DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 5 2004

Welch Allyn, Inc.
c/o Mr. David Klementowski
Sr. Manager, Regulatory Affairs
4341 State Street Road
Skaneateles Falls, NY 13153

Re: K033642
Trade Name: Welch Allyn Medical Research Laboratories (MRL) Inc. SmartLink Wireless Monitoring System
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: February 25, 2004
Received: May 04, 2004

Dear Mr. Klementowski:

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) 594-4646. 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 may be obtained 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. for
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: SmartLink Wireless

Indications For Use: The SmartLink Wireless system's primary function is to transfer 12 lead ECG and other vital signs data from a Welch Allyn PIC50 Defibrillator/Monitor at a remote location to a personal computer station, and to display the data on the computer's monitor. The data is intended to be used by Emergency Room staff for the purpose of patient assessment prior to arrival of the patient at the Emergency Room, in order to reduce the delay in treating the patient upon arrival.

The SmartLink Wireless system can be used to:

- Provide users of Welch Allyn PIC 50 products in the field the capability of transmitting patient vitals using wireless technology to a remote location. At the remote location the information will be used for diagnostic purposes by trained medical personnel. Patient's vitals may include 12 lead data, IBP, NIBP, $ETCO_2$, Respiratory rate, Heart rate, Temperature, SPO_2, and optional single lead ECG snapshot.
- Send automatic pager notification when a new patient record is received at the personal computer station.
- Forward the patient data to any number of e-mail address at remote computers or personal digital assistants.

The SmartLink Wireless system is not intended to be used as a primary alarm source. Patient information received by the SmartLink Wireless system should not be examined for the purpose of generating alarms.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for BDT

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033642