K092085

Section I 510(k) Summary of Safety and Effectiveness

Applicant:

NeoForce Group Inc
35 Commerce Drive
Ivyland, Pa 18974
Registration Number: 3005599562

OCT - 7 2009

Contact Person:

Monica Ferrante
VP Regulatory
Ph 215-672-6800
Fax 215-672-1123

Device trade/proprietary name:

ISPIRA Resuscitation System

Device common/usual/classification name:

Emergency Resuscitation Device

Classification:

Anesthesiology
21 CFR 868.5925
Ventilator, Emergency Power, BTL, Class II

Performance Standards:

None applicable

Predicate Device:

K892885 Fisher & Paykel, Neopuff Resuscitator
K080692 Airon Corp, MACS CPAP
K053140 Ambu, Mark IV

Device Description

The ISPIRA Resuscitation System is intended to deliver a consistent tidal volume rescue breath of oxygen or blended gas to a pediatric or adult patient. Peak Inspiratory Pressure and flow are set by the user. The device also provides a maximum pressure relief capability which is adjustable. The device is intended for emergency resuscitation and is manually operated. In addition to resuscitation the device also provides CPAP capability.

Intended Use

The NeoForce ISPIRA Resuscitation System is a manually operated, gas powered resuscitator intended for controlled and accurate pulmonary resuscitation and emergency respiratory support of pediatric and adult patients with a body weight of more than 22 lbs (10 kg.) in the hospital, pre-hospital (EMS) and sub-acute / alternate site facility environments via Face Mask, Laryngeal Mask or Endotracheal tube.

The device is also intended to provide CPAP to spontaneously breathing patients in the hospital, pre-hospital (EMS) and sub-acute / alternate site facility environments via Face Mask, Laryngeal Mask or Endotracheal tube.

Substantial Equivalence

The ISPIRA is believed to be substantially equivalent to currently marketed manual emergency resuscitation and CPAP devices with regards to intended use, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Monica Ferrante
Vice President Regulatory
NeoForce Group, Incorporated
35 Commerce Drive
Ivyland, Pennsylvania 18974

OCT - 7 2009

Re: K092085
Trade/Device Name: ISPIRA Resuscitation System
Regulation Number: 21CFR 868.5925
Regulation Name: Powdered Emergency Ventilator
Regulatory Class: II
Product Code: BTL
Dated: July 9, 2009
Received: July 9, 2009

Dear Ms. Ferrante:

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 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,

for

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

Enclosure

Indication for Use Statement

510(k) Number:

Device Name: ISPIRA Resuscitation System

Indications for Use:

The NeoForce ISPIRA Resuscitation System is a manually operated, gas powered resuscitator intended for controlled and accurate pulmonary resuscitation and emergency respiratory support of pediatric and adult patients with a body weight of more than 22 lbs (10 kg.) in the hospital, pre-hospital (EMS) and sub-acute / alternate site facility environments via face mask, laryngeal mask or endotracheal tube.

The device is also intended to provide CPAP to spontaneously breathing patients in the hospital, pre-hospital (EMS) and sub-acute / alternate site facility environments via face mask, laryngeal mask or endotracheal tube.

This is a prescription device.

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

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

L Schutter

(Optional Format 1/2/96)

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

510(k) Number: K092085