K093081

Summary of Safety and Effectiveness

510k Summary

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter:

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FEB - 5 2010

Name and address of contact person:

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Name of the Device: Pocket BVM.

Classification name: The subject of this application is a Manual Emergency Ventilator.

Common name: Manual Emergency Ventilator.

Predicate Devices: The Pocket BVM is substantially equivalent to the Ambu SPUR II Adult Single Patient Use Resuscitator manufactured by Ambu Inc. (subject of K042682).

Indications For Use:

The Pocket BVM Resuscitator is intended for manual pulmonary resuscitation and emergency respiratory support of adult patients.

Description of the Device:

The Pocket BVM is a manual emergency ventilator device whose purpose is to manually apply positive pressure to a patient's airways to support ventilation and oxygenation. The Pocket BVM incorporates bags and valve assemblies and is intended to provide emergency respiratory support to a patient through a face mask or a tube inserted into the patient's airway.

The Pocket BVM can apply ventilation to a patient either through a mask (supplied with the device) or an artificial airway (not supplied).The Pocket BVM device maintains the functionality of existing devices and also has the advantage of small external dimensions (when packed) and light weight. It can be unpacked and made operational in seconds. The Pocket BVM complies with ISO 10651-4:2002; Particular requirements for operator powered resuscitators.

Substantial Equivalence:

The Pocket BVM is substantially equivalent to the Ambu SPUR II Adult Single Patient Use Resuscitator manufactured by Ambu Inc. (subject of K042682). The operation and technological characteristics of the Pocket BVM are identical to the predicate device's operation and technological characteristics. Both devices have the same intended use and are Emergency Manual Ventilators. Examination of

specifications and test data leads to the conclusion that the devices aresubstantial equivalence

Non-clinical testing:

The Pocket BVM has been tested and complies with all the requirements of ISO 10651-4:2002,

February 4, 2010

Date

Mr. Ron Reisman, President

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

MicroBVM Systems Limited
C/O Dr. Eli M. Orbach
General Manager
International Regulatory Consultants
POB 6718
Efrat 9435
ISRAEL

FEB - 5 2010

Re: K093081
Trade/Device Name: Pocket BVM
Regulation Number: 21 CFR 868.5915
Regulation Name: Manual Emergency Ventilator
Regulatory Class: II
Product Code: BTM
Dated: January 22, 2010
Received: January 29, 2010

Dear Dr. Orbach:

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

APPENDIX 2

Indications For Use (separate page):

510(k) Number (if known) K093081

Device Name Pocket BVM

Indications For Use:

The Pocket BVM Resuscitator is intended for manual pulmonary resuscitation and emergency respiratory support of adult patients.

U.S. Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

(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)

(Division Sign-Off) (Optional Format 1-2-96)

Division of Anesthesiology, General Hospital

Infection Control, Dental Devices

510(k) Number: K093081