K073079

510(k) SUMMARY

Michigan Instruments Inc.'s Thumper® Model 1008

FEB 14

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Michigan Instruments, Inc.
4717 Talon Court, SE
Grand Rapids, MI 49512
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Date Prepared: October 29, 2007

Name of Device and Name/Address of Sponsor

Thumper® Model 1008
Michigan Instruments, Inc.
4717 Talon Court, SE
Grand Rapids, MI 49512

Common or Usual Name

Mechanical Cardiopulmonary Resuscitation Device

Classification Name

External Cardiac Compressor, Product Code DRM, Regulation Number 870.5200

Predicate Devices

Thumper® Cardiopulmonary Resuscitator, Model 1007 (K972525)
ZOLL® AutoPulse® (K063602)

Purpose of the Special 510(k) Notice

The Thumper® Model 1008 is a modification to Thumper® Model 1007.

Intended Use

The Thumper® Model 1008 is intended to perform CPR on adult patients in cases of clinical death as defined by a lack of spontaneous breathing and pulse.

Technological Characteristics

The Thumper® Model 1008 is a pneumatically-powered, electronically controlled external cardiac compressor used on adult patients in a state of clinical death and in immediate need of respiratory and circulatory support. The Thumper® Model 1008 uses a gas-powered piston assembly with a massager pad and associated backboard to perform the function of a rescuer pressing on the patient's chest with his or her hands. A built-in ventilator that is compatible with a facemask or advanced airway replaces the rescuer's mouth-to-mouth breathing for the patient. The action of the piston and the action of the associated ventilator have been designed to perform mechanical Cardiopulmonary Resuscitation ("CPR") according to contemporary American Heart Association ("AHA") CPR guidelines for manual CPR. The Thumper® Model 1008 delivers standard AHA compliant CPR in two modes. The first is a 30:2 compression-ventilation ratio with a compression duration that is 50% of the cycle length at a rate of 100 compressions per minute. The second is a continuous compressions mode having a compression duration that is 50% of the cycle length at a rate of 100 compressions per minute with nine asynchronous breaths per minute.

Performance Data

Appropriate testing was conducted to evaluate conformance to product specifications and substantial equivalence to the predicate devices.

Substantial Equivalence

The Thumper® Model 1008 has the same intended use/indications, and similar principles of operation, and technological characteristics as the Thumper® Model 1007 and the AutoPulse. The minor technological differences in the Thumper® Model 1008 do not raise any new questions of safety or effectiveness. Performance data demonstrates that the Thumper® Model 1008 is as safe and effective as the predicate devices. Thus, the Thumper® Model 1008 is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2008

Michigan Instruments, Inc.
c/o Bruce H. Barkalow, Ph. D.
4717 Talon Court, SE
Grand Rapids, MI 49512

Re: K073079
Thumper® Model 1008
Regulation Number: 21 CFR 870.5200
Regulation Name: External cardiac compressor
Regulatory Class: Class III (three)
Product Code: DRM
Dated: October 31, 2007
Received: November 05, 2007

Dear Dr. Barkalow:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

B Zimmerman for

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K073079

Device Name: Thumper® Model 1008

Indications for Use: (same as Predicate device Thumper® Model 1007)

"This device is used 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____
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Zimmerman

Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K073079