510(k) SUMMARY

K132110

Manufacturer's Name:	Natus Nicolet Ireland Limited IDA Business Park Gort, County Galway Ireland
Official Correspondent:	Michael Galvin Manager, Quality Assurance Natus Nicolet Ireland Limited IDA Business Park Gort, County Galway Ireland
Telephone Number:	+353-(0)91-647451
Fax Number:	+353-(0)91-630050
Summary Date:	July 8, 2013
Trade Names:	Natus Warmette® Blanket Cabinet Natus Warmette® Dual Cabinet
Common or Usual Name:	Warming Cabinets
Classification Name And Number:	Unclassified, Product Code: LGZ
Predicate Device:	K112702 Imperial Surgical Blanket and Solution Warming Cabinets
Device Description:	The Natus Warmette® Cabinets are made of stainless steel and are well insulated to reduce heat loss and noise. Cabinet doors are double glazed with safety glass. A pull out shelf inside the top of the cabinet contains the heating element, fan, thermostat and temperature sensor. The electronics are located on the outside top of the cabinet and the power cable is connected at the back of the electronic cabinet. Wheeled shelves and baskets run on mounted rails and automatically stop when they reach the full out position. The shelves and baskets can be removed for cleaning or repositioning.

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The Natus Warmette® Blanket Cabinet is factory-set to 130^0F (54^0C) with a temperature range of 95^0 – 176^0F (35^0 – 80^0C). For the Natus Warmette® Dual Cabinet, the blanket and linen compartment is factory-set to 130^0F (54^0C) with a temperature range of 95^0 – 176^0F (35^0 – 80^0C); while the fluid compartment is factory-set to 110^0F (43^0C) with a temperature range of 97^0 – 122^0F (36^0 – 50^0C).

Intended Use:

The Natus Warmette® Blanket Cabinet is designed to store and warm blankets and hospital linens; while the Natus Warmette® Dual Cabinet is designed to store and warm blankets and hospital linens in one compartment, and fluids (irrigation and/or injection) in the other compartment within the storage times and warming temperatures recommended by the manufacturers of those items.

Technological Characteristics:

The cabinet and its contents are warmed by circulating warm air which is heated by a warming element. The hot air is circulated by a fan and distributed evenly through the outlets. The temperature is regulated by the temperature regulator T1 to the set temperature.

Thermostat T2 functions as over temperature protection and will take over the temperature control in case the air temperature exceeds set maximum temperature by 9^0F (5^0C). At the same time the red lamp on the front panel will be lit to indicate that there is a malfunction. Inside the heating element itself, there is an additional over temperature protection that is self-resetting. It will be activated in case the fan stops or goes too slow.

Nonclinical Tests:

Tests conducted on the cabinets consist of verification of the functional controls and calibration, electrical safety, and a physical inspection of each cabinet. Each cabinet must meet the specified test requirements per a formal, written test procedure.

Substantial Equivalence:

The Natus Nicolet Warmette® Blanket and Dual Cabinets are equivalent to the devices cleared under K112702, as is presented in the following table.

Comparison Table:

	Imperial Surgical Blanket and Solution Warming Cabinets	Natus Warmette® Blanket and Dual Cabinets
Predicate 510(k) number	**K112702**	**New device**
Intended Use	Designed to store and warm blankets, hospital linens, irrigation fluids and/or injection fluids with the recommended warning temperatures and storage time guidelines provided by the manufacturers of such products.	Same
Heating System	Convection Electric heating element with circulating fan	The cabinet and its contents are warmed by circulating warm air which is heated by a warming element. The hot air is circulated by a fan and distributed evenly through outlets. The temperature is regulated by the temperature regulator T1 to the set temperature.
Unit Configuration	Single / dual	Same
Cabinet Dimensions (H x W x D) in inches	7000 & 8000 Series options: 34 x 29 x 20 34 x 29 x 26 74 x 29 x 22 74 x 29 x 28 9000 Series: 15 x 23 x 19	Warmette® Blanket and Dual Cabinets: • With adjustable feet (standard): 71.25 – 73.25 x 26 x 25 • With wheel kit (optional): 72.5 x 26 x 25
Model	Wall or Counter	Wall
Interior and Exterior Surfaces	Stainless Steel interior and exterior on table top and full size models. Counter top model made with baked on power coated steel outer shell with Stainless Steel interior.	Made of high quality stainless steel. Polyurethane foam insulation for minimal heat leakage and optimal sound insulation.
Installation	Free standing	User manual specifies that cabinet is to be secured to the wall using the built in brackets at the top of the cabinet.
Door	Stainless steel or double pane glass set in stainless steel frame on table top and full size models. Counter top model has Plexiglas mounted on to anodized aluminum door frame.	The door has double glazed safety glass.

	Imperial Surgical Blanket and Solution Warming Cabinets	Natus Warmette® Blanket and Dual Cabinets
Predicate 510(k) number	**K112702**	**New device**
Door Lock	No	Magnetic handle
Cabinet Storage Capacity	Dual compartment and full size cabinets equipped with 3 stainless steel perforated shelves. Table top model equipped with 1 stainless steel perforated shelf.	Cabinets are equipped with rails for shelves or baskets. The Natus Warmette® Blanket Cabinet can accommodate 4 shelves. The Natus Warmette® Dual Cabinet (Blanket and Fluid) can accommodate 2 shelves in the blanket compartment and 2 shelves and 1 basket in the fluid compartment.
Cabinet Volume	Single compartment shallow depth design capacity 14.6 cu ft Table top model capacity 7.5 cu ft Dual compartment capacity 18.1 cu ft overall (4.3 cu ft upper – 13.8 cu ft lower) Table top shallow design capacity 5.2 cu ft Counter top version has capacity of 2.0 cu ft (approx.).	For Natus Warmette® Blanket Cabinet: Volume = 14.66 cu ft Inside dimensions = 55 x 22 x 21 in (H x W x D) For Natus Warmette® Dual Cabinet: Each compartment (Blanket or Fluid): Volume = 5.65 cu ft Inside dimensions = 23 x 22 x 21 in (H x W x D)
Voltage Requirements	120V AC 60Hz	120V, 60Hz or 230V, 50Hz
Software	N/A	N/A
Controls	Electronic temperature controller with LED display. Illuminated power switch / breaker (red). Amber neon indicator for Element on. Red neon indicator for trouble.	Electronic temperature controller with LED display. The ON/OFF switch isolates the cabinet electronics from mains power. A red over-temperature lamp will be lit to indicate a malfunction.
Temperature Selection Range	Factory set: For Blankets: 86°F to 160°F (30° to 71°C) For Irrigation Fluids: 86°F to 150°F (30° to 66°C) For Injection Fluids: 86°F to 104°F (30° to 40°C) Must be specified at time of ordering.	Factory set: For Natus Warmette® Blanket Cabinet: 130°F (54°C); range 95° to 176°F (35° to 80°C) For Natus Warmette® Dual Cabinet: • Blanket compartment: 130°F (54°C); range 95° to 176°F (35° to 80°C) • Fluid compartment: 110°F (43°C); range 97° to 122°C (36° to 50°C)

	Imperial Surgical Blanket and Solution Warming Cabinets	Natus Warmette® Blanket and Dual Cabinets
Predicate 510(k) number	**K112702**	**New device**
Temperature resetting	Settings are factory set and locked. The device can be unlocked in the field and user can change settings if they wish to.	The user site's technician can change the factory preset temperature setting to meet the site's specific requirements. Temperature can be blocked at a fixed value.
Over-Temperature Alarm Point	Visual alarm if chamber exceeds 6°C above set temperature. Internal sensor shuts off heating elements when over temperature occurs.	A capillary thermostat ensures independent over temperature prevention. A bimetal thermostat is integrated in the heating element. Additionally, the red over-temperature lamp will be lit to indicate a malfunction.

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

October 3, 2013

Natus Nicolet Ireland Limited
C/O Mr. Michael Galvin
Manager, Quality Assurance
IDA Business Park
Gort, Country Galway
IRELAND

Re: K132110
Trade/Device Name: Natus Warmette® Blanket and Dual Cabinets
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: LGZ
Dated: July 8, 2013
Received: July 9, 2013

Dear Mr. Galvin:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132110

Device Name: Natus Warmette® Blanket and Dual Cabinets

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Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
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