DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Draeger Medical Systems, Incorporated
Ms. Gale Winarsky
Manager, Regulatory Affairs
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K141565
Trade/Device Name: Globe-Trotter® GT5400
Regulation Number: 21 CFR 880.5410
Regulation Name: Neonatal transport incubator
Regulatory Class: Class II
Product Code: FPL
Dated: July 2, 2014
Received: July 3, 2014

Dear Ms. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Digitally signed by Richard C. Chapman -S
Date: 2014.09.10 13:08:06 -04'00'

for

Erin I. Keith, M.S.
Division 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141565

Device Name
Globe-Trotter® GT5400

Indications for Use *(Describe)*
The Globe-Trotter GT5400 neonatal transport system is intended for the transport of newborns weighing up to 10 kg (22 lb) between healthcare facilities. It provides means to control air temperature, deliver oxygen, resuscitate, provide passive humidification, and ventilate with active humidification (optional).

The Globe-Trotter GT5400 neonatal transport system is intended for use by trained health care professionals and 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Dräger

510(k) Summary
acc. to 807.92

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

Establishment Registration Number: 2510954

Contact Person: Gale Winarsky
Manager, Regulatory Affairs

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

Date summary was prepared: 06/09/2014

Device Name:

Trade Name:	Globe-trotter® GT5400
Classification Name:	Incubator, Neonatal Transport
Regulation Number:	21 CRF 880.5410
Product Code:	FLP
Class:	II

Legally Marketed Device Identification: Substantial equivalence is claimed to the TI500 Globe-Trotter Transport System K001019, Aviator Transport Incubator K103527.

Intended Use:

The Globe-Trotter GT5400 (GT5400) is a neonatal transport system intended for the transport of newborns weighing up to 10 kg between health care facilities. A fully configured system provides means to control air temperature, deliver oxygen, resuscitate, provide passive humidification and ventilate with active humidification. The GT5400 can be used for intra-hospital transport as well as between facilities via air or ground.

The device is intended to be used by trained health care professionals. It is not intended for home use.

Device Description:

The GT5400 is a combination of individual currently marketed medical devices without modification of their individual principles of operation. The GT5400 system is comprised of three main parts with standard and optional components.

- Transport Incubator
- Modular Frame
- Life Support Console (LCS).

Variants – The GT5400 has two variants, Air Vehicle configuration (AV) and Ground Vehicle (GV) configuration.

Dräger

Comparison of Technological Characteristics with Predicate Devices:

Specification	Predicate	Predicate	Device Under Review	Comments
Device Name	**TI500 Globe-trotter Neonatal Transport System** **(TI500 GT or GT500)**	**Airborne Life Support Transport Incubator Aviator**	**Globe-Trotter GT5400** **(GT5400)**	
Manufacturer	Draeger Medical Systems, Inc.	International Biomedical	Draeger Medical Systems, Inc.	
510(k)	K001019	K103527		
Regulation #	880.5410	880.5410	880.5410	Incubator, Neonatal Transport
Product Code	FPL	FPL	FPL	
Classification	II	II	II	
Intended Use	Intended for the transport of high risk premature, low birth weight, or critically ill newborns between healthcare facilities. The means of transportation can be either ground or airborne (rotary or fixed wing). The system is also suitable for either transport of stationary care within the hospital. It includes up to three system components. These components include a frame which houses the incubator and the pneumatic module assembly, and a facility for gas cylinder storage. The system is arranged to serve as a com-	The transport incubator is intended for use by personnel trained in neonatal care to facilitate the movements of neonates by air or ambulance.	Intended for the transport of newborns weighing up to 10 kg (22 lb.) between health care facilities. It provides a means to control air temperature, deliver oxygen, resuscitate, provide passive humidification and ventilate with active humidification.	The general intended use of the GT5400 has not changed from the predicate TI500GT. The patient weight is linked to the TI500 incubator. The TI500 incubator is used in the GT5400 and the TI500 GT therefore the patient weight is the same for both devices.

Specification	Predicate	Predicate	Device Under Review	Comments
Device Name	**TI500 Globe-trotter Neonatal Transport System** **(TI500 GT or GT500)**	**Airborne Life Support Transport Incubator Aviator**	**Globe-Trotter GT5400** **(GT5400)**	
	plete unit for the care of an infant in need of transportation.			
Indications for Use	Transport of high risk premature, low birth weight or critically ill newborns. It provides a means to control air temperature and oxygen concentration, to add relative humidity and to provide resuscitation.	The transport incubator is intended for use by personnel trained in neonatal care to facilitate the movements of neonates by air or ambulance.	Transport of newborns weighing up to 10 kg (22 lb.) between health care facilities. It provides means to control air temperature, deliver oxygen, resuscitate, provide passive humidification, and ventilate with active humidification. The Globe-Trotter GT5400 neonatal transport system is intended for use by trained health care professionals and it is not intended for home use	Both the GT5400 and the TI500GT provide passive humidity. The GT5400 also provides active humidification during ventilation via the currently marketed NeoPod T System (Humidifier for Neonatal Transport Ventilators) K870173
Target Population/Patient Population	Newborn infants	Newborn infants	Newly born infants up to 10 kg. (22lbs)	The premise of the population has not changed from the predicates. The weight is now provided as additional information for the user.
Environment of Use	Intra-hospital transport as well as transport between health care facilities	Transport between health care facilities	Same as TI500 GT	
System Specifications				
Device Classification	Class I, Type BF, continuous operation	Not found on Mfg. website	Same as TI500 GT	
Nominal System length	129.5 cm (50.9") without cart	UNK	163.9 cm (64.5 ")	The predicate TI500 GT is offered with or without a cart. The

Specification	Predicate	Predicate	Device Under Review	Comments
Device Name	**TI500 Globe-trotter Neonatal Transport System** **(TI500 GT or GT500)**	**Airborne Life Support Transport Incubator Aviator**	**Globe-Trotter GT5400** **(GT5400)**	
				GT5400 is offered without a cart.
Nominal System Width	56.5 cm (22")	UNK	57.8 cm (22.75")	
Nominal System Height	58.4 cm (22.9")	UNK	≤42.6 - ≤58.5 cm (16.8 in – 23 in)	
Nominal Weight	83.9 kg (184.9 lb.) or 71.6 kg (157.9 lb.) depending on configuration	UNK	80-116 kg (176-254 lbs.) depending on options	
Infant Weight	Not published	UNK	10 kg (22 lbs.)	The patient weight is linked to the incubator. Although not previously published the predicate TI500 GT and the GT5400 are the same.
Operating temperature (normal)	10-30 deg C (50-86 deg F)	UNK	Same as TI500 GT	
Operating temperature (limited use)	10-40 deg C (50-104 deg F)	UNK	10-30 deg C (50-86 deg F)	
Storage temperature	-40 - +70 deg.C (-40 - 158 deg. F) Based on Incubator	UNK	-20-+60 deg C (-4-140 deg F)	Device packaging is marked with storage temperature requirements
Relative Humidity Operating Range	0-95% RH, non-condensing	UNK	5-95% RH, non-condensing	
Altitude Operating Range	As published in the TI500 transport incubator IFU Sea level to 3 km (10000 ft.) non-pressurized ambient; or sea level to 12 km (40,000ft.), pressurized ambient	UNK	Sea level to 3 km (10000 ft.) non-pressurized ambient	There is essentially no difference between the operating altitudes of the predicate TI500 GT and the GT5400. The additional statement "or sea level to 12 km (40,000ft.), pressurized ambient" has been removed from the GT5400 as it is understood that you can be at any altitude as long as the aircraft cabin is

Specification	Predicate	Predicate	Device Under Review	Comments
Device Name	**TI500 Globe-trotter Neonatal Transport System** **(TI500 GT or GT500)**	**Airborne Life Support Transport Incubator Aviator**	**Globe-Trotter GT5400** **(GT5400)**	
				pressurized.
Environmental				
Operating (OP)Temp Range	10° C to 30° C (50° F to 86° F) ambient (normal) 10° C to 40° C (50° F to 104° F) ambient (limited)	UNK	10° C to 30° C (50° F to 86° F) ambient (normal) 10° C to 30° C (50° F to 86° F) ambient (limited)	
OP Relative Humidity Range	0% RH to 95% RH, non-condensing	UNK	Same as predicate TI500 GT	
OP Altitude Range	Not defined	UNK	Sea level to 3km (10,000 ft.) non-pressurized ambient	GT5400 was tested to RTCA DO160 which provided the Altitude Range data.
Storage/Transport (S/T) Temp Range	Not defined	UNK	-20° C to + 60° C (-4° F to +140° F) ambient	No change to product function
Electrical				
External Power Requirements	AC 110/120V, 50/60 Hz, Six 10A breakers-<480W worst case (incubator, compressor charger, and monitor)	AC 120V 50-400Hz	AC 110/120V, 50/60 Hz, 12A max. – Power consumption varies with system configuration	The power consumption of the Incubator portion is the same for both the predicate TI500 GT and the GT5400. The GT5400 has more OEM devices along with auxiliary outlets for other user added devices. Therefore the design of the GT5400 is 12 A instead of 10 A
	AC 230V, 50/60Hz, Six 5A breakers - <400W worst case (incubator, compressor charger, and monitor)	AC 230V 50-400Hz	AC 230V, 50/60Hz, 8A max. – Power consumption varies with system configuration	
Auxiliary Power Sockets	Yes	UNK	Yes	

Specification	Predicate	Predicate	Device Under Review	Comments
Device Name	**TI500 Globe-trotter Neonatal Transport System** **(TI500 GT or GT500)**	**Airborne Life Support Transport Incubator Aviator**	**Globe-Trotter GT5400** **(GT5400)**	
Leakage Current	110/120V - 300 µA 230V - 500 µA or less	UNK	≤5 mA (normal condition) ≤10mA (single fault condition)	
Physical Specifications				Dimensions Provided are the Maximum
Published Length	129.5 cm (50.9")	UNK	≤163.9 cm (64.5")	
Published Width	56.5 cm (22.2")	UNK	≤ 57.8 cm (22.75")	
Published Height	58.4 cm(22.9")	UNK	≤58.5 cm (23 in)	
Published Weight	83.9 kg (184.9 lb.)	UNK	≤ 101.1 kg (222.9 lb.)	
Sub System Features				
Transport Incubator	Draeger Medical Systems, Inc. TI500 K001019 Incubator is sold as a stand-alone or as part of the TI500 Globetrotter Neonatal Transport System	International Biomedical Incubator as part of the Airborne Life Support Transport Incubator (Aviator) K103527 Incubator is sold as part of the system	Draeger Medical Systems, Inc. TI500 for GT5400 Modified TI500 Incubator is only sold as part of the GT5400 system	The TI500 incubator is a component of every GT5400 basic system. All GT5400s used during the verification activities included the modified TI500. Modifications for the GT5400 version of the TI500 were tested and showed no impact to the performance of the incubator.
Incubator Hood	Low or High	UNK	Same as predicate TI500GT	
Tubing Support	None Provided	UNK	Provided	Tubing support is commonly used to

Specification	Predicate	Predicate	Device Under Review	Comments
Device Name	**TI500 Globe-trotter Neonatal Transport System** **(TI500 GT or GT500)**	**Airborne Life Support Transport Incubator Aviator**	**Globe-Trotter GT5400** **(GT5400)**	
				hold tubing and wires to keep them organized within an incubator. The GT5400 provides a third party tubing support currently marketed for use in "any incubator or warming table".
Blender	Biomed Devices Blender K925982	Biomed Devices Blender K925982	Same as predicates	
Mechanical Ventilator	Biomed Devices MVP10 Pre-Amendment	Biomed Devices MVP10 Infant Transport Vent. Pre-Amendment	Same as predicates	A ventilator is a standard part of the GT5400 basic system, however the user may choose between the MVP10 and CV2i ventilator.
	N/A	Biomed Devices CV2i w/ O2 Monitor Infant Transport Vent. K942938	Same as predicate Airborne	
Auxiliary O2 Flow Control	Y	UNK	Y	
O2 Monitor	Y	Y	Y	GT5400 uses Teledyne Analytical Instruments MX300, K024155 – Like the TI500 GT predicate, an O2 Monitor is standard when

Specification	Predicate	Predicate	Device Under Review	Comments
Device Name	**TI500 Globe-trotter Neonatal Transport System** **(TI500 GT or GT500)**	**Airborne Life Support Transport Incubator Aviator**	**Globe-Trotter GT5400** **(GT5400)**	
				MVP10 Ventilator is selected The MX300 is marketed for use on neonates.
Modular Frame	Y	Y	Y	Standard as part of the GT5400 basic system
Suction	Y	Y	Y	Standard as part of the GT5400 basic system
Infusion Pump	N	B. Braun Perfusor Space Pump K092313	Same as used with predicate Airborne	Optional for GT5400 The Perfusor Space Pump is marketed for use on neonates
CO2 Monitor	N	N	Oridion Medical, Microcap Capnograph K981114	Optional for GT5400 The Microcap is marketed for use on neonates
Vital Signs Monitor	N	Welch Allyn Propaq Monitor	Welch Allyn, Propaq LT Monitor w/o Radio K033378	Optional for GT5400 The Propaq LT is marketed for use on neonates
Active Humidification	N	Y	Westmed Inc. Neopod T System (Lavabed System) K870173	Standard as part of the GT5400 basic system The Neopod T system includes the disposable breathing circuit for humidification and is marketed for use on neonates
Disposable Breathing Circuit w/out Humidification	Y	Y	Biomed Devices Breathing Circuit Pre-Amendment	Circuit provided with initial shipment of GT5400. Marketed for use on neonates
Resuscitation Bag	Y	Y	N	Resuscitation bags are purchased from resuscitation suppliers by each facility

Specification	Predicate	Predicate	Device Under Review	Comments
Device Name	**TI500 Globe-trotter Neonatal Transport System** **(TI500 GT or GT500)**	**Airborne Life Support Transport Incu-bator Aviator**	**Globe-Trotter GT5400** **(GT5400)**	
				based on their preference. These decisions and purchases are made independent of the transport system, therefore a bag is not provided with the GT5400.
Examination Light	Y	Y	Y	The exam light for the TI500 GT was incandescent. The exam light for the GT5400 is LED
Pressure Gauges	Analog	Analog	Digital	Testing showed the digital gauge to be functionally equivalent to the analog gauge
Cylinder storage	Y – Static holder with straps to secure the cylinder.	Y	Y – Movable cylinder tray with straps to secure the cylinder.	
Battery	1	1	1 or 2	1 battery is std. as part of the GT5400. A second battery is optional for the ground vehicle configuration. The 2 battery feature was included in the system configuration during verification.
Accessory deck with mounting rails	N	N	Y	Accessory deck is standard as part of the GT5400 system. It allows the user to add devices of their choosing to the system. Weight limit restriction is identified as 60 lbs. for ground transport and 30 lbs. for air transport. These configurations were tested during the system verification.

Specification	Predicate	Predicate	Device Under Review	Comments
Device Name	**TI500 Globe-trotter Neonatal Transport System (TI500 GT or GT500)**	**Airborne Life Support Transport Incubator Aviator**	**Globe-Trotter GT5400 (GT5400)**	
Chart/Cell Phone Holder	N	UNK	Y	Standard as part of the GT5400 system. This feature was included in the system configuration during verification testing.

Discussion of Non-clinical Studies:

The GT5400 was tested in accordance with applicable standards, guidance and internal design control procedures including performance testing, functional/operation testing, verification and validation, biocompatibility assessment, risk analysis and verification of risk control measures and was determined to be as safe and effective for its intended use as the predicates.

Biocompatibility:

The biocompatibility assessment shows that new materials added to the GT5400 with patient contact are currently used in products or legally marketed devices for use with neonates.

Sterilization:

Not applicable

Standards and Guidance:

Performance Standards: None

International Standards:

IEC 60601-1:2005 - Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance

IEC 60601-1-2:2007 - Medical electrical equipment, Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

IEC 60602-1-6:2010 - Medical Electrical Equipment, Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability

IEC 62366:2007 - Medical devices – Application of Usability engineering to medical devices

ISO 14971:2007 - Medical Devices - Application of Risk Management to Medical Devices

EN 1789 – Rescue Systems – Transportation of Incubators
Part 1: Interface conditions

EN 13718-1:2008 - Medical Vehicles and Their Equipment - Air Ambulances

Part 1: Requirements for Medical De-vices Used in Air Ambulances
Part 2: Operational and Technical Requirements of Air Ambulances

EN13976-1 – Rescue Systems – Transportation of Incubators
Part 1: Interface conditions
Part 2: System Requirements

RTCA DO - 160 Environmental Conditions and Test Procedures for Airborne Equipment
Section 7 (Operational Shocks and Crash Safety)

FAR 23/CAR 523 FAR 29/CAR 529 - Federal Aviation Regulations (FAR) and Canadian Air Regulations (CAR) sections FAR 23/CAR 523 and FAR 29/CAR 529

Guidance:

Neonatal and Neonatal Transport Incubators – Premarket Notifications 09/18/1998

Draft Guidance: Applying Human Factors and Usability Engineering to Optimize Medical Device Design, 06/22/2011

Conclusion Drawn from Non-Clinical Studies:

The results of the non-clinical testing, and comparison to the predicate devices show that the modified GT5400 meets the performance requirements of the standards and guidance mentioned above and is substantially equivalent to the predicate devices.