



July 2, 1997

510(k) Summary - Thumper® Model 1007

- **Submitter -** James D. Maatman, President
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- **Trade Name -** Thumper® Model 1007

- **Common name -** Mechanical Cardiopulmonary Resuscitator

- **Classification name -** External cardiac compressor, product code 870.5200

- **Substantially equivalent devices -**
Thumper® Model 1004:
a "preamendment device."

Thumper® Model 1005:
510(k) Clearance dated May 15, 1985), reference number
K851139.

- **Description of Thumper® Model 1007**
The Thumper® Model 1007 is a pneumatically powered external cardiac compressor used on a patient in a state of clinical death and in immediate need of respiratory and circulatory support. The Thumper® Model 1007 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 to 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 CPR according to contemporary American Heart Association (AHA) CPR guidelines for manual CPR. The Thumper® Model 1007 delivers standard CPR in a 5:1 compression-ventilation ratio with a compression duration that is 50% of the cycle length at a rate of 90 compressions per minute.

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- **Intended use** - The Thumper® Model 1007 is intended for use on persons in immediate need of manual cardiopulmonary resuscitation (CPR) as described in the American Heart Association, *Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiac Care*, 1992. The Thumper® Model 1007 type of medical device is referred to in the AHA CPR Guideline as an “automatic mechanical chest compressor.” It is used as an adjunct to manual CPR for use by trained personnel to optimize compression and reduce rescuer fatigue in prolonged resuscitation efforts.
- **Technical characteristics** - The Thumper® Model 1007 is very similar and performs the same clinical function as the predicate devices, Thumper® Model 1004 and Thumper® Model 1005. The main distinguishing characteristics of the Thumper® Model 1007 are in response to Thumper® Model 1004 and Thumper® Model 1005 clinical user input and requests for product changes:
 - The Model 1007 is smaller and lighter than the predicate devices.
 - The complexity and number of the Model 1007 controls has been reduced
 - The Model 1007 controls have improved ergonomics and ease of use.
 - The built-in ventilator of the Model 1007 is of the constant flow, time-cycled operation as opposed to the previous pressure limited time-cycled operation.
 - The Model 1007 built-in ventilator delivers 100% oxygen as compared to approximately 80% delivered oxygen of the Model 1004 and Model 1005
- **Bench Test** - The Thumper® Model 1004, Thumper® Model 1005, and Thumper® Model 1007 were comparatively tested. An exemplar model of each unit was first qualified by passing its respective quality assurance test. Then, in turn, each exemplar was tested using a MII calibrated spring load. This unit (MII model T106) was designed and built based on a clinical study of human chest elastic properties during CPR. The T106 was instrumented to produce piston deflection waveforms for comparison. Simultaneously with the operation of the Thumper® piston, the associated built-in ventilators for each exemplar were used to ventilate a calibrated test lung, MII Pneu® View Model 2601i, set to lung compliance and resistance values typical of an adult CPR situation. The resultant piston compression rate (cycles/min), depth of compression (inches), compression duration duty cycle (%) demonstrate compliance with AHA standards for manual CPR. The ventilators for each exemplar demonstrated comparable ventilation of the test lung.

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- **Conclusions from Bench Tests** - The Thumper Model 1007 provides compressive piston action similar to the Thumper Model 1004 and Thumper Model 1005. The compression action of the Thumper Model 1007 at 90 compressive cycles per minute with a compression duty cycle of 50% against the T106 spring test load complies with present AHA manual CPR standards. The Thumper® Model 1007 built-in ventilator ventilated the test lung in the same manner as the Thumper® Model 1004 and Thumper® Model 1005. All three models of the Thumper® comply with 2-rescuer manual CPR ventilation by providing ventilation on a 5:1 compression to ventilation ratio. The bench tests indicate the Thumper® Model 1007 is substantially equivalent in design and performance to both the predicate devices, Thumper® Model 1004 and Thumper® Model 1005.


James D. Maatman, President
Michigan Instruments, Inc.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. James D. Maatman
President
Michigan Instruments, Inc.
4717 Talon Court, S.E.
Grand Rapids, Michigan 49512-5409

Re: K972525
Thumper® Model 1007
Regulatory Class: III (Three)
Product Code: DRM
Dated: September 25, 1997
Received: September 26, 1997

Dear Mr. James D. Maatman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. James D. Maatman

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>."

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number: K972525

Device Name: Thumper® Cardiopulmonary Resuscitator

Indications for Use:

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.

PLEASE DO NOT WRITE BELOW THIS LINE

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K 972525

Prescription Use
(Per 21 C.F.R. § 801.109)

Over-the-Counter Use