

K962359

510(k) Summary

(Summary of information contained in the 510(k) premarket notification)

Submitter's Name and Address: Physio-Control Corporation
11811 Willows Road Northeast
P.O. Box 97006
Redmond, WA 98073

NOV - 6 1997

Contact Person: Sherri L. Pocock
(206) 867-4332

Date Summary Prepared: June 18, 1996

Device:

Physio-Control Corporation LIFEPAK 300 automated external defibrillator
(modified)

Classification:

a) Low Energy DC-Defibrillator (including paddles) 21 CFR 870.5300;
Class II;

FDA has considered automated defibrillators to be class III devices

Substantial Equivalence:

The intended use and function of the LIFEPAK 300 defibrillator (modified) are substantially equivalent to those of the LIFEPAK 300 defibrillator 510(k) no. K925936.

The unmodified LIFEPAK 300 AED (510(k) no. K925936) will not allow the operator to deliver a shock if the device detects motion; the modified LIFEPAK 300 will allow the operator to deliver a shock in the presence of motion if a shockable rhythm is detected.

Description:

The LIFEPAK 300 is a portable external cardiac defibrillator. It can operate in either the semi-automated mode or the manual mode. A lesser trained emergency responder such as an EMT can use the device in the semi automated mode; the device analyzes the cardiac rhythm and indicates "shock advised" if it detects a shockable rhythm. If the device is

in the manual mode a person trained in cardiac rhythm interpretation, such as a paramedic, can deliver a defibrillation shock without relying on the automated analysis of the device.

Intended Use:

Emergency treatment of patients in cardiac arrest.

Technological characteristics of new and predicate devices:

The technological characteristics are the same. Only software has been modified from the original LIFEPAK 300 AED.

Summary of Performance Information:

Performance testing provided with the 510(k) includes qualification testing and software/system validation testing.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

NOV - 6 1997

Mr. Michael D. Willingham
Vice President
Quality & Regulatory Affairs
Physio-Control Corporation
11811 Willows Road Northeast
Post Office Box 97006
Redmond, Washington 98073-9706

Re: K962359
LIFEPAK® 300 Automated External Defibrillator (AED)
Regulatory Class: III (three)
Product Code: 74 MKJ
Dated: August 21, 1997
Received: August 29, 1997

Dear Mr. Willingham:

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. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under section 531 through 542 of the Act for

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devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

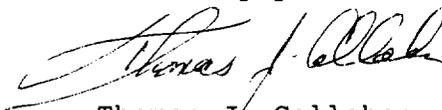
On August 16, 1993, the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has identified the above device as a device which requires tracking. Because the device is subject to tracking, you are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. The specific requirements of the regulation are found in 21 CFR 821 as described in the August 16, 1993, Federal Register beginning on page 43447.

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) 594-4659. 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>".

Please be advised that, in the future, FDA may require postmarket surveillance of this device under the authorities granted under section 522 of the Federal Food, Drug and cosmetic Act. This issue is currently under consideration by FDA and you will be notified of our decision in writing.

Sincerely yours,



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

Enclosures

510(k) Number (if known): K962359

Device Name: LIFEPAK 300 Automatic Advisory Defibrillator

Indication for Use:

For emergency treatment of patients in cardiac arrest who are unconscious and lack pulse and spontaneous breath. The device may be used for automated ECG analysis or, alternatively as a standard cardiac monitor for manual ECG assessment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)