K102068

NOV 16 2010

5. 510(k) Summary

SUMMARY

Submitter's name:	Resuscitation International, Inc.
Address:	35100 Bob Hope Dr. Rancho Mirage, CA 92270
Phone: Fax number:	760-778-3460 760-778-3468
Name of contact person:	Robyn Scopis Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411 Fax: 949-552-2821
Date the summary was prepared:	November 9, 2010
Name of the device: Trade or proprietary name: Common or usual name: Classification name: Classification Product Code	Miniaturize Chest Compressor (MCC) Miniaturize Chest Compressor (MCC) Mechanical Cardiopulmonary Resuscitator compressor, cardiac, external Class III DRM

The legally marketed devices to which we are claiming equivalence [807.92(a)(3)]:

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K972525	1	Thumper .	1	Michigan Instruments, Inc.

Description of the device:
The miniaturized compressor (MCC) is an automated, portable chest compressor, which provides continuous chest compressions as an adjunct to performing manual CPR. It is powered by compressed oxygen or air.

The MCC provides consistent CPR support for cardiac arrest patients under conditions, which might otherwise hinder the effectiveness of manual techniques.

Indications:

To perform Cardiopulmonary Resuscitation (CPR) on adult patients and only adult patients in cases of clinical death as defined by a lack of spontaneous breathing and pulse.

Intended Use:

To perform Cardiopulmonary Resuscitation (CPR) on adult patients and only adult patients in cases of clinical death as defined by a lack of spontaneous breathing and pulse.

Summary of the technological characteristics of our device compared to the predicate device:

The predicate and Resuscitation International Miniaturize Chest Compressor (MCC) were compared in the following areas and found to have similar technological characteristics and to be equivalent:

Physical Characteristics
Material Characteristics
Operating Characteristics
Indications for Use

Nonclinical Tests Submitted:

Bench Testing - The purpose of these tests are to evaluate the performance of the Miniaturized Chest Compressor (MCC) and to measure its effectiveness during simulated cardiopulmonary resuscitation (CPR).

Animal Testing - To evaluate the effects of three different mechanical chest compressors devices on CPR efficacy and ultimately on outcomes after prolonged cardiac arrest.

Biocompatibility - Biocompatibility testing was completed to establish the safety of all patient contact materials. Testing was done to ISO 10993 standards.

Clinical Tests Submitted:

No clinical testing was performed.

Nonclinical and Clinical Conclusions:

Nonclinical testing shows results for the MCC are within the range recommended by the CPR guidelines. Animal testing results show the MCC as effective as the predicate. Biocompatibility was successfully completed.

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

Resuscitation International, Inc.
c/o Ms. Robyn Scopis
Regulatory Consultant
7322 Avenue Sausalito
Irvine, CA 92606

NOV 16 2010

Re: K102068
Miniaturize Chest compressor (MCC)
Regulation Number: 21 CFR 870.5200
Regulation Name: Compressor, Cardiac, External
Regulatory Class: Class III (three)
Product Code: DRM
Dated: October 19, 2010
Received: October 21, 2010

Dear Ms. Scopis:

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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K102068

NOV 16 2010

Device Name: Miniaturize Chest Compressor (MCC)

Indications for Use:

To perform Cardiopulmonary Resuscitation (CPR) on adult patients and only adult patients in cases of clinical death as defined by a lack of spontaneous breathing and pulse.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices

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