K024215

MAY 1 4 2004

Enertron Engineering Co.

Suite 200, 1033 E. Main Street, Alhambra, CA 91801, U.S.A.
Telephone: 408-253-3389 Fax: 408-351-7772

SUMMARY

- Submitter: **Jen, Ke-Min,** Official Correspondent

  ENERTRON ENGINEERING CO.

  Suite 200, 1033 E. Main Street
  Alhambra, CA 91801, U.S.A
  TEL—408-253 3389
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- Classification name: ***EXTERNAL CARDIAC COMPRESSOR***
- Classification number: ***DRM, Class III***
- *Regulation Number:* ***870.5200***
- Proprietary name: ***ENERTRON Various Models of CPR JACK***
- Common name of device: ***EXTERNAL CARDIAC COMPRESSOR***
- Predicate Device: ***THUMPER MODEL 1007, K972525***

  ELCARE GRIP, K010526

- Intended use

The device is an external device that is manually powered and is used to compress the chest periodically in the region of the heart to provide blood flow during cardiac arrest for adult patients.

- Description of the Subject Device

The ENERTRON CPR JACK is a portable cardiopulmonary resuscitation device with a patented feature of consistent and precision compression depth. It includes a frame structure and a compression mechanism. The compression mechanism has a handle connected with a connecting bar to drive a plunger. The compression mechanism keeps the plunging movements in a perpendicular direction. A depth controlling scale is included on the frame structure for presetting the compression depth of the plunger.

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Thus, CPR JACK could provide an adjustable preset compression depth. Enertron had conducted two performance tests, one of 4000 strokes and another of 250,000 strokes. These tests demonstrated that consistent compression depth ranging from 1.5" to 2.0" could be consistently maintained. ***According to a CPR laboratory study of the American Heart Association 1996, it was stated that "Consistence of chest compression or blood flow is desirable to ensure returning of live."***

The design of the ENERTRON CPR JACK adopts very few numbers of components. Therefore it is a light weight device and is made easy to carry. In addition, a rescuer can sit on the sitting bars of the frame with the weight of the rescuer offsetting the reaction force while performing compression on a patient. Therefore, a heavy platform is not necessary as it is not necessary to move the patient for more space under the CPR JACK frame structure. This saves rescue time and efforts.

The ENERTRON CPR JACK has an option to add a base board. The base board is for securing the frame structure in a moving environment such as an ambulance or a rescuing boat. Its purpose is to perform the cardiopulmonary resuscitation steadily in a moving environment.

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- COMPARISON –

ITEMS	NEW DEVICE	Predicate device 1	Predicate device 2
Model	ENERTRON	MICHIGAN INSTRUMENTS INC.	ELCARE INNOVATION INC.
Name	CPR JACK	THUMPER 1007	MODIFIED GRIP
Classification name	External cardiac compressor	External cardiac compressor	Cardiopulmonary resuscitation aids
Product code	DRM	DRM	LIX
Panel	Cardiovascular	Cardiovascular	Cardiovascular
510K NUMBER	K024215	K972525	K010526
Intended use	*The device is an external device that is manually powered and is used to compress the chest periodically in the region of the heart to provide blood flow during cardiac arrest for adult patients.*	The device is used to perform CPR on adult patients and only adult patients in cases of clinical death as defined by a lack of spontaneous breathing and pulse.	To assist a rescuer in maintaining performance during application of CPR to a victim of cardiac arrest.
Construction material	*Stainless steel* *Rubber* *Foam*	ABS Rubber plastics	ABS Plastics Foam
Depression source	*Manual*	Gas power	Manual
Oxygen input	Manual	Compressed oxygen with valve control	Manual
Restraining patient with	Frame and / or belt	2 retraining belts	none
Force Indicator	*Depth indicator*	YES	LED type
Breathing source	*Manual*	Compress oxygen	Manual
Sternal Depression depth 3.8 – 5.1 cm (1.5" – 2.0")	*0.0 – 2.0 inches*	0 - 3.15 inches	40-100 lbs
Stroke count	*Manual 100 / min*	Automatic 100 / min	Manual 80 /min
Compress / breath	*15:2*	*15:2*	*15:2*
Force applied	*40-100 pounds* *manual*	40 –100 pounds indication	40-100 lbs manual
Weight	*CPR JACK 5.1kgs* *With Board 7kgs*	20 lbs	About 8.8 kgs
Dimension (L x H x W)	*20"x 20" x 7"*	19" x22"x 9"	About 4.7"x7.8"x1.2"

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- Benchmark Tests
  - Performance tests demonstrated that user could reliably set the device and provide compressions of consistent depth for different size patients.
  - Static load and durability tests were performed to ensure the quality of the CPR JACK.

- Discussion

The intended uses for the CPR JACK and the two predicate devices are almost the same. The CPR JACK imposes no safety and effectiveness hazards and it serves the intended purposes more effectively.

Two of the predicate devices have knob force indication and the new device (CPR JACK) has a **DEPTH** indication. According to the AHA recommendation an effective CPR depends mainly on the compression depth, not on compression force. So the new device imposes no safety hazards but effectiveness.

The maximum compression depth for the new device is 2.00 inches and for the Thumper 3.15 inches. The maximum compression for Elcare Grip is 100 lbs. According to the AHA guideline, 2.00 inches should be the maximum compression depth. The CPR JACK has a limiting mechanism for restricting the depth to a maximum of 2.00 inches. Enertron had conducted two performance tests to demonstrate that the consistent compression depth ranging 1.5" to 2.0" could be maintained. These tests were a 4000-stroke test and a 250,000 stroke test. Thus the new device imposes no safety hazards and its effectiveness had been tested.

There is no force indicator for the new device. This is different from its two predicate devices. There is a knob indicator for the Thumper device and a LED force indicator for the Elcare device. It is known that an effective CPR is related to the consistency of compression depth, not to the compression force. The force indicator is not a major contributing factor for a successful CPR. Force indication may be proportional to the actual compression depth but the effectiveness of such correlation may vary from patient to patient. The new device is at least as safe as the predicate devices and is conceivably more effective than its predicates.

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The compression of the new device and Elcare Grip are performed manually. The Thumper is air powered. These differences are relevant to the compression depth consistence. The new device has depth setting mechanism and passes the depth consistence tests, with an accuracy of 99.99%. Thus the compression depth of 1.5" through 2.0" can be consistently maintained for the new device. A rescuer needs to have strength to compress for a long period of time. Assume the rescuer has enough strength to execute the CPR manually with the basic requirements for a basic CPR, the three devices are considered to be substantially equivalent.

The stroke count by Thumper is automatically performed. The Grip does that manually with an indicator. The new device does it totally manually. Since the rescuer has to pass the basic CPR training, the stroke control should be a known knowledge to CPR rescuers. Differences in stroke count by the three devices are not important as the rescuers are certified to perform the CPR.

Although the new device and the predicate devices use different constructing materials, they all passed the biological compatibility tests. They all will not cause any contacting biocompatibility hazard to patients. In this regard, they are substantially equivalent.

To restrain a patient, the new device uses the stainless frame and a restraining belt. The Thumper device uses two restraining belts, and the Grip device uses none. During the CPR process using the new device, there is has no moving hazard to the patient since there is a stainless frame and a restraining belt to restrain the patient in position. In this regard, the three devices are substantially equivalent.

Based on the above information and discussion, we certify that the subject device of Class III is to be substantially equivalent to the predicate devices in the US.

Ke-Min Jen, Official Correspondent
Enertron Engineering Company

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2004

Enerton Engineering Co.
C/O Dr. Ke-Min Jen
ROC Chinese-European Industrial Research Society
1033 E. Main Street
Alhamba, CA 91801

Re: K024215
Trade Name: CPR Jack
Dated: March 10, 2004
Received: March 12, 2004
Regulation Number: 870.5200
Regulation Name: External Cardiac Compressor
Regulatory Class: III
Product Code: DRM

Dear Dr. Ke-Min Jen:

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.

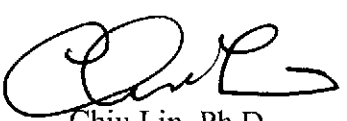
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-5613. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

Applicant : **ENERTRON ENGINEERING CO.**

510(k) Number : K024215

Device Name : **ENERTRON Various Models of CPR JACK**

Indications for Use :

The device is an external device that is manually powered and is used to compress the chest periodically in the region of the heart to provide blood flow during cardiac arrest for adult patients.

(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 _____

Per 21 CFR 801.109 (Optional Format 1-2-96)

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

510(k) Number: K024215