SEP 1 4 2004

K040479

Attachment XVI
Premarket Notification [510(k)] Summary
As Required By 21 CFR 807.92

Submitted By:
Welch Allyn, Inc.
4341 State Street Road
P.O. Box 220
Skaneateles Falls, New York 13153-0220
Phone: (315) 685-3694
Fax: (315) 685-2532
Contact: Christopher A. Klaczyk, Sr. Regulatory Engineer

Trade Name: Pediatric Energy Reducer for AED 10™
Pediatric Energy Reducer for AED 20™

Proprietary Name: Same as Trade Name

Common Name: Defibrillator, Automatic, External

Product Code: 74MKJ

Classification: All products are Class III per 21 CFR 870.5310, *Defibrillator, Automatic, External*

Predicate Device: Medtronic Physio-Control Infant/Child Reduced Energy Electrodes (K022732)
Class III
Common Names: Defibrillator, Automatic, External (MKJ) and Electrode, Electrocardiograph, Multi-Function (MLN)

Description: The reusable Pediatric Energy Reducer products are small, lightweight, passive accessory devices for use with Welch Allyn automatic external defibrillators (AED). The Pediatric Energy Reducer product is inserted between the AED and suitable size non-attenuating defibrillation electrodes. The Pediatric Energy Reducer product attenuates the energy from the defibrillator by a factor of four, making the energy delivered to the electrodes suitable for use on pediatric patients. The Pediatric Energy Reducer product only affects the amplitude of the delivered waveform; the wave shape and arrhythmia detection algorithms are not affected by device use. The device consists of a resistive voltage divider circuit encapsulated in a protective plastic housing. Suitable connectors are provided to engage the Pediatric Energy Reducer to the AED and the electrodes to the Pediatric Energy Reducer.

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Intended Use: The Pediatric Energy Reducer product is intended to be used to treat patients in cardiopulmonary arrest. It should only be used on patients who are unconscious, without a pulse and not breathing spontaneously. It is intended for use in either in-hospital or out-of-hospital arrests. The Pediatric Energy Reducer is to be used only in conjunction with Automatic External Defibrillator (AED) and disposable electrode products marketed by Welch Allyn, or as formerly marketed by Medical Research Laboratories (MRL). The AED 10™ was formerly marketed as the MRL JumpStart and AED 20™ was formerly marketed as the MRL LifeQuest AEDefibrillator.

The Pediatric Energy Reducer product is intended to be used to treat infants and children up to approximately 8 years of age or 25 kg (55 lbs) weight; therapy should not be delayed to determine the child's exact age or weight.

It is intended to be used with normal (non-attenuating) adult electrodes on patients who are sufficiently large for the electrodes to be applied (in the anterior / posterior position), or with normal (non-attenuating) pediatric electrodes on smaller patients.

Comparison: The Pediatric Energy Reducer product used in conjunction with non-attenuating defibrillation electrodes provides functionality equal to that of the predicate product. The two products use the same technology to provide the attenuation function. The only difference between the subject device and the predicate is that, where the predicate device incorporates the resistive attenuation circuit as part of the disposable electrode assembly, Welch Allyn provides the attenuator as a separate accessory. This facilitates the use of less costly non-attenuating electrodes for all patients, eliminating the potential to confuse attenuating electrodes with non-attenuating electrodes as well as the need to assure sufficient stock of the two styles of electrodes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 2004

Welch Allyn, Inc.
c/o Mr. Christopher Klaczyk.
Senior Regulatory Engineer
4341 State Street Road
P.O. Box 220
Skaneateles Falls, NY 13153-0220

Re: K040479
Trade name: Pediatric Energy Reducer, Models AED-10 and AED-20
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: July 22, 2004
Received: July 23, 2004

Dear Mr. Klaczyk:

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) 594-4648. 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K040479

Device Name: Pediatric Energy Reducer

Indications For Use:

The Pediatric Energy Reducer product is intended to be used to treat patients in cardiopulmonary arrest. It should only be used on patients who are unconscious, without a pulse and not breathing spontaneously. It is intended for use in either in-hospital or out-of-hospital arrests. The Pediatric Energy Reducer is to be used only in conjunction with Automatic External Defibrillator (AED) and disposable electrode products marketed by Welch Allyn, or as formerly marketed by Medical Research Laboratories (MRL). The AED 10™ was formerly marketed as the MRL JumpStart and AED 20™ was formerly marketed as the MRL LifeQuest AEDefibrillator.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040479

Prescription Use X
(Part 21 CFR 801 Subpart D)

or

Over-The-Counter Use _____
(Part 21 CFR 807 Subpart C)