

K983393

MAY 5 1999

510(k) Summary

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

Contact Person: Michael D. Willingham
(425) 867-4329

Date Summary Prepared: September 23, 1998

Device:

Physio-Control Corporation Biphasic LIFEPAK® 500 Automated External Defibrillator

Classification:

Low-Energy DC - Defibrillators (including Paddles): Class II (21 CFR 870.5300) (Federal Register Vol. 45, No. 25; Tuesday, February 5, 1980)

Automatic External Defibrillators have been considered Class III devices by FDA.

Substantial Equivalence:

This defibrillator is substantially equivalent to the currently marketed Physio-Control LIFEPAK 500 automated external defibrillator, 510(k) no. K955854; the LIFEPAK® 100 AED, 510(k) no. K832833; the Heartstream Forerunner AED, 510(k) no. K955628; the Laerdal Heart-Start 3000 AED, 510(k) no. K896919; and the Mine Safety and CRC Heart Aid defibrillators, both Preamendment devices.

Description:

The Biphasic LIFEPAK 500 Automated External Defibrillator (AED) is a portable battery powered device which applies a brief, high energy pulse of electricity to the heart via defibrillation electrodes on the chest. A software algorithm analyzes the patients electrocardiogram (ECG) and informs the operator whether it detects a shockable rhythm. The operator can then press the shock button to deliver energy after confirming that the patient is unconscious, pulseless and apneic.

Intended Use:

The Biphasic LIFEPAK 500 Automated External Defibrillator may be used in the hospital or pre-hospital setting by emergency responders to terminate certain potentially fatal cardiac arrhythmias.

Technological characteristics of new and predicate devices:

The features and functionality of the new LIFEPAK 500 AED are the same as those of the currently marketed LIFEPAK 500 AED with one exception: The currently marketed LIFEPAK 500 AED uses a monophasic damped sine waveform; the new LIFEPAK 500 AED uses a biphasic truncated exponential waveform.

Summary of Performance Information:

Test information demonstrates that the safety and effectiveness of the biphasic LIFEPAK 500 are substantially equivalent to those of the predicate devices:

Information on regression testing of the waveform circuit change has been provided in the 510(k).

Information provided in the 510(k) demonstrates substantial compliance with applicable sections of AAMI DF39-1993, "Automated External Defibrillators and Remote-Control Defibrillators," and AAMI DF2-1989, "Cardiac Defibrillator Devices."

The efficacy of the biphasic truncated exponential waveform was demonstrated in a multisite clinical study. The results of this and other studies provided with the 510(k) demonstrate the substantial equivalence of the biphasic truncated exponential waveform.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 5 1999

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

Re: K983393
LIFEPAK 500® Biphasic Automatic External Defibrillator
Regulatory Class: III (three)
Product Code: 74 MKJ
Dated: January 29, 1999
Received: February 4, 1999

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 legally marketed predicate 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 (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, 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 pre-market notification submission does not affect any obligation you might have under section 531 through 542 of the Act for

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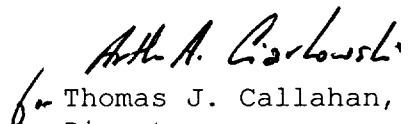
devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

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) 594-4648. 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/dsma/dsmamain.html>".

Sincerely yours,


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

Enclosures

LIFEPAK® 500 automatic external defibrillator - Indications for Use

The LIFEPAK 500 AED is to be used only on patients in cardiopulmonary arrest. The patient must be unconscious, pulseless, and not breathing spontaneously before using the defibrillator to analyze the patient's ECG rhythm. It is not intended for use on children less than eight years of age, *per AHA guidelines.*

The LIFEPAK 500 AED is intended for use by personnel who are authorized by a physician/medical director and have, at a minimum, the following skills and training:

- CPR training
- AED training equivalent to that recommended by the American heart Association
- Training in the use of the LIFEPAK 500 AED

Federal law restricts this device to sale by or on the order of a physician.

Art H. Carlisle

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

510(k) Number K983393

✓ Prescription Use

— OTC