K120937

JUL 6 2012

510(k) Summary

7/3/2012

Atom Medical Corporation
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Official Contact: Tsuyoshi Sugino – Regulatory Affairs Manager

Proprietary or Trade Name: Sunflower Radiant Warmer

Common/Usual Name: Infant Radiant Warmer

Classification Name/Code: Product Code: FMT, Regulation: 880.5130 Name: warmer, infant radiant

Device: Sunflower Radiant Warmer

Predicate Device: Hill-Rom Air-Shields (Draeger) - Resuscitaire Radiant Warmer K003335

Device Description:
The Sunflower Warmer is a radiant-warming open-type incubator for newborns and premature neonates. It is intended for pre-operative and post-operative intensive care in neonatal surgery, temperature control in neonatal hypothermia, observation and examination in newborn nurseries, prevention of body temperature drop shortly after delivery, etc. The Sunflower Warmer has the capability to control the infant's skin temperature as well as the CPR timer. It is provided in eight mechanical variants, the canopy (heat source) is identical in all variants.

Indications for Use:
The Sunflower Warmer is intended for thermoregulation, skin temperature monitoring, and Apgar timing of newborn infants.

Environment of Use: Hospital or institutional

Summary of Substantial Equivalence
The Sunflower Radiant Warmer was compared to the predicate Hill-Rom Air-Shields (Draeger) - Resuscitaire Radiant Warmer K003335

Indications for Use – The Sunflower Radiant Warmer is intended for thermoregulation and skin temperature monitoring of newborn infants. The sunflower Radiant Warmer has the same intended use as the Hill-Rom Air-Shields (Draeger) - Resuscitaire Radiant Warmer K003335 except it does not provide resuscitation functions.

Patient Population – The Sunflower Radiant Warmer is indicated for newborns and premature neonates as is the predicate.

Environment for use – The Sunflower Radiant Warmer has the identical environments for use as the predicate (hospital/institutional)

Prescriptive – The Sunflower Radiant Warmer is prescriptive as is the predicate.

Design and Technology – The Sunflower Radiant Warmer has equivalent design and features as the predicate and has the identical technology to the predicate with regard to radiant heating.

Performance and Specifications – The Sunflower Radiant Warmer has equivalent specifications of performance as the predicate with regard to radiant heating.

Compliance with standards – The Sunflower Radiant Warmer and predicate device declare compliance with IEC 60601-1, IEC 60601-1-2. Additionally the Sunflower Radiant Warmer complies with IEC 60601-2-21.

Device Comparison

	Sunflower Radiant Warmer	**Hill-Rom Air-Shields (Draeger)-Resuscitaire Radiant Warmer K003335**
General Attributes		
Indications for Use	The Sunflower Warmer is intended for thermoregulation, skin temperature monitoring, and Apgar timing of newborn infants.	The Resuscitaire® Radiant Warmer is intended for thermoregulation, skin temperature monitoring, Apgar timing, and resuscitation of newborn infants.
Patient Population	Newborn and Premature Neonates	Newborn Infants
Environment of Use	Hospital or institutional	Hospital or institutional
Prescriptive	Yes	Yes
Patient Connection	Yes via temperature probe	Yes via temperature probe
Technology	Electric heater	Electric heater
Technical specifications		
Dimensions	Equivalent, see Section 11 for detailed dimensions for the various configurations	Equivalent
Weight	20-89 kg depending on variant	100-127 kg depending on variant
Power	120V±10%, 60Hz, 700VA	120V, 50-60Hz, 750 W
Performance		
Heater Capacity	500W	Similar based on power consumption
Alarms	Baby Check Set temperature High Temperature Probe Short or open circuit / No probe Power failure System failure	Check patient Baby temperature High temperature Probe Short or open circuit / No probe Power failure
Set Temperature Range	34.0~38.0°C (in 0.1°C increments)	34-38° C
Skin Temperature Display	30.0~42.0°C Accuracy: ±0.3°C	18-43° C +/- 0.2° C

	Sunflower Radiant Warmer	Hill-Rom Air-Shields (Draeger)- Resuscitaire Radiant Warmer K003335
Technical specifications		
Skin Temperature sensing	Thermistor	Thermistor
Heater output setting range	0~100% (in 5% increments)	0-100%, 10% increments
Modes	Manual, Servo (automatic based on skin temperature probe)	Manual, Servo (automatic based on skin temperature probe)
Environmental		
Operating	18 to 30°C RH 30 to 75% (non-condensing)	15°C to 35°C
Storage	0°C to 50°C RH 30-75% (non-condensing)	-20°C to 55°C

Conclusion

The Atom Sunflower Warmer is substantially equivalent to the predicate Hill-Rom Air-Shields (Draeger) - Resuscitaire Radiant Warmer K003335 in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with international standards

Performance Testing

We have performed bench tests which included the list below and found that the Sunflower warmer met all pass /fail criteria, cited standards requirements and was found to be equivalent in comparison to the predicate.

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995
- IEC 60601-1-2: Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004)).
- IEC 60601-2-21: 2009 Medical Electrical Equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers
- Alarm testing
- Skin Temperature Accuracy testing
- Temperature Control Testing
- Mattress temperature Distribution Testing
- Pre-warming mode
- Testing has been performed to insure power switch does not malfunction under heat stress.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Atom Medical Corporation
C/O Mr. Paul E. Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134

JUL 6 2012

Re: K120937
Trade/Device Name: Sunflower Radiant Warmer
Regulation Number: 21 CFR 880.5130
Regulation Name: Infant Radiant Warmer
Regulatory Class: II
Product Code: FMT
Dated: June 11, 2012
Received: June 13, 2012

Dear Mr. Dryden:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K120937

Device Name: Sunflower Radiant Warmer

Indications for Use:

The Sunflower Warmer is intended for thermoregulation, skin temperature monitoring, and Apgar timing of newborn infants.

Prescription Use X (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

7/6/2012

(Division Sign-Off)
Division of Anesthesiology General Hospital
Infection Control, Dental Devices

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