K061071

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AUG 2 9 2006

Section I 510(k) Summary of Safety and Effectiveness

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
35 Commerce Drive
Ivyland, Pa 18974

Mary Staniewicz
Ph 215-672-6800
Fax 215-672-1123

Device trade/proprietary name:

V-808 Atom Transcapsule

Device common/usual/classification name:

Neonatal Transport Incubator

Classification:

General Hospital
21 CFR 880.5410
Infant Incubator, FPL, Class II

Anesthesiology
21 CFR 870.2700
Oximeter, DQA, Class II

Performance Standards:

None applicable

Predicate Device:

K941106 TI500 Transport Incubator
K990966 Masimo Set Pulse Oximeter

Device Description

This product consists of a hood section, a mattress platform section, a middle deck section, a conditioning chamber section, an operation section and a pedestal section. 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, an oxygen supply function to deliver oxygen into the inner hood from outside, and a function to determine and display the oxygen concentration of the enclosed compartment covered by the hood. It is further equipped with a function to measure and display the skin temperature of the neonate, as well as a pulse oximeter function to determine oxygen saturation and pulse rate non-invasively.

It is a transport incubator, wherein said functions are intended to be used in treatment, procedures and observation of low-birth-weight and sick neonates, allowing provision of heat to the neonate when the body temperature is low.

Intended Use

The V-808 Atom Transcapsule is a neonatal transport incubator. The incubator is a device with a transparent hood intended to contain a premature infant or a neonatal infant within the compartment covered by said hood and intended to safely convey the infant accommodated in that compartment, providing the infant with isolated environment from ambient air where temperature – controlled air is supplied. The V-808 also provides oxygen monitoring and supply as well as an integrated pulse oximetry capability.

Description of Modifications

The difference between the V-808 and the TI500 predicate device is the SpO2 feature. The Pulse Oximetry SpO2 is provided by Masimo and is also a currently marketed device. The V-808 combines two medical device technologies on to one platform, the neonatal transport incubator and pulse oximeter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2006

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

Re: K061071
Trade/Device Name: V-808 Atom Transcapsule
Regulation Number: 880.5410
Regulation Name: Neonatal Transport Incubator
Regulatory Class: II
Product Code: FPL
Dated: August 11, 2006
Received: August 14, 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 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

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Section A SMDA Requirements

A.1 Indication for Use Statement

510(k) Number:

Device Name: V-808 Atom Transcapsule

Indications for Use:

The V-808 Atom Transcapsule is a neonatal transport incubator. The incubator is a device with a transparent hood intended to contain a premature infant or a neonatal infant within the compartment covered by said hood and intended to safely convey the infant accommodated in that compartment, providing the infant with isolated environment from ambient air where temperature – controlled air is supplied. The V-808 also provides oxygen monitoring and supply as well as an integrated pulse oximetry capability.

This device is not intended for home use.

This is a prescription device.

...ion Sign-Off)
...sion of Anesthesiology, General Hospital,
...ction Control, Dental Devices
...) Number: K061071

Prescription Use **X** OR Over-the-Counter Use
(Per 21 CFR 801.109)

(Please do not write below this line continue on another page if needed)
Concurrence of CDRH, Office of Device Evaluation (ODE)