K102299

MAR 18 2011

510(k) SUMMARY

Submitter: Genuine First Aid LLC
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Contact/Consultant: Gary Lehnus
Lehnus & Associates Consulting
150 Cherry Lane Rd
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(570) 620-0198
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Trade Name: Genuine First Aid CPR Mask

Common Name: Emergency CPR Mask

Classification Name: Valve, Non-Rebreathing
Product Code: CBP
Classification: Class II
Panel: Anesthesiology
Regulatory Classification: 21CFR 868.5870

Predicate Device: Medisource CPR Mask with Oxygen Port - K081516

Device Description:

Genuine First Aid CPR Face Mask and oxygen port, made up of medical grade PVC and one-way valve made up of medical grade K-resin. The mask is used for mouth-to-mask breathing. There is a shield between the person who gives respiration and the victim.

Single use, CPR mask includes:
One-way filter valve
PVC mask with oxygen port
Elastic Strap
Packaged for easy portability and quick access

Specifications:

Dimensions: (122mm x 100mm x 90mm)
mask connector 22mm ID
oxygen port 6mm OD
Inspiratory resistance: <5 cmH2O (at 50 L/min)
Expiratory resistance: <5 cmH2O (at 50 L/min)

Operation Temperature: -18℃~ 40℃

Storage Temperature: -30℃ ~ 50℃

Storage relative humidity: <85%

Indications For Use:

The Genuine First Aid CPR Face (with oxygen port) is single use designed for mouth to mask ventilation to health emergency victims requiring oxygen support (inhalation) or cardiopulmonary resuscitation (CPR) rescue techniques of a non-breathing adult. It is also used as a barrier that will direct expired air from the patient away from the user. This device should only be used by persons who have received adequate training.

Substantial Equivalency Summary

Features	Medisource	Genuine First Aid CPR mask
Configuration	One piece	One piece
Use	Single	Single
Size	Adult	Adult
Material	PVC、silicone、Non-Woven	PVC、silicone、Non-Woven
Intended Use	Mouth to mask ventilation	mouth to mask ventilation
Ventilation	manual	manual
Oxygen	Oxygen port optional use	Oxygen port optional use
Oxygen port	standard 6mm nipple	standard 6mm nipple
Connector	Standard 22 mm	Standard 22 mm
Expiratory resistance	1.94 cmH2O （at 50 L/min）	3 cmH2O （at 50 L/min）
Inspiratory resistance	2.04 cmH2O （at 50 L/min）	2 cmH2O （at 50 L/min）
Includes	Universal breathing tube One-way filtered valve Head strap With or without oxygen port	Universal breathing tube One-way filtered valve Head strap With or without oxygen port

PERFORMANCE TESTING

Biocompatibility testing:

Biocompatibility test	ISO10993-1,-5,-10 requirement	Testing results
vitro cytotoxicity	required	passes
skin irritation	required	passes
delayed-type	required	passes

hypersensitivity		

Conclusion:
The potential for causing irritation is remote for the follow reasons:

- The raw material and mask have been tested beyond the requirements of ISO10993 for skin contact.
- The time of contact and percentage of body exposure is very low.
- The injection molding process does not significantly alter the raw material characteristics

Patient contact components description

Device component	Material of construction	Patient /rescuer contact	Contact time
One way valve	K-resin/silicone	mouth (rescuer)	3-60minutes
Face mask	PVC	Skin(Patient)	3-60minutes
Elastic strap	Non-woven	Hair /skin(Patient)	3-60minutes

Expiratory resistance and Inspiratory resistance performance testing was done using the test methods described in ISO10651-4:2002, Lung ventilators-Part 4:Particular requirements for operator-powered resuscitators. Some minor modifications were made to the methods

Device tested	Standard requirement	Genuine First Aid CPR mask
Expiratory resistance	<5 cmH2O （at 50 L/min）	3 cmH2O （at 50 L/min）
Inspiratory resistance	<5 cmH2O （at 50 L/min）	2 cmH2O （at 50 L/min）

Recognized consensus standards

ISO5356-1:2004	Anaesthetic and respiratory equipment-Conical connectors - Part1: Cones and sockets
ISO10651-4:2002	Lung ventilators-Part 4:Particular requirements for operator-powered resuscitators
ISO10993-1:2003	Biological Evaluation of Medical Device-Part 1: evaluation and testing

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

Genuine First Aid LLC
C/O Mr. Gary Lehnus
Lehnus & Associates Consulting
150 Cherry Lane Road
East Stroudsburg, Pennsylvania 18301

MAR 18 2011

Re: K102299
Trade/Device Name: Genuine First Aid CPR Face Mask
Regulation Number: 21 CFR 868.5870
Regulation Name: Nonbreathing Valve
Regulatory Class: II
Product Code: CBP
Dated: March 11, 2011
Received: March 16, 2011

Dear Mr. Lehnus:

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,

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

Indications for Use

510(k) Number (if known): K102299

Device Name: Genuine First Aid CPR Face Mask

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Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (OIVD)

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

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