K061280

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Attachment 5.0

Updated 510(k) Summary of Safety and Effectiveness

JUN 27 2006

Applicant:

Atom Medical Inc
Iwakata Bldg 3rd Floor 3-18-15, Hungo
Tokoyo, Bunkyo-ku 1130033 Japan
Registration No: In process

Contact Person:

Neoforce Group
5985 Honey Hollow Road
Doylestown, Pa. 18901

Mary Staniewicz
Ph 215-794-0495
Fax 215-794-0495

Device trade/proprietary name:

V2200 Infant Incubator

Device common/usual/classification name:

Infant Incubator

Classification:

General Hospital
21 CFR 880.5400
Infant Incubator, FMZ, Class II

Performance Standards:

None applicable

Predicate Device:

K001242 C2000 Isolette Infant Incubator
K021809 V2100G Infant Incubator

Device Description

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This product consists of a hood, a sensor module, a mattress platform, a middle deck section, a conditioning chamber, a humidity chamber, an operation control section, a power source, a relay box, an oxygen supply/filter box, an oxygen controller and a weight monitor. It is equipped with an incubator air temperature control function to circulate the air containing the heat energy generated by the heater attached to the conditioning chamber inside the hood by means of a fan in order to maintain the incubator air temperature at a fixed level. The device is also equipped with a skin temperature control function to maintain the infant's skin temperature at a fixed level in response to the patients temperature as measured by the skin probe. There is a humidity control function to adjust the amount of vapor generated in the humidity chamber. The following additional features can be installed into the incubator: an oxygen control function to draw oxygen and outside air and control the oxygen concentration delivered to the patient compartment to the desired level; and a weight monitor to facilitate taking the infants weight without moving them from the incubator. This device is designed to be used in treatment, procedures and observation of low-birth-weight and sick neonates, providing heat to the neonate when the body temperature is low and also to provide humidity if desired

Intended Use

The V2200 Infant Incubator is a device to keep premature infants or neonatal infants in a warm environment which is covered by a hood and isolated from ambient air and of which internal air temperature and humidity, are controlled. It is intended for inpatient use in maternity nurseries, and neonatal care environments of hospitals or other healthcare facilities.

Description of Modifications

The difference between the V2200 and the V2100G is the user interface display. The user interface display in the V2100G is housed in the main body of the device and is a monochrome LED display of parameters. The new user interface display is an independent component that is mounted on a moveable arm to allow more convenient positioning by the caregiver. In addition, the display is a multicolor LCD display providing a more flexible user interface.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2006

Atom Medical, Incorporated
C/O Ms. Laura Danielson
Responsible Third Party Official
TÜV Products Service
1775 Old Highway 8
New Brighton, Minnesota 55112-1891

Re: K061280
Trade/Device Name: V-2200 Infant Incubator
Regulation Number: 880.5400
Regulation Name: Neonatal Incubator
Regulatory Class: II
Product Code: FMZ
Dated: June 1, 2006
Received: June 12, 2006

Dear Ms. Danielson:

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.

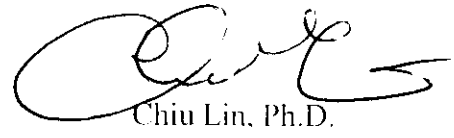
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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

510(k) Number (if known): K061280

Device Name: V-2200 Infant Incubator

Indications for Use:

The V-2200 Infant Incubator is a device to keep premature infants or neonatal infants in a warm environment which is covered by a hood and isolated from ambient air and of which internal air temperature and humidity, are controlled. It is intended for inpatient use in maternity nurseries, and neonatal care environments of hospitals or other healthcare facilities.

This device is not intended for home use.

This device is not intended as a transport incubator.

This is a prescription device.

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

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[illegible]ology, General Hospital,
[illegible]evices
[illegible] K061280