K103833

510(k) Summary of Safety and Effectiveness

APR 20 2011

Applicant:

Neoforce Group, Inc.
35 Commerce Drive
Ivyland, Pa. 18974
Owner/Operator number: 9083179
Registration Number: 3005599562

Contact Person:

Neoforce Group, Inc.
35 Commerce Drive
Ivyland, Pa. 18974

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

NeoPIP™ Resuscitation Circuit with PEEP

Device common/usual/classification name:

Attachment, Breathing, Positive End Expiratory Pressure

Classification:

Anesthesiology
21 CFR 868.5965
Attachment, Breathing, Positive End Expiratory Pressure, BYE, Class II

Performance Standards:

None applicable

Predicate Device:

K070416 NeoPEEP Neonatal Resuscitation Circuit with PEEP

Device Description

The NeoPIP™ Resuscitation Circuit with PEEP control valve is a breathing circuit intended for use with manual resuscitation devices for emergency neonatal resuscitation.

Intended Use

The NeoPIP™ Resuscitation Circuit with PEEP is indicated as an accessory to add positive end expiratory pressure breathing capability to a T-Piece Resuscitator. The PEEP valve is incorporated into the breathing circuit T-Piece with a standard fitting for face mask, laryngeal mask or endotracheal tube. The NeoPIP Resuscitation Circuit with PEEP is indicated for use in neonatal patients < 10Kg.

Performance Data

The technological characteristics of the NeoPIP Resuscitation Circuit with PEEP are the same as the predicate device with regards to design and materials. Equivalence is also based on performance data which demonstrate that the subject NeoPIP device performs equivalently to the NeoPEEP Resuscitation Circuit with PEEP.

Substantial Equivalence

The NeoPIP™ Resuscitation Circuit with PEEP is believed to be substantially equivalent, based on intended use, design, operational and technological characteristics, and principles of operation, to the Fisher & Paykel NEOPUFF Infant Resuscitator patient circuit with PEEP and to the Marshall Products NeoPEEP NeoNatal Resuscitation Circuit with PEEP.

This summary was prepared on April 19, 2011.

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 Regulatory
Neoforce Group, Incorporated
35 Commerce Drive
Ivyland, Pennsylvania 18974

APR 20 2011

Re: K103833
Trade/Device Name: NeoPIP™ Resuscitation Circuit with PEEP
Regulation Number: 21 CFR 868.5965
Regulation Name: Positive end expiratory Pressure Breathing Attachment
Regulatory Class: II
Product Code: BYE
Dated: April 11, 2011
Received: April 11, 2011

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

Updated Indications for Use Statement

1 Indication for Use Statement

510(k) Number:

Device Name: NeoPIP™ Resuscitation Circuit with PEEP

Indications for Use:

The NeoPIP™ Resuscitation Circuit with PEEP is indicated as an accessory to add positive end expiratory pressure breathing capability to a T-Piece Resuscitator. The PEEP valve is incorporated into the breathing circuit T-Piece with a standard fitting for face mask, laryngeal mask or endotracheal tube. The NeoPIP Resuscitation Circuit with PEEP is indicated for use in neonatal patients < 10Kg.

(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)

(Optional Format 1/2/96)

)ivision Sign-Off)
'ivision of Anesthesiology, General Hospital
ıfection Control, Dental Devices

510(k) Number: K103833