510(K) Summary for CPR Mask

Summary Prepared Date: 07/11/2010

Submitter:
FIRSTAR HEALTHCARE CO., LTD.
No.4-5, 2nd Industrial District, Dongshen Cun Dongchong Town,
Panyu District Guangzhou, China 511475

Submission Correspondent:
Mr. Leon Lu
Director of Regulatory Affairs
MEDevice Services, LLC
3500 South Dupont Highway
Dover, DE 19901 USA
Tel: 1-877-202-1588 Fax: 1-888-202-8884
Email: info@medeviceservices.com
www.medeviceservices.com

General Information:
Common or Usual Name: FS-104 CPR Mask
Classification Name: valve, non-rebreathing
Product Code: CBP
Panel: Anesthesiology
Classification: Class II
Regulatory Reference: 21 CFR §868.5870
Single Use: Yes
Sterile: No

Submission Purpose: New device

Predicate Device:

- K081516 MedSource CPR Mask with Oxygen Port (Prescription Use) manufactured by MEDSOURCE INTERNATIONAL, LLC
- K042727 POCKET SIZE RESUSCITATOR/MODEL: M16201R AND M16201A manufactured by FOREMOUNT ENT. CO., LTD.

Indications for Use:
The FS-104 CPR mask with oxygen port is indicated for use of mouth to mask ventilation via the ventilation mask with non-rebreathing valve for adult and child whose weight exceeds 40kg. It is for prescription use.

The FS-104 CPR mask with oxygen port is intended for single use only.

Device Description:

(1) The CPR mask with oxygen port is composed of foldable cushion mask with Oxygen Port, one- way valve, disposable filter, and elastic head trap.

(2) The CPR mask with oxygen port provides a physical barrier between the rescuer and victim, eliminating direct contact of the rescuer's lips with unknown subject.

(3) The CPR mask with oxygen port promotes an airtight seal to the face allowing ventilation through both the mouth and nose simultaneously. Proper training in ventilation and CPR should be obtained before using this device.

(4) The CPR mask with oxygen port can be functioned in such a way that no any part of device extends into the patient's oral cavity by more than 2 cm.

(5) For the device with capability of using oxygen is to sale as prescription device

Comparison to the Predicate Devices:

The FS-104 CPR mask with oxygen port is claimed with the same or similar indication for use, operation function, performance and of the predicate devices. The performance is same or similar to the predicate device.

Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence is as follows:

Compliance to applicable voluntary standards includes ISO 10993-1 for bio-compatibility as well as the specified testing standard of ISO 10993-5 and ISO 10993-10, and ASTM F920 for the performance of device.

Conclusions:

The FS-104 CPR mask with oxygen port is as safe and effective as the predicate devices. It has the same or similar intended uses, indications, technological characteristics, and principles of operation as those of the predicate devices. The minor differences between the FS-104 CPR mask with oxygen port and its predicate devices raise no new issues of safety or effectiveness. Thus, the FS-104 CPR mask with oxygen port is substantially equivalent to its predicate devices.

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

Firstar Healthcare Company, Limited
C/O Mr. Leon Lu
Director of Regulatory Affairs
MEDevice Services, LLC
3500 South Dupont Highway
Dover, Delaware 19901

JUL 22 2010

Re: K083418
Trade/Device Name: FS-104 CPR Mask
Regulation Number: 21 CFR 868.5870
Regulation Name: Nonrebreathing Valve
Regulatory Class: II
Product Code: CBP
Dated: July 11, 2010
Received: July 14, 2010

Dear Mr. Lu:

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): K083418

Submitter: FIRSTAR HEALTHCARE CO., LTD.

Device Name: FS-104 CPR Mask

Indications For Use:

The FS-104 CPR mask with oxygen port is indicated for use of mouth to mask ventilation via the ventilation mask with non-rebreathing valve for adult and child whose weight exceeds 40kg. It is for prescription use.

The FS-104 CPR mask with oxygen port is intended for single use only.

Prescription Use ___√___ 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 (ODE)

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

510(k) Number: K083418