

K060461  
P.1.A2

**Section I 510(k) Summary of Safety and Effectiveness**

**Applicant:**

Atom Medical Inc  
Iwakata Bldg 3<sup>rd</sup> Floor 3-18-15, Hongo  
Tokoyo, Bunkyo-ku 1130033 Japan  
Registration No: In process

REF 000000

**Contact Person:**

Neoforce Group  
3135 Commerce Drive  
Doylestown, Pa. 18901

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

**Device trade/proprietary name:**

V-505 Infa Warmer

**Device common/usual/classification name:**

Infant Radiant Warmer

**Classification:**

General Hospital  
21 CFR 880.5130  
Infant Radiant Warmer, FMT, Class II

**Performance Standards:**

None applicable

**Predicate Device:**

K940951 Resuscitaire Infant Radiant Warmer  
K002355 V-505 Infa Warmer

**Device Description**

The Atom Infa Warmer V-505 is designed to maintain an infants body temperature by means of infrared radiant heat emitted from a heater located

above the mattress. Temperature control is achieved either by manual adjustment of the heater output or by servo control based on changes in the infant's skin temperature. All models of the V-505 may also be purchased with the following optional functions: a pulse oximeter that measures the infant's SpO2 and pulse rate, an oxygen delivery system consisting of either an oxygen blender or an oxygen flowmeter, and a suction unit. Other device features (depending on the model) include a timer, illumination lamps, an RS232 connector for communication with an external computer, a rotating/tilting canopy, a tilting mattress platform, baby guards, and support column rails for attaching an optional tray set or IV pole.

#### Intended Use

The V-505 Atom Infa Warmer is a radiant warming, open type incubator intended to provide an optimum clinical environment for observation, examination, temperature regulation, and management of neonates. Optional functions include pulse oximetry and oxygen delivery.

#### Description of Modifications

The differences between the V-505 original submission and the V-505 modifications include label clarifications and changes to overlays for English product, compliance to the current International EMI standards, minor software modifications to improve display clarity and ease of use for the US market and compliance to International particular standard for Radiant Warmers.

#### Substantial Equivalence

The Atom Infa Warmer V-505 is believed to be substantially equivalent, based on intended use, design, operational and technological characteristics, and principles of operation, to the Draeger Medical Resuscitaire Radiant Warmer and to the Atom Infa Warmer V-505 cleared in the original submission K002355. Atom Medical believes that the information provided demonstrates that the modifications to the original V-505 are precise enough to demonstrate this equivalence. The V-505 and predicate are all intended to maintain a newborn's body temperature by radiant heat and to provide a controlled environment for the observation, examination and management of newborns. The V-505 and the predicate devices all operate in both the manual and servo modes for temperature control. All devices also offer a variety of features including oxygen flowmeter and/or blender, suction control, Apgar timer, tilting mattress, tilting/rotating canopy, illumination lights, and an RS232 communications module. All devices have similar displays, alarms, and user controls.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 28 2006

Atom Medical, Incorporated  
C/O Ms. Mary Staniewicz  
Chief Financial Officer  
NeoForce Group, Incorporated  
35 Commerce Drive  
Ivyland, Pennsylvania 18974

Re: K060461

Trade/Device Name: V-505 Infa Warmer  
Regulation Number: 21 CFR 880.5130  
Regulation Name: Infant radiant warmer  
Regulatory Class: II  
Product Code: FMT  
Dated: April 7, 2006  
Received: April 10, 2006

Dear Ms. Staniewicz:

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

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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): K060461

Device Name: V-505 Atom Infa Warmer

Indications for Use:

The V-505 Atom Infa Warmer is a radiant warming, open type incubator intended to provide an optimum clinical environment for observation, examination, temperature regulation, and management of neonates. Optional functions include pulse oximetry and oxygen delivery.

This device is not intended for home use.

This is a prescription device.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony G. ...

Director, Biologics, General Hospital,  
Medical Dental Devices

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