510(K) Summary for the MedSource CPR Mask

ubmitter:

K081516

MedSource International, LLC
5346 Shoreline Drive
Mound, Minnesota 55364
952-472-0131

Contact/Consultant:

AUG 2 6 2008

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General Information

- Common or Usual Name: Emergency CPR Mask
- Proprietary Name: MedSource CPR Mask With Oxygen Port (Prescription Use)
  - MedSource CPR Mask Without Oxygen Port (Over-the-Counter Use)

- Product Code:CBP
- Panel: Anesthesiology
- Classification: Class II
- Regulatory Reference: 21 CFR §868.5870
- Single Use: Yes
- Sterile: No
- Packaging Materials: PE & PET Polymer film and medical package paper using heat as the sealing method

Indications for Use (with Oxygen Port):

The MedSource CPR Mask is designed to assist in providing immediate life support (mouth to mask ventilation) to health emergency victims requiring oxygen support (inhalation) or cardiopulmonary resuscitation (CPR) rescue techniques.

Indications for Use (without Oxygen Port):

The MedSource CPR Mask is designed to assist in providing immediate life support (mouth to mask ventilation) to health emergency victims requiring cardiopulmonary resuscitation (CPR) rescue techniques.

510(K) Summary for the MedSource CPR Mask

Device Characteristics:

The MedSource CPR Mask has the following characteristics:

A one piece, single use, full-size, light-weight PVC mask system which includes:

- A Universal breathing tube.
- A One-way filtered valve.
- A Head strap.
- With Oxygen Port or Without Oxygen Port.
- Packaged for easy portability and quick access.

Patient Contact

Device Component	Material of Construction	Patient Contact	Contact Time
CPR one-way valve	PVC/Silicon valve	Mouth	3-60 minutes
Face Mask	PVC	Skin	3-60 minutes
Strap	Non-Woven	Skin/Hair	3-60 minutes

Suggestively Equivalent Comparison Point	**Predicate Devices**	**Result of Comparison**
Intended Use	Laerdal® Pocket Mask With and without oxygen port K861401 Foremount Pocket Size Resuscitator K042727	Substantially equivalent
Technological Characteristics (Materials of Construction, Dimensions, Performance in expiratory and inspiratory resistance)	Spiracle Pocket Size Resuscitator K042727 Laerdal® Pocket Mask K861401	Materials of construction-same or similar Performance-minor variations Dimensions-minor variations
Instructions for Use	Spiracle Pocket Size Resuscitator K042727 Laerdal® Pocket Mask K861401	Very similar

Recognized Consensus Standards:

Standard	***Title***	**Status of Compliance**
ISO 5356-1:2004	*Anaesthetic and Respiratory Equipment – Conical Connectors: Part 1: Cones and Sockets.*	Used as a guide but did not do performance testing
AS 4259-1995	*Ancillary Devices for Expired Air Resuscitation.*	Used as a guide but did not do performance testing
ISO10993-1 (2nd edition-1997-12-15	*Biological Evaluation Of Medical Devices—Part 1: Evaluation and Testing*	Compliant to applicable sections

510(K) Summary for the MedSource CPR Mask

Performance Testing

Expiratory And Inspiratory Resistance Performance testing was done using the test methods described in AS-4259-1995, *Ancillary Devices for Expired Air Resuscitation. Some minor modifications were made to the e methods*

Device Tested	Inspiratory Resistance	Expiratory Resistance
MedSource CPR Mask	1.94 cm H_2O @ 50 lpm flow	2.04 cm H_2O @ 50 lpm flow
Spiracle CPR Mask	2.04 cm H_2O @ 50 lpm flow	2.14 cm H_2O @ 50 lpm flow

Discussion of Results:

1. The results in the above table demonstrate that the MedSource CPR Mask performance exceeds the performance of the predicate device.
2. For both inspiratory and expiratory resistance, the difference between the MedSource CPR mask and the Spiracle foldable mask is 5%. This demonstrates that the MedSource CPR Mask performance and the Spiracle foldable mask perform substantially the same under the same test conditions assuming there are inherent variations in the test methods... Accuracy and repeatability are not discussed in the AS 4259-1995 standard.

Biocompatibility

Raw Material Biocompatibility Testing

Biocompatibility Test	ISO 10993 Requirement	Testing results
Cytotoxicity	Required	Passes
Sensitization	Required	Passes
Irritation or Intracutaneous reactivity	Required	Passes
Pyrogen	Not required	Passes
Haemocompatibility	Not required	Passes
Systemic Toxicity	Not required	Passes

Conclusion:

The potential for causing irritation is very remote for the following reasons:

1. The raw materials have been tested beyond the requirements of ISO 10993 for skin contact.
2. The time of contact and percentage of body exposure is very low.
3. The injection molding process is not significantly alter the raw material characteristics

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MedSource International, LLC
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, Minnesota 55313

AUG 26 2008

Re: K081516
Trade/Device Name: MedSource CPR Mask with Oxygen Port / Model PM103
MedSource CPR Mask / Model PM104
Regulation Number: 21 CFR 868.5870
Regulation Name: Nonrebreathing Valve
Regulatory Class: II
Product Code: CBP
Dated: August 20, 2008
Received: August 21, 2008

Dear Mr. Job:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

Enclosures

Indications for Use

510(k) Number (if known):

Device Name: MedSource CPR Mask with Oxygen Port / Model PM103

Indications for Use:

The MedSource CPR Mask is designed to assist in providing immediate life support (mouth to mask ventilation) to health emergency victims requiring oxygen support (inhalation) or cardiopulmonary resuscitation (CPR) rescue techniques.

The CPR Mask with Oxygen Port is for prescription use.

Prescription Use ___X___ OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K081516