K070416

Section I 510(k) Summary of Safety and Effectiveness

Applicant:

Marshall Products Ltd
13 Ferry Court, Ferry Lane
Bath, United Kingdom BA2 4JW
Owner/Operator number: 9095220
Registration No: In process

MAY 2 9 2007

Contact Person:

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

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

Device trade/proprietary name:

NeoPeep Neonatal 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:

K892885 NEOPUFF Infant Resuscitator
K981415 0-20 cm H2O PEEP Valve

Device Description

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

Intended Use

The NeoPEEP Neonatal Resuscitation Circuit with PEEP valve is indicated as an accessory to add positive end expiratory pressure breathing capability to a Manual Resuscitator. This valve is designed into the breathing circuit T-Piece with a standard fitting for face mask or endotracheal tube attachment.

Substantial Equivalence

The Marshall Products NeoPeep Neonatal 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

MAY 29 2007

Re: K070416
Trade/Device Name: NeoPEEP Neonatal 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: May 16, 2007
Received: May 21, 2007

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 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) 276-0120. 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 (240) 276-3150 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

Attachment B

Indication for Use Statement

510(k) Number: K 070416

Device Name: NeoPEEP Neonatal Resuscitation Circuit with PEEP

Indications for Use:

The NeoPEEP Neonatal Resuscitation Circuit with PEEP valve is indicated as an accessory to add positive end expiratory pressure breathing capability to a Manual Resuscitator. This valve is designed into the breathing circuit T-Piece with a standard fitting for face mask, laryngeal mask or endotracheal tube attachment.

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

(Optional Format 1/2/96)

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

510(k) Number: K070416