July 15, 2022

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

Re: K220742
Trade/Device Name: NxtGen Infant Transport Incubator
Regulation Number: 21 CFR 880.5410
Regulation Name: Neonatal Transport Incubator
Regulatory Class: Class II
Product Code: FPL
Dated: June 15, 2022
Received: June 17, 2022

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Payal Patel
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)*

K220742

Device Name
NxtGen Infant Transport Incubator

Indications for Use *(Describe)*

The NextGen Transport Incubator is intended for use by personnel trained in neonatal care to facilitate the movements of neonates by air or ambulance. The transport incubator provides heat in a controlled manner to neonates through an enclosed temperature controlled environment. The transport incubator is also intended to carry equipment designed for airway management and monitoring of the neonatal infant's status. The device provides two modes of heat: Manual (operator) controlled or Skin (servo) controlled. All transport incubators may be optionally configured with pulse oximetry, a suction device, and an integrated heated mattress. In addition, the NextGen Incubator may be configured with optional blue LED phototherapy to treat indirect hyperbilirubinemia.

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 - K220742

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: July 8, 2022

Device Identification:

Trade Name: NxtGen Infant Transport Incubator
Common Name: Transport Incubator
Regulatory Class: II
Regulation: 880.5410
Product Code: FPL
Panel: General Hospital

Predicate Device:

International Biomedical – Voyager Infant Transport Incubator – K103524

Device Description:

The NxtGen Infant Transport Incubator is designed to provide a thermally stable environment for the infant during transport. The incubator is designed to maintain temperatures within desired limits as prescribed by the caregiver.

The NxtGen Infant Transport Incubator has two modes of temperature control available – manual temperature mode and skin temperature control mode (or servo mode). The device includes several optional features including: integrated ambient oxygen monitor, integrated pulse oximeter, integrated phototherapy lighting, integrated electronic suction device, and an integrated heated mattress.

Indications for Use:

The NxtGen Transport Incubator is intended for use by personnel trained in neonatal care to facilitate the movements of neonates by air or ambulance. The transport incubator provides heat in a controlled manner to neonates through an enclosed temperature controlled environment. The transport incubator is also intended to carry equipment designed for airway management and monitoring of the neonatal infant's status. The device provides two modes

of heat: Manual (operator) controlled or Skin (servo) controlled. All transport incubators may be optionally configured with pulse oximetry, a suction device, and an integrated heated mattress. In addition, the NextGen Incubator may be configured with optional blue LED phototherapy to treat indirect hyperbilirubinemia.

Summary Technological Comparison:

The NxtGen Infant Transport Incubator 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 NxtGen Infant Transport Incubator is equivalent to the intended use of the predicate k103524. The differences in the intended use do not raise questions about the safety or effectiveness for the subject device.

System Specification	International Biomedical NXTGEN Transport Incubator New Device	International Biomedical Voyager Transport Incubator Primary Predicate Device	Differences	Discussion of Differences
	Base Model Specifications			
General	K220742	K103524		
Indications for Use	The NxtGen Transport Incubator is intended for use by personnel trained in neonatal care to facilitate the movements of neonates by air or ambulance. The transport incubator provides heat in a controlled manner to neonates through an enclosed temperature controlled environment. The transport incubator is also intended to carry equipment designed for airway management and monitoring of the neonatal infant's status. The device provides two modes of heat: Manual (operator) controlled or Skin (servo) controlled. All transport incubators may be optionally configured with pulse oximetry, a suction device, and an integrated heated mattress. In addition, the NxtGen Incubator may be configured with optional blue LED phototherapy to treat indirect hyperbilirubinemia.	The transport incubator is intended for use by personnel trained in neonatal care to facilitate the movements of neonates by air or ambulance. The transport incubator circulates warmed air at an operator selected and controlled temperature when transporting neonatal infants to hospitals prepared for neonatal infant care. The transport incubator is also intended to carry equipment designed for airway management and monitoring of the neonatal infant's status.	Similar	The intended use of the proposed device and the predicate device is for transporting neonatal infants using controlled air temperature. Differences involve the addition of servo temperature control, which is a common temperature control feature on other transport incubators on the market, including K141565 (Draeger GT-5400). Servo (or baby temperature) controlled temperature is a safe and effective heating method that is common in infant incubators and is defined in the safety standard 60601-2-20.
Patient Population	Neonate	Neonate	Same	N/A
Patient Weight (Max)	10 Kg (22 LBS)	7.3 Kg (16 LBS.)	Larger capacity	The only change is a larger capacity patient weight. Patient weight capacity within the chamber does not have an effect on safety and effectiveness of the device and is considered in the safety testing performed.

System Specification	International Biomedical NXTGEN Transport Incubator New Device	International Biomedical Voyager Transport Incubator Primary Predicate Device	Differences	Discussion of Differences
Environment of Use	Intra-hospital and transport between healthcare facilities.	Intra-hospital and transport between healthcare facilities.	Same	N/A
Prescriptive	Yes	Yes	Same	N/A
Heating Technology	Convective Air	Convective Air	Same	N/A
Hood Design	Double Wall	Double Wall	Same	N/A
Skin Temp Monitoring	Yes	Yes	Same	N/A
Skin Temperature Probe (T1-Primary)	700-3401 (Disposable) 739-1603 (Reusable)	N/A	New optional control mode feature	The T1 temperature probe provides feedback on the patient temperature to the NxtGen system as a part of the servo control mode. The addition of servo temperature control, which is a common temperature control feature on other transport incubators on the market, including k141565 (Draeger GT-5400) does not raise new questions of safety and effectiveness and is defined and tested in FDA recognized standard 60601-2-20.
Temperature Probe (T2-Reference)	700-3409 (YSI 400 series compatible)	700-3409 (YSI 400 series compatible)	Same	N/A
Infant Mattress	Cast-coated polyurethane Polyester - Ventex Recovery 6	Cast-coated polyurethane Polyester - Ventex Recovery 6	Same	The infant mattress is the same mattress used with the predicate incubator and also the same cover material as the new optional heated mattress cover and also the same as the mattress in the International Biomedical NuBorne Infant Warmer K173516.
	Operating Mode			
Air Controlled Mode	Yes	Yes	Same	N/A
Temperature Set Point Range-Air Temp	17.0°-38.9°C	17.0°-38.9°C	Same	N/A
Air Controlled Alarm Point	± 1.5 °C from Temperature Set Point Range-Air Temp	± 1 °C from Temperature Set Point Range-Air Temp	Similar	The proposed new device alarm point is still within the prescribed temperature alarm range in the 60601-2-20 standard and is more consistent with current technology.
Servo Controlled Mode	Yes	No	New optional control mode	The addition of servo temperature control, which is a common temperature control feature on other transport incubators on the market, including K141565 (Draeger GT-5400) is a safe and effective heating method and is defined in the safety standard 60601-2-20.
Temperature Set Point Range-Baby Temp	33°C-37.5°C	N/A	New control mode feature	The addition of servo temperature control, which is a common temperature control feature on other transport incubators on the market, including K141565 (Draeger GT-5400) is a safe and effective heating method and is defined in

System Specification	International Biomedical NXTGEN Transport Incubator New Device	International Biomedical Voyager Transport Incubator Primary Predicate Device	Differences	Discussion of Differences
				the safety standard 60601-2-20.
Servo Controlled Alarm Point	± 0.7 °C from Temperature Set Point Range-Baby Temp	N/A	New control mode feature	The addition of servo temperature control, which is a common temperature control feature on other transport incubators on the market, including K141565 (Draeger GT-5400) is a safe and effective heating method and is defined in the safety standard 60601-2-20.
PreWarm Mode	Yes	No	New standby mode	Pre-Warm mode is simply a stand-by mode where the incubator can be turned on and "warmed up" without a patient present. This is common practice in hospitals so that the incubator is ready to go when a patient is placed inside. Because the device does not run in pre-warm mode with a patient, the mode has no additional safety and effectiveness impact.
	Incubator Features			
Approximate Warm-up Time	12 minutes ± 20% (Low Profile Chamber) 16 Minutes ± 20% (XL Chamber)	20 Minutes	Different warm-up time	The warm-up time allows for the device to be heated sooner compared to the predicate device. There is no impact to safety and effectiveness.
	Electrical Description			
External Power	AC 100-240 V, 50 -60 Hz.	AC 110/120 V, 50-60 Hz. AC 230 V, 50-60 H	Same	N/A
Internal Power	1-12 V DC, Lead Acid Battery, sealed, rechargeable. 1-12 V DC, Lithium-Iron Phosphate, rechargeable	1-12 V DC, Lead Acid Battery, sealed, rechargeable.	Same New battery option	N/A Lithium –Iron Phosphate battery is battery technology most commonly used in medical devices that offer superior life to the older Lead Acid type of batteries. Assessed through performance testing.
Battery Life Expectance	4.5 hours	3 hours	Different	Battery life expectancy is increased compared to the predicate. This will make long transports safer as the device will not stop working or require AC power as quickly. Assessed through performance testing.
Expected Battery Cycles	200 cycles	200 cycles	Same	N/A
	Physical Description			

System Specification	International Biomedical NXTGEN Transport Incubator New Device				International Biomedical Voyager Transport Incubator Primary Predicate Device				Differences	Discussion of Differences
Dimensions		**Height** inches (cm)	**Width** inches (cm)	**Depth** inches (cm)	**Weight** lbs. (kg)	**Height** inches (cm)	**Width** inches (cm)	**Depth** inches (cm)	**Weight** lbs. (kg)	Similar	Weight capacity is greater compared to the predicate.
	Incubator without infant chamber or handles	10.7 (27.2)	32.1 (81.5)	18.4 (40.5)	65 (29.5)	Incubator without infant chamber	10 (25.4)	37.5 (95.2)	19.2 (48.8)	78 (35)	
	Low Profile Infant Chamber	11.3 (28.7)	30 (76.2)	16.7 (42.4)	18.9 (8.6)	Standard Infant Chamber	10.75 (27.3)	29 (73.7)	17 (43.2)	17 (7.7)	
	XL Infant Chamber	13.3 (33.8)	30 (76.2)	16.7 (42.4)	21.1 (9.6)	Large Infant Chamber	11.25 (28.6)	29 (73.7)	17 (43.2)	20 (9.1)	
Material											
Material Used for Indirect Patient Contact	Metal (e.g. Aluminum); Molded Plastic				Metal (e.g. Aluminum); Molded Plastic				Same	N/A	
Material used for direct patient contact	Cell Cast Acrylic; Textile (Ventex Recovery 6)				Cell Cast Acrylic; Textile (Ventex Recovery 6)				Same	N/A	
	Optional Components										
	Heated Mattress										
Integrated Heated Mattress	Yes				No				New mattress functionality	The integrated heated mattress is not a new technology or item used in neonatal care. Heated mattresses are common in transport incubators already on the market, as can be found in K141565 (Draeger GT-5400).	
Mattress Dimensions	31.8 ± 61.0 ± 2.5 cm				31.8 ± 61.0 ± 2.5 cm				New mattress feature	The integrated heated mattress and its components are compliant with ISO 80601-2-35. For verification of compliance refer to Intertek Safety Report 104427163LAX-005.	
Mattress Max Temperature	40°C				N/A				New mattress feature	The integrated heated mattress and its components are compliant with ISO 80601-2-35. For verification of compliance refer to Intertek Safety Report 104427163LAX-005.	
Power Rating	20 Watt				N/A				New mattress feature	The integrated heated mattress and its components are compliant with ISO 80601-2-35. For verification of compliance refer to Intertek Safety Report 104427163LAX-005.	
Heated Mattress Element	738-2409				N/A				New mattress feature	The integrated heated mattress and its components are compliant with ISO 80601-2-35. For verification of compliance refer to Intertek Safety Report 104427163LAX-005.	
Heated Mattress Cover	736-1114				N/A				New mattress feature	The integrated heated mattress and its components are compliant with ISO 80601-2-35. For verification of compliance refer to Intertek Safety Report 104427163LAX-005.	
Heated	Cast-coated polyurethane				Cast-coated polyurethane				Same	N/A	

System Specification	International Biomedical NXTGEN Transport Incubator New Device	International Biomedical Voyager Transport Incubator Primary Predicate Device	Differences	Discussion of Differences
Mattress Cover Material	Polyester - Ventex Recovery 6	Polyester - Ventex Recovery 6		
	Pulse Oximetry			
Integrated SpO2	Yes	Yes	Same	N/A
Integrated O2 Monitor	Yes	Yes	Same	N/A
Oxygen Saturation	1%-100%	1%-100%	Same	N/A
Pulse Rate	During No Motion Conditions: 25-239 bpm During Motion Conditions: 47-127 bpm	During No Motion Conditions: 25-239 bpm During Motion Conditions: 47-127 bpm	Same	N/A
Resolution	Oxygen Saturation: 1% Pulse Rate: 1 bpm	Oxygen Saturation: 1% Pulse Rate: 1 bpm	Same	N/A
Sensor Peak Wavelengths	Masimo: 660 nm (red light), 905 nm (infrared light) Nellcor: 660 nm (red light), 900 nm (infrared light)	Masimo: 660 nm (red light), 905 nm (infrared light) Nellcor: 660 nm (red light), 900 nm (infrared light)	Same	N/A
Sensor Maximum Power Output	Masimo: less than 15 mW (at 50 mA pulsed) Nellcor: less than 15 mW	Masimo: less than 15 mW (at 50 mA pulsed) Nellcor: less than 15 mW	Same	N/A
Masimo Sensor Accuracy	**During No Motion Conditions** Oxygen Saturation - Neonates: 70 - 100% ± 3%; 0 - 69% unspecified Oxygen Saturation - Pediatrics: 70 - 100% ± 2%; 0 - 69% unspecified Pulse Rate - Neonates / Pediatrics: 25 - 240 bpm ± 3 bpm **During Motion Conditions** Oxygen Saturation - Neonates / Pediatrics: 70 - 100% ± 3%; 0 - 69% unspecified Pulse Rate - Neonates / Pediatrics: 25 – 240 bpm ± 5 bpm **Low Perfusion (where 0.02% Pulse Amplitude and % Transmission > 5%)** Oxygen Saturation - Neonates / Pediatrics: ± 2% Pulse Rate - Neonates /	**During No Motion Conditions** Oxygen Saturation - Neonates: 70 - 100% ± 3%; 0 - 69% unspecified Oxygen Saturation - Pediatrics: 70 - 100% ± 2%; 0 - 69% unspecified Pulse Rate - Neonates / Pediatrics: 25 - 239 bpm ± 3 bpm **During Motion Conditions** Oxygen Saturation - Neonates / Pediatrics: 70 - 100% ± 3%; 0 - 69% unspecified Pulse Rate - Neonates / Pediatrics: 25 - 239 bpm ± 5 bpm **Low Perfusion (where 0.02% Pulse Amplitude and % Transmission > 5%)** Oxygen Saturation - Neonates / Pediatrics: ± 2% Pulse Rate - Neonates /	Same	N/A

System Specification	International Biomedical NXTGEN Transport Incubator New Device		International Biomedical Voyager Transport Incubator Primary Predicate Device		Differences	Discussion of Differences
	Pediatrics		Pediatrics			
Nellcor Sensor Accuracy	**During No Motion Conditions**		**During No Motion Conditions**		Same	N/A
	Oxygen Saturation - Neonates	70 - 100% ± 2%	Oxygen Saturation - Neonates	70 - 100% ± 2%		
	Oxygen Saturation - Neonates	60-80% ± 3%	Oxygen Saturation - Neonates	60-80% ± 3%		
	Pulse Rate - Neonates	20 - 250 bpm ± 3 bpm	Pulse Rate - Neonates	20 - 250 bpm ± 3 bpm		
	During Motion Conditions		**During Motion Conditions**			
	Oxygen Saturation - Neonates	70 - 100% ± 3%	Oxygen Saturation - Neonates	70 - 100% ± 3%		
	Pulse Rate - Neonates	48 – 127 bpm ± 3 bpm	Pulse Rate - Neonates	48 – 127 bpm ± 3 bpm		
	Low Perfusion (where 0.02% Pulse Amplitude and % Transmission > 5%)		**Low Perfusion (where 0.02% Pulse Amplitude and % Transmission > 5%)**			
	Oxygen Saturation - Neonates / Pediatrics	± 2%	Oxygen Saturation - Neonates / Pediatrics	± 2%		
	Pulse Rate - Neonates / Pediatrics	48 – 250 bpm ± 3 bpm	Pulse Rate - Neonates / Pediatrics	48 – 250 bpm ± 3 bpm		
	Ambient Oxygen Monitor					
Measurement Range	10.0% to 100%		10.0% to 100%		Same	N/A
Resolution	0.1%		0.1%		Same	N/A
Response Time	< 16 seconds for 90% response < 25 seconds for 97% response		< 16 seconds for 90% response < 25 seconds for 97% response		Same	N/A
Accuracy	± 4.0% over measurement range		± 4.0% over measurement range		Same	N/A
Stability	Less than 2% drift over 8 hours at constant temperature and pressure		Less than 2% drift over 8 hours at constant temperature and pressure		Same	N/A
Required Sample Flow	Minimal 3cc/minute, 100cc/minute typical		Minimal 3cc/minute, 100cc/minute typical		Same	N/A
Operating Temperature	5°to 40° C (31° - 104° F)		5°to 40° C (31° - 104° F)		Same	N/A
	Observation Light					
Observation Light	Yes		Yes		Same	N/A
Power Rating	10 Watt		10 Watt		Same	N/A
Audible Noise Level	< 60 dB		< 60 dB		Same	N/A
Intensity	150 Lumens		150 Lumens		Same	N/A

System Specification	International Biomedical NXTGEN Transport Incubator New Device	International Biomedical Voyager Transport Incubator Primary Predicate Device	Differences	Discussion of Differences
(minimum)				
Light Heat Output	< 10° C Warmer than ambient	< 0.5 ° C warmer than ambient @ 5”	Documentation Change	The claimed light heat output range was increased for the NxtGen system although the electrical and mechanical specifications contributing to the light heat output have not been changed. The NxtGen Phototherapy light and its components are in compliance with 60601-2-50. For verification of compliance refer to 104447422LAX-002
	Phototherapy Light			
Integrated Phototherapy Light	Yes	Yes – k160238	Same	N/A
Power Rating	10 Watt	10 Watt	Same	N/A
Light Spectrum Range	450 - 465 nm	450 - 465 nm	Same	N/A
Maximum Irradiance at mattress	Low Chamber: 35 µW/cm2/nm (Light Bar @ 7.8” above mattress) XL Chamber: 22 µW/cm2/nm (Light Bar @ 9.8” above mattress)	27 µW/cm2/nm (Light Bar @ 8.8” above mattress)	New chamber size	The chamber size difference between the NxtGen and Voyager accounts for the differences in maximum irradiance values at the mattress. The maximum irradiance levels for both the Low chamber and XL chamber are within a common range for neonatal phototherapy lights already on the market as referenced in K120168 (GE Healthcare Lullaby Phototherapy System)
Effective Irradiated Area	Low Chamber: 12.3 in □ 9.2 in ellipse XL Chamber: 15.1 in □ 10.8 in ellipse	10 in x 8 in ellipse	Different	The effective irradiated area is greater compared to the predicate. This will increase the phototherapy treatment area and allow a greater amount of patient’s skin will be inside the effective irradiated area.
Light Expected Service Life	8 years	8 years	Same	N/A
Light Pre-Aging Time	Not Required	Not Required	Same	N/A
Audible Noise Level	< 60dB	< 60 dB	Same	N/A
Intensity Ratio $E_{bi\ min}/E_{bi\ max}$	>40 %	> 40%	Same	N/A
Light Heat Output	< 10° C warmer than ambient	< 0.5 ° C warmer than ambient @ 5”	Documentation change	The claimed light heat output range was increased for the NxtGen system although the electrical and mechanical specifications contributing to the light heat output have not been changed. The NxtGen Phototherapy light and its components are in compliance with 60601-2-50. For verification of compliance refer to 104447422LAX-002
Phototherapy Light Variation in Intensity	< 10%	< 10%	Same	N/A

System Specification	International Biomedical NXTGEN Transport Incubator New Device	International Biomedical Voyager Transport Incubator Primary Predicate Device	Differences	Discussion of Differences
over 5 hrs after Warm-Up				
	Integrated Electronic Suction			
Integrated electronic suction	Yes	No	New Electronic Suction Option	The integrated electronic suction is not a new technology or item used in neonatal care. Electronic suction is common in transport incubators already on the market, but typically as a stand-alone device. Incorporating the electronic suction into the controls of the incubator make it more easily accessible to the end user.
Power Rating	20 Watt	N/A	New Electronic Suction Option	The integrated electronic suction system and its components are compliant with ISO 10079-1. For verification of compliance refer to Intertek Safety Report 104427163LAX-008
Airflow at Vacuum Inlet	10 LPM	N/A	New Electronic Suction Option Component	The integrated electronic suction system and its components are compliant with ISO 10079-1. For verification of compliance refer to Intertek Safety Report 104427163LAX-008
Vacuum Maximum Pressure	150 mmHg (Actual value can be between 108-163 mmHg.)	N/A	New Electronic Suction Option Component	The integrated electronic suction system and its components are compliant with ISO 10079-1. For verification of compliance refer to Intertek Safety Report 104427163LAX-008
Vacuum Pressure Range	10-150 mmHg	N/A	New Electronic Suction Option Component	The integrated electronic suction system and its components are compliant with ISO 10079-1. For verification of compliance refer to Intertek Safety Report 104427163LAX-008
Vacuum Indicator Accuracy	$\pm$ 5 mmHg	N/A	New Electronic Suction Option Component	The integrated electronic suction system and its components are compliant with ISO 10079-1. For verification of compliance refer to Intertek Safety Report 104427163LAX-008
Noise Level	< 60 dB	N/A	New Electronic Suction Option Component	The integrated electronic suction system and its components are compliant with ISO 10079-1. For verification of compliance refer to Intertek Safety Report 104427163LAX-008
Suction Canister Volume (up to 20 deg incline)	800 mL	N/A	New Electronic Suction Option Component	The integrated electronic suction system and its components are compliant with ISO 10079-1. For verification of compliance refer to Intertek Safety Report 104427163LAX-008
Suction Canister	738-1701	N/A	New Electronic Suction Option Component	The electronic suction canister is already on the market, as referenced in K771737 (SUCTION CANISTER).
18" Suction Tubing	738-1702	N/A	New Electronic	The electronic suction tubing is already on the market, as referenced in K914601 (SUCTION

System Specification	International Biomedical NXTGEN Transport Incubator New Device	International Biomedical Voyager Transport Incubator Primary Predicate Device	Differences	Discussion of Differences
			Suction Option Component	CONNECTING TUBING).
72" Suction Tubing	738-2355	N/A	New Electronic Suction Option Component	The electronic suction tubing is already on the market, as referenced in K914601 (SUCTION CONNECTING TUBING).
Vacuum Filter	738-1657	N/A	New Electronic Suction Option Component	The integrated electronic suction system and its components are compliant with ISO 10079-1. For verification of compliance refer to Intertek Safety Report 104427163LAX-008
	Alarms			
Alarms	High Temp Set Point Air Flow Skin Temp Fault	High Temp Set Point Air Flow Skin Temp Fault	Same	N/A

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 60601-1-12, Medical Electrical Equipment, Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
- 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 60601-2-20, Medical Electrical Equipment, Part 2-20: Particular Requirements for the Basic Safety and Essential Performance of Transport Incubators
- ISO 10079-1, Medical suction equipment - Part 1: Electrically powered suction equipment
- IEC 60601-2-50, Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment

- IEC 80601-2-35, Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use
- IEC 80601-2-55, Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
- IEC 80601-2-61, Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

Bench Testing:

The following additional tests were performed

- Software Verification & Validation Testing
  - Software verification and validation testing was conducted and documentation was provided for review.
- 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 NxtGen Infant Transport Incubator 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 NxtGen Infant Transport Incubator 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 NxtGen Infant Transport Incubator 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 NxtGen Infant Transport Incubator is substantially equivalent to the listed predicate. Through functional performance testing the subject device has demonstrated substantial equivalence to the predicate device.

Any differences between NxtGen Infant Transport Incubator and the predicate do not raise any new questions of safety and effectiveness.