510(k) Summary

[As described in 21 CFR 807.92]

Submitted by:

Welch Allyn Inc.
4341 State Street Road
Skaneateles Falls, NY 13153-0220

Contact Person:

John Sawyer
Vice President, QA/RA
Phone: (315) 685-4571
Fax: (315) 685-2532
E-mail: sawyerj@welchallyn.com

NOV 2 9 2007

Date Prepared:

August 24, 2007

Trade Name:

Welch Allyn CP 100™ and CP 200™ Electrocardiographs

Common Name:

Electrocardiograph

Classification Reference:

Class II, Electrocardiograph (21 CFR 870.2340, Product Code DPS) and Diagnostic Spirometer (21 CFR 868.1840, Product Code BZG)

Predicate Device:

PageWriter Trim Series Cardiograph
Philips Medical Systems
510(k) Number: K001265
Electrocardiograph, 21 CFR 870.2340
Class II, DPS

Medikro D9 Spirometer
Caird Technology Inc
510(k) Number: K031422
Diagnostic Spirometer, 21 CFR 868.1840
Class II, BZG

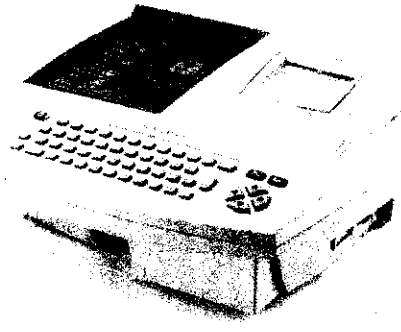
Description of the Device:

The Welch Allyn CP 100™ Electrocardiograph:
The Welch Allyn CP 100™ electrocardiograph features a full alphanumeric key board, an LCD display, full-size user-programmable reports, and the ability to operate on either battery or AC power.

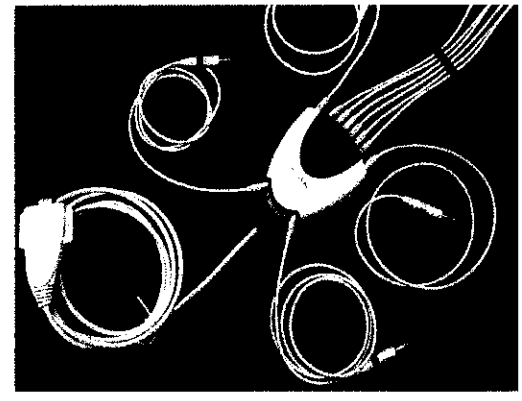
ECG tests sent to a memory card are compatible with the Welch Allyn CardioPerfect™ workstation, which in turn can connect with other electronic patient-information systems, such as billing and medical records.

The CP 100™ electrocardiograph is specifically intended for acquiring and printing ECG signals from adult and pediatric patients. It will be used in clinical settings by trained healthcare providers.

The optional interpretation algorithm analyzes these ECG signals to generate measurements and interpretive statements. The interpretive results are intended only as guidance for qualified physicians and must not be relied upon as diagnoses.



Welch Allyn CP 100™



The Welch Allyn CP 200™ Electrocardiograph:
The Welch Allyn CP 200™ electrocardiograph can display, print, save, and send ECGs electronically. It features a full alphanumeric keyboard, a color display to preview ECGs and edit settings, storage for up to 50 ECG and 50 spirometry records, full-size user programmable reports, and the ability to operate on either battery or AC power.

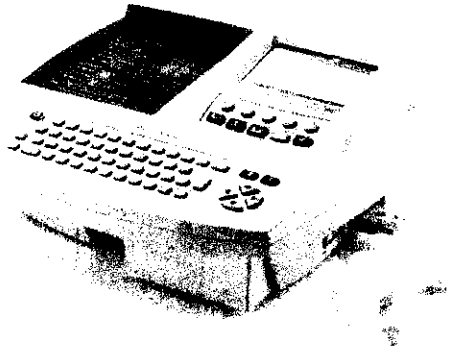
For centralized ECG data storage, the CP 200™ electrocardiograph can connect to a Welch Allyn CardioPerfect™ workstation, which in turn can connect with other electronic patient-information systems, such as billing and medical records.

The CP 200 electrocardiograph is specifically intended for acquiring, viewing, storing, and printing ECG signals from adult and pediatric patients. It will be used in clinical settings by trained health care providers.

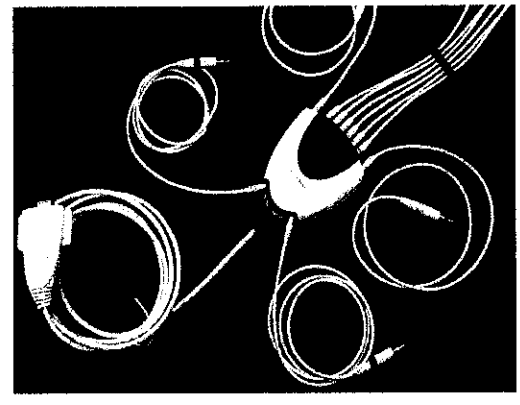
The optional interpretation algorithm analyzes these ECG signals to generate measurements and interpretive statements. The interpretive results are intended only as guidance for qualified physicians and must not be relied upon as diagnoses.

The electrocardiograph provides and optional interface to a pulmonary function device.

Communication of ECG and spirometry data with a central data-management system is optional.



Welch Allyn CP 200™



Intended Use:

The Welch Allyn Electrocardiography and Spirometry Products (Subject Devices) are intended for use by trained operators in health facilities. The subject devices provide the following diagnostic functions:

- Acquiring, viewing, storing and printing ECG waveforms using ECG Front End Modules and associated accessories that provide signal acquisition for up to twelve (12) leads of patient ECG waveforms through surface electrodes adhered to the body.
- Using optional algorithms to generate measurements, data presentations, graphical presentations and interpretative statements on an advisory basis. These are presented for review and interpretation by the clinician based upon knowledge of the patient, the result of physical examination, the ECG tracings and other clinical findings.
- Using the optional Spirometry module and associated accessories to acquire, view, store and print measures and waveforms of pulmonary function including, but not limited to, maximal volume and flow of air that can be moved in and out of the patient's lungs. These measures are used in the diagnosis and monitoring of lung diseases and interventions for the treatment of certain lung diseases. The

spirometer should only be used with patients able to understand the instructions for performing the test.

Indications for Use:

The electrocardiograph is one of the tools that clinicians use to evaluate, diagnose, and monitor patient cardiac function.

The 12-lead ECG interpretive algorithm provides a computer-generated analysis of potential patient cardiac abnormalities, which must be confirmed by a physician with other relevant clinical information.

The optional spirometry module is indicated for use in clinical situations to assess a patient's pulmonary health status and evaluate symptoms, signs, or abnormal laboratory test results.

Technological Characteristics:

The Welch Allyn Electrocardiography and Spirometry Products are intended for use by trained operators in healthcare facilities.

The 12-lead ECG interpretive algorithm provides a computer-generated analysis of potential patient cardiac abnormalities, which must be confirmed by a physician with other relevant clinical information.

The optional spirometry module is indicated for use in clinical situation to assess a patient's pulmonary health status and evaluate symptoms, signs, or abnormal laboratory test results.

The following table summarizes the similarities between the subject Welch Allyn CP 100™ and CP 200™ Electrocardiographs and the predicate Philips PageWriter Trim Series Cardiograph (K031422) and Caird Technology Medikro D9 Spirometer (K971336).

Designation	Philips Medical Systems PageWriter Trim Series Cardiograph (Trim II)	Welch Allyn Medical Systems CP Series Electrocardiographs (Model CP200)
Operating Principle	Electrocardiographs	Electrocardiographs
Display	Monochrome display	Color LCD: View and adjust the ECG waveforms. With spirometry option, also view patients' spirometry efforts and results.
Keyboard	Full alphanumeric keyboard	Full alphanumeric keypad
ECG Storage	Storage for 50 ECGs	Storage for up to 50 ECG and 50 Spirometry records

Designation	Philips Medical Systems PageWriter Trim Series Cardiograph (Trim II)	Welch Allyn Medical Systems CP Series Electrocardiographs (Model CP200)
Battery Operation	- Typically 40 ECGs on a single charge or 30 minutes of continuous rhythm recording and no fail operation during ECG printing. - Battery recharge – eight hours to full capacity.	- Use the electrocardiograph almost anywhere. On battery power, 4hours of continuous use or continuous printing of 100 ECG pages. The continuous test is based on performing 5 ECG's in a period of 4 hours. - Battery recharge – 12 hours to full capacity.
Power	The electrocardiograph can run on AC or battery power.	The electrocardiograph can run on AC or battery power.
Printer	Thermal printer (internal)	Thermal printer (internal)
Sterility	Wipe the external surfaces of the cardiograph with a soft cloth dampened in any of the approved cleaning solutions listed below: Mild soap and water Isopropyl alcohol Disinfect the patient cable. Use a damp soft cloth with one of the disinfectants or cleaning agents listed below. Cidex Ortho Phthaladehyde Cetylcide Vesphene 2 Aqueous Phenolic Germicidal Agent	Wipe the exterior of the patient cable and electrocardiograph and with a damp cloth using mild detergent diluted in water. Disinfect the patient cable. Use a damp cloth of chemical disinfectants containing one of the following: ethanol (70% - 80%) propanol (70% - 80%) aldehydes (2% - 4%)
Safety	Testing to applicable standards: • AAMI EC11 • IEC 60601-1 • UL 2601.1 • IEC 60601-2-25 • IEC 60601-1-2	Recognized and applicable standards: • EC11 (AAMI/ANSI) • UL 60601-1 • IEC 60601-1 • IEC 60601-1-1 • IEC 60601-1-2 • IEC 60601-1-4 • IEC 60601-2-25 • IEC 60601-2-51
Weight	16.3 lb	11.6 lb
Dimensions	15.3 x 12.2 x 6.9 in	16.2 x 15.6 x 6.2 in
Filters	➢ AC noise ➢ Artifact ➢ High and low pass	➢ 0.5 Hz high-performance baseline filter ➢ 35 Hz muscle-tremor filter ➢ AC interference filter
ECG Acquisition	ECG signal acquisition of up to 12 leads	ECG signal acquisition of up to 12 leads
Network Connection	10 Base-T Ethernet LAN card	Wireless
Fax	Support for PCMCIA fax modem	None
Modem	V.90, K56flex	None
Spirometry	None	Support for Spirometry (K971336 – Medikro D9 Spirometer)
Indication for Use	Where the clinician decides to evaluate the electrocardiogram of adult and pediatric patients as part of decisions regarding possible diagnosis, potential treatment, effectiveness of treatment or to rule-out causes for symptoms.	The electrocardiograph is one of the tools that clinicians use to evaluate, diagnose, and monitor patient cardiac function. The 12-lead ECG interpretive algorithm provides a computer-generated analysis of potential patient cardiac abnormalities, which must be confirmed by a physician with other relevant clinical information. The optional spirometry module is indicated for use in clinical situations to assess a patient's pulmonary health status and evaluated symptoms, signs, or abnormal laboratory test results.

Designation	Philips Medical Systems PageWriter Trim Series Cardiograph (Trim II)	Welch Allyn Medical Systems CP Series Electrocardiographs (Model CP200)
Target Population	Adult and pediatric patients.	- Resting ECG: Adult and pediatric patients. - Resting ECG Interpretation: Adult and pediatric patients. - Spirometry: Adult and pediatric patients.
Where Used	Healthcare facilities	Healthcare facilities

Subject Area	Caird Technology Inc. Medikro D9 Spirometer	Welch Allyn Medical Systems CP Series Electrocardiographs (CP200) Spirometer
510 (k) Number	K971336	OEM Device (Medikro D9 Spirometer – K971336)
Target Population	Adult and pediatric patients.	Spirometry: Adult and pediatric patients.
Where Used	Hospital and Clinic use only	Healthcare facilities
Indication for Use	Some of the conditions for use are as follows: • Shortness of Breath • Chronic Cough • Occupational Exposure to Dust or Chemicals • Assist in the Diagnosis of Bronchitis • Assist in the Diagnosis of Asthma • Wheezing • Assist in the monitoring of Bronodialators	The optional spirometry module is indicated for use in clinical situations to assess a patient's pulmonary health status and evaluate symptoms, signs, or abnormal laboratory test results.

The Welch Allyn CP 100™ and CP 200™ Series electrocardiograph/spirometry has equivalent electrocardiograph characteristics as the Philips PageWriter Trim Series and Medikro D9 Spirometer.

The technological differences do not affect the safety or effectiveness of the device.

Summary of Effectiveness:

The Welch Allyn CP Series team has determined that the software "Level of Concern" is Moderate. (See section 10 for CP 100™ & CP 200™ software Level of Concern)

The implementation of the MEANS interpretive software in the CP 100™ and CP 200™ electrocardiographs device, and its performance, is equivalent in every respect to the implementation of this software in the CardioPerfect™ with MEANS device submitted to the agency by Cardio Control BV (= Welch Allyn acquired Cardio Control BV) and cleared per K962854. Both of these product families have implemented the 1996 version of the MEANS algorithms. The Department of Medical Informatics of Erasmus University Rotterdam independently validated the MEANS algorithms in 1996. A copy

of the specificity and sensitivity from that study, as presented for the Welch Allyn CardioPerfect™ with MEANS submission K962854.

The MEANS algorithms were verified and found to be consistent with the requirements of IEC 60601-2-51:2003, particular requirements for safety, including essential performance, of recording and analyzing single channel and multi-channel electrocardiographs.

All requirements of the recognized and applicable standards are in compliance: EC11 (AAMI/ANSI), UL 60601-1, IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-25 and IEC 60601-2-51.

As a point of clarification, only the CP 200™ product will include spirometry functionality. The CP 200™ uses the same flow transducer, signal-conditioning electronics and tubing as the Medikro D9 Spirometer (K971336); all of the components external to the personal computer of the Medikro D9. The CP 200™ makes use of its embedded computer in place of the personal computer used in the Medikro D9. Because the user interface, display and embedded computer differ from that of the Medikro D9, the CP 200™ requires custom software to provide the functionality of the Spiro2000 software provided with the Medikro D9.

The spirometry functionality of the CP 200™, including the custom software, was validated by Robert O. Crapo, M.D., Medical Director of the pulmonary Laboratory at LDS Hospital in Salt Lake City, Utah. He performed testing using the standard "Standardization of Spirometry: 1994 Update and 2005 version" published by the Americal Thoracic Society (ATS). The test report issued by Dr. Crapo's laboratory – LDS Hospital, dated March 2, 2007, the CP 200™ device meets all stated accuracy and precision requirements defined in the ATS standard.

Additionally, risk management (risk, SFMEA and safety analysis) activities have been conducted in accordance with ISO 14971 Medical Devices – Application of risk management to medical devices and comply with IEC 60601-1-4 Medical Electrical Equipment Part 1: General Requirements for Safety, Part 4: Programmable Electrical Medical Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 9 2007

Welch Allyn, Inc.
c/o Mr. John Sawyer
Vice President, QA/RA
4341 State Street Road
Skaneateles Falls, NY 13153-0220

Re: K072449
Welch Allyn CP 100™ and CP 200™ Electrocardiographs
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS and BZG
Dated: October 22, 2007
Received: October 24, 2007

Dear Mr. Sawyer:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

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

Enclosure

K072449

Indications for Use Statement

510(k) Number (if known): K072449

Device Name: Welch Allyn CP 100™ and CP 200™ Electrocardiographs

Indications for Use:

The electrocardiograph is one of the tools that clinicians use to evaluate, diagnose, and monitor patient cardiac function.

The 12-lead ECG interpretive algorithm provides a computer-generated analysis of potential patient cardiac abnormalities, which must be confirmed by a physician with other relevant clinical information.

The optional Spirometry module is indicated for use in clinical situations to assess a patient's pulmonary health status and evaluate symptoms, signs, or abnormal laboratory test results.

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

(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 K072449