K102649

JAN 6 2011

Section I 510(k) Summary of Safety and Effectiveness

Applicant:

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

Contact Person:

Monica Ferrante
VP Regulatory
Ph 215-672-6800 x203
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Device trade/proprietary name:

NeoPIP Infant Resuscitator with Flow Meter

Device common/usual/classification name:

Emergency Resuscitation Device

Classification:

Anesthesiology
21 CFR 868.5915
Manual Emergency Ventilator, BTM, Class II

Performance Standards:

None applicable

Predicate Device:

K892885 Fisher & Paykel, Neopuff Infant Resuscitator
K072021 NeoPIP Infant Resuscitation Unit
K092085 Ispira Resusciation System

Device Description

The NeoPIP Infant Resuscitator with Flow Meter is intended to deliver oxygen or blended gas to a neonate while controlling peak inspiratory pressure. Positive end expiratory pressure is controlled at the patient end of the breathing circuit. The device also provides a maximum pressure relief capability which is

adjustable. The device is intended for emergency resuscitation and is manually operated.

Intended Use

The NeoPIP Infant Resuscitator with Flow Meter is a manually operated, gas powered device intended for controlled and accurate resuscitation of neonates and infants in the clinical environment.

Substantial Equivalence

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

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

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

Re: K102649
Trade/Device Name: NeoPIP Infant Resuscitator with Flow Meter
Regulation Number: 21 CFR 868.5915
Regulation Name: Manual Emergency Ventilator
Regulatory Class: II
Product Code: BTM
Dated: December 21, 2010
Received: December 22, 2010

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. 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,

for

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

Section A SMDA Requirements

A.1 Indication for Use Statement

510(k) Number:

Device Name: NeoPIP Infant Resuscitator with Flow Meter

Indications for Use:

The NeoPIP Infant Resuscitator with Flow Meter is a manually operated, gas powered device with integrated flow meter intended for controlled and accurate resuscitation of neonates and infants in the clinical environment.

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
(Per 21 CFR 801.109)

OR Over-the-Counter Use

L Schultz (Optional Format 1/2/96)
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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