K053403

FEB 1 2006

V. 510(K) SUMMARY

510(k) Summary

This document provides a brief summary of the LUCAS® device and its supporting information.

1 General data

510(k) submitter

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Contact person

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Date prepared December 5, 2005

Trade name LUCAS

Common name Mechanical chest compressor

Classification name External cardiac compressor

Product code DMR

Predicate devices Thumper 1007 cleared under K972525
Autopulse model 100 cleared under K040453

2 Description of the device

LUCAS is a pneumatically powered mechanical chest compression system providing controlled automated chest compressions on adult patients who have acute circulatory arrest.

LUCAS consists of an upper part containing a pneumatically driven piston rod, which acts on the patient's chest via a pressure pad. The pressure pad is surrounded by a suction cup.

The support legs of the upper part are fastened to the back plate prior to starting compressions.

LUCAS can be powered by oxygen or air from a wall outlet in a hospital or an ambulance, or from a cylinder.

LUCAS is designed to provide:

- Consistent and uninterrupted compressions according to the guidelines given by American Heart Association (AHA);
- Good circulation during the patient transport process;
- Safety during transportation for both emergency medical personnel and patient, allowing emergency medical personnel to wear safety belts during transportation while LUCAS delivers continuous, consistent and uninterrupted compressions;
- Hands-free compressions in any situation.

LUCAS can be applied to the patient in less than 20 seconds.

3 Intended use / Indications for use

LUCAS® External Cardiac Compressor is to be used for performing external cardiac compressions on adult patients who have acute circulatory arrest defined as absence of spontaneous breathing and pulse, and loss of consciousness.
LUCAS® can be used in cases where manual chest compression would be used.
LUCAS® is only intended for temporary use.

4 Comparison to predicate devices

LUCAS, as well as the predicate devices, are able to provide chest compressions according to the guidelines given by the American Heart Associations (AHA).

LUCAS and Thumper are acting and functioning in the same way based on a pneumatically powered device equipped with a compression pad on a piston.

Autopulse provides chest compressions based on an electrical powered device where the compression pad is a part of a circumference belt.

5 Summary of substantial equivalence

The comparison in this submission demonstrates that LUCAS is substantially equivalent to the predicate products. The indications for use, basic overall function, and materials used are substantially equivalent.

6 Materials

All materials used in the manufacture of LUCAS are suitable for its purpose and are well known and proven by use.

7 Testing

Appropriate product testing was conducted and included a number of function tests during different operating conditions. These tests demonstrated that the functionality, safety and capability of the LUCAS comply with the product specifications and supports substantial equivalence to predicate devices.

In all instances, the LUCAS functioned as intended and all results observed were as expected.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 2006

Jolife AB
c/o Mr. Howard Holstein
555 Hogan & Hartson
Washington, DC 20004

Re: K053403
Jolife AB's LUCAS® External Cardiac Compressor
Regulation Number: 21 CFR 870.5200
Regulation Name: External Cardiac Compressor
Regulatory Class: Class II (Two)
Product Code: DRM
Dated: December 6, 2005
Received: December 6, 2005

Dear Mr. Holstein:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Lachman

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): -- K053403

Device Name: LUCAS®

Indications for Use:

LUCAS® External Cardiac Compressor is to be used for performing external cardiac compressions on adult patients who have acute circulatory arrest defined as absence of spontaneous breathing and pulse, and loss of consciousness.

LUCAS® can be used in cases where manual chest compression would be used.

LUCAS® is only intended for temporary use.

Prescription Use : X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use: (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)

Donna R Vachner

(Division Sign-Off)
Division of Cardiovascular Devices

510(K) Number K053403

(Posted November 13, 2003)