power, ME1 can maintain a set temperature of 11°C (51.8°F) above ambient (20 to 30°C (68 - 86°F)) for at least one hour	n/a	Different	ME1 can continue to provide thermal care in the event of a power outage or disconnection from wall power either by accident or for transfer within the hospital on the ME1 trolley. This feature is supported by non-clinical testing reported in the Verification Test Report for the Pilot Production Build Essential Incubator, CHH-1493-TR (page 62). This feature has no impact on the patient population to be treated.
Battery Life	1500 charge cycles	n/a	Different – predicate does not include	This feature is supported by non-

	mOm Essential Incubator (ME1)	Isolette® 8000 plus	Comparison	Impact of Differences on patient population, clinical use environment and testing to support differences
	Subject	**Predicate**		
			a battery	clinical testing provided on the Technical Datasheet by the battery manufacturer (URB1270 Technical Datasheet). This feature has no impact on the patient population to be treated or the clinical environment in which it is to be used.
Earth leakage	<350 µA	< 500 µA	Similar	The ME1 has a smaller residual current than the predicate device as determined via non-clinical testing; the smaller residual current had no impact on the patient population to be treated or clinical environment in which it is to be used
General Performance				
Parameters controlled	Temperature	Temperature Humidity (optional) Oxygen (optional)	Similar	The intended population of the ME1 are pre-term and term infants who do not require a humidity-controlled environment. There is no negative impact to the safety or effectiveness of the device as a result of not having humidity and/or oxygen functions
Operations	Controller based – air temperature mode	Controller based – air temperature mode and skin temperature mode	Similar	ME1 does not provide skin temperature mode control to avoid the risk of masking clinical conditions; difference does not impact the patient population to be treated nor the environment in which it is to be used
Skin temperature set point range	n/a	34-37°C (93.2-98.6 °F)	Different	

	mOm Essential Incubator (ME1)	Isolette® 8000 plus	Comparison	Impact of Differences on patient population, clinical use environment and testing to support differences
	Subject	**Predicate**		
Air temperature set point range	28 to 37°C in 0.5°C increments (82.4 – 98.6 in 0.9°F increments)	20 to 39°C (68-102.2°F)	Similar	The temperature range provided by the ME1 was identified during formative user requirement investigation, and has been adjusted based on our Post Market Surveillance to meet the full range required by clinicians using our device. There is no impact to the patient population to be treated due to the tightened air temperature ranges
Air temperature control override range	-	37-39°C (98.6-102.2°F)	Different	
Air setpoint display range	28-37°C (82.4 – 98.6°F)	15 to 45°C (59-113°F)	Different	It is important for the clinicians to see the temperature that has been set for the incubator to reach. By only displaying the allowed range of set temperatures on the ME1 it avoids the impression that the device can provide a wider range of temperatures. The difference has no impact on the patient population to be treated
Air temperature upward deviation limit	+ 1.5°C (+2.7°F)	+ 1.5 to +2.5°C (+2.7 to 4.5°F)	Similar	The ME1 ensures that the accuracy of the air temperature is within the tolerance of + 1.5°C (+2.7°F) for a given Set Temperature; ensuring that the incubator provides medically appropriate thermal care, as decided by the clinician. The difference in the tolerance has no impact on the patient population to be treated
Air temperature downward deviation limit range	- 1.5°C (-2.7°F)	-1.5 to -2.5°C (-2.7 to -4.5°F)	Similar	

	mOm Essential Incubator (ME1)	Isolette® 8000 plus	Comparison	Impact of Differences on patient population, clinical use environment and testing to support differences
	Subject	**Predicate**		
Warm up time at ambient temperature	40 minutes	< 35 minutes	Similar	Timely provision of thermal care is important for cold infants. However, in normal practice incubators are kept on and ready during births or in relevant hospital departments and will not be impacted by a difference in warm-up time. This difference does not impact the patient population to be treated
Variability /Stability	< 0.5°C (<0.9°F)	< 0.5°C (<0.9°F)	Identical	N/A
Overshoot	2°C (3.6°F)	< 0.5°C (<0.9°F)	Similar	The overshoot during warm-up meets the requirements of the non-clinical testing performed in accordance with IEC 60601-2-19; this difference has no impact on the patient population to be treated nor on the environment in which it is to be used
Uniformity with a level mattress	< 0.8°C (<1.4°F)	<0.8°C (<1.4°F)	Identical	N/A
Misc. Specifications				
Noise Level inside infant compartment	≤ 60 dB(A)	≤ 47 dB(A) with 37dB(A) or less ambient (without servo O2 control)	Similar	The noise level of the subject device in normal conditions meets the requirements of IEC 60601-2-19; this difference has no impact on the patient population to be treated nor on the environment in which it is to be used
Air Velocity inside infant	<0.07 m/sec (Maximum measured)	<0.10m/sec (4in/sec); average of 5 points at 10cm (4 in) above	Similar	The air velocity meets the requirements of IEC 60601-2-19; this

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	Subject	**Predicate**		
compartment	0.054m/sec average of 5 points at 10cm (4 in) above mattress	mattress		difference has no impact on the patient population to be treated nor on the environment in which it is to be used
Maximum CO2 level	≤ 0.3%	< 0.8%	Similar	CO_2 can be dangerous for an infant if it builds up within the enclosed incubator environment. The ME1 CO_2 level remains lower than the predicate; this difference has no impact on the patient population to be treated nor on the environment in which it is to be used
Components				
Acoustical level (all alarms on)	70 dB(A)	75 dB(A) maximum	Similar	The lower noise level in alarm conditions meets the requirements of IEC 60601-2-19; Loud noises can impact infant sleep and intra cranial pressure and recommendations point to low infant environmental sound levels. While alarm sound levels are higher than is desirable for the infant, they are required to let a care giver know that there may be a higher risk situation and therefore the benefit outweighs the risk; this difference has no impact on the patient population to be treated nor on the environment in which it is to be used

	mOm Essential Incubator (ME1)	Isolette® 8000 plus	Comparison	Impact of Differences on patient population, clinical use environment and testing to support differences
	Subject	**Predicate**		
Hand ports (Porthole Doors)	Yes – 2 on the front of the incubator	Yes – 4 total 2 on either side of the incubator	Similar – both configurations allow for access to the infant for care and/or medical emergencies	Infants in the incubator need to be cared for or may need to be accessed for medical procedures. Users of the ME1 have found the 2 port doors and incubator door adequate for their needs based on non-clinical testing performed; this difference has no impact on the patient population to be treated nor on the environment in which it is to be used
Iris Ports	No	Yes – 2 One on either end of the incubator	Different – lack of iris ports does not impact the safety or effectiveness of the device	
Access panel	Yes	Yes	Identical	N/A
Air filter	Yes	Yes	Identical	N/A
Oxygen filter	n/a	Yes	Different	The design of the ME1 device allows for oxygen to be delivered via an external source to the infant while inside of the incubator via the IV-ports; this difference has no impact on the patient population to be treated nor on the environment in which it is to be used

	mOm Essential Incubator (ME1)	Isolette® 8000 plus	Comparison	Impact of Differences on patient population, clinical use environment and testing to support differences
	Subject	**Predicate**		
Probes / Sensors	Skin temperature (optional)	Skin temperature Humidity (optional) Oxygen (optional)	Similar – both devices allow for the measurement of skin temperature; the optional features of the predicate device are not required for the functionality of the ME1 device	Infants in an incubator require frequent monitoring. An embedded skin temperature probe enables this without any additional equipment; the optional features of the predicate device are not required for the functionality of the ME1 device and do not impact the patient population intended to be treated by the ME1 or the environment in which it is to be used
Serial port	No	Yes	Different	The absence of a serial port and COM Port does not affect the function of the ME1 device as a neonatal incubator, the patient population to be treated or the envinroment in which it is to be used
COM Port (output only)	No output COM Port	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. 60V DC nominal voltage.	Different	
Accessories	Cart (Trolley), castor wheels with brakes	Trolley, castor wheels with brakes	Identical	N/A
Optional Components	N/A	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	Different	The optional accessories available for the predicate do not impact the basic function of the ME1 as a neonatal incubator, the patient population it intends to treat or the environment in which it is to be used

	mOm Essential Incubator (ME1)	Isolette® 8000 plus	Comparison	Impact of Differences on patient population, clinical use environment and testing to support differences
	Subject	**Predicate**		
Biocompatibility and Sterility				
Biocompatibility	According to ISO 10993 and ISO 18562: • ISO 10993-1 • ISO 10993-5 • ISO 10993-10 • ISO 10993-23 • ISO 18562-1 • ISO 18562-2 • ISO 18562-3	According to ISO 10993	Similar	The ME1 was subjected to additional biocompatibility testing to confirm the lack of particulates, volatile organic compounds, or leachables present within the air pathway; the difference has no impact on the environment in which it is to be used
Sterile	No	No	Identical	N/A

The mOm Essential Incubator and the predicate device have the same intended use, as neonatal incubators. Both the subject and predicate are controller-based incubators that can control temperature.

The subject device and the predicate device have similar technological characteristics. The mOm Essential Incubator has a subset of the indications and the same risks, basic technology, and potential adverse events as the predicate (K172154). The primary technological difference between the predicate and the subject devices is that the subject device includes an air temperature control mode, whereas the predicate includes both air temperature and skin temperature modes. Also, the subject device does not include the control of oxygen and humidity, which are options in the predicate device.

NON-CLINICAL TESTING/PERFORMANCE DATA:

Bench testing of the mOm Essential Incubator met all relevant requirements for neonatal incubators. Testing was performed in accordance with applicable standards, to characterize and evaluate the device, including performance testing, functional/operational testing, verification and validation, biocompatibility, human factors, risk analysis and verification of risk control measures. Testing included accessories and optional components.

Electrical safety, electromagnetic compatibility (EMC) and Performance:

Electrical safety testing and performance testing were conducted on the mOm Essential Incubator. Testing shows that the device complies with the requirements of IEC 60601-1, IEC 60601-1-6, IEC 60601-1-8, and IEC 60601-2-19. EMC testing was also conducted on the mOm Essential Incubator. Testing shows that the device complies with the requirements of IEC 60601-1-2:

- IEC 60601-1:2005 + IEC 60601-1:2005/A1:2012 + IEC 60601-1:2005/A2:2020. Edition 3.2 2020-08 consolidated version. Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014+IEC 60601-1-2:2014/A1:2020. Edition 4.1 2020-09 consolidated version. Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. Requirements and tests.
- IEC 60601-1-6:2010 + IEC 60601-1-6:2010/A1:2013 + IEC 60601-1-6:2010/A2:2020 for use in conjunction with IEC 62366:2015+A1:2020. Edition 3.2 2020-07 consolidate version. Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance. Collateral standard. Usability.
- IEC 60601-1-8:2006+IEC 60601-1-8:2006/A1:2012+IEC 60601-1-8:2006/A2:2020. Edition 2.2 2020-07 consolidated version. Medical electrical equipment – Part 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 60601-2-19:2020. Edition 3.0 2020-09. Medical electrical equipment – Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators.

Software verification and validation:

The software controlling operations in the mOm Essential Incubator 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. Software verification and validation testing were conducted as outlined in the FDA guidance document entitled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," May 2005.

Performance data demonstrate that the device functions as intended and has a safety and effectiveness profile that is similar to the predicate device.

Biocompatibility:

To evaluate the biocompatibility of the mOm Essential Incubator, a risk management approach, in accordance with ISO 10993-1 and ISO 18562 series, was chosen when considering the requirements for the chemical, physical and biological characteristics of the device. Testing was also conducted in accordance with the FDA guidance entitled "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'," September 2020.

The following tests were performed on the mOm Essential Incubator:

- Test for volatile organic compounds
- Emission of particles and Inorganic gases
- Material characterization
- Cytotoxicity evaluation
- Irritation evaluation
- Sensitization evaluation

These tests were performed in compliance to the following standards:

- ISO 10993-1:2018, including corrected version 2018-10. Edition 2020-12. Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process.
- ISO 10993-5:2009. Edition 2009-06. Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10:2021. Edition 2023-02. Biological evaluation of medical devices — Part 10: Tests for skin sensitization.
- ISO 10993-23:2021. Edition 2021-03. Biological evaluation of medical devices — Part 23: Tests for irritation.
- ISO 18562-1:2017. Edition 2020-02. Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process.
- ISO 18562-2:2017. Edition 2020-02. Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter.
- ISO 18562-3:2017**.** Edition 2020-02. Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds (VOCs).

The evaluation of the results from material investigations, chemical characterization, and evaluation of literature, show that the mOm Essential Incubator is biologically safe for its intended use and application.

Human Factors:

Summative Human Factors testing was conducted in accordance with IEC 62366-1 and IEC 62366-2:

- IEC 62366-1:2015/A1:2020, incorporating amendment 1:2020 and corrigendum July 2016, Medical devices - Part 1. Application of usability engineering to medical devices. Published 2020-06.
- IEC 62366-2:2016, Medical devices-Part 2. Guidance on the application of usability engineering to medical devices. Published 2016-04.

Cleaning and Disinfection:

Cleaning and Life testing has been conducted on the mOm Essential Incubator to evaluate the integrity of the incubator and its components after repeated cleaning and use, in accordance with the IFU. No issues were encountered that would affect the safety or usability of the incubator after three (3) years of simulated deep cleans and disassembly/re-assembly.

CONCLUSION:

The mOm Essential Incubator (ME1) has the same intended use and the same or similar technological characteristics as the predicate. Performance data demonstrates that the device functions as intended, and is as safe and effective as the predicate device.