JUL 1 1 2014

K141582

510(k) Summary

[As described in 21 CFR 807.92]

Submitted by: Welch Allyn Inc.

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Director Regulatory Affairs

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Date Prepared: June 11, 2014

Trade Name: Welch Allyn CP150™ Electrocardiograph with Spirometry Option

901049 Electrocardiograph

Common Name: Electrocardiograph and Diagnostic Spirometer

Classification Reference: Class II, Electrocardiograph (21 CFR 870.2340, Product Code DPS)

Class II, Diagnostic Spirometer (21 CFR 870.1840, Product Code BZG)

Predicate Device: Welch Allyn CP150™ Electrocardiograph

510(k) Number: K131573

Electrocardiograph, 21 CFR 870.2340

Class II, DPS

Description of the Device:

The Welch Allyn CP150™ Electrocardiograph with Spirometry Option is an electrocardiograph used to process the electrical signal transmitted through two or more electrocardiograph electrodes and to produce a visual display of the electrical signal produced by the heart and it provides an optional interface to a pulmonary function device that allows the user to acquire, view, store, and print measures and waveforms of pulmonary function. Its features include a 7" color touch screen display for ECG and Spirometry preview and user-friendly interface, full-size user-programmable reports, and the ability to operate on either battery or AC power.

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

The CP150™ Electrocardiograph with Spirometry is able to connect via USB cable or via wired ethernet (RJ45 connector) across the ethernet network, which in turn can connect with other electronic patient-information systems, such as billing and medical records. The USB port can also be used to connect other accessory devices.

The CP150™ Electrocardiograph is specifically intended for acquiring and printing ECG signals from adults 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.

The CP 150™ spirometry option allows the user 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 a 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 who are 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 measure patient cardiac function.

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

The Spirometer is a device that measures lung air volume and airflow rate for pulmonary disease diagnosis and screening. These measurements provide information about a patient's pulmonary function which may be compared with normal values or the patient's previous values. The device is designed to test pulmonary function and obtain spirometric indices for

- adult and pediatric patients 12 years and older,
- hospital and clinic use only.

Contraindications (specific to Spirometry)

Relative contraindications to performing spirometry:

- hemoptysis of unknown origin (forced expiratory maneuver may aggravate the underlying condition)
- pneumothorax

- unstable cardiovascular status (forced expiratory maneuver may worsen angina or cause changes in blood pressure) or recent myocardial infarction or pulmonary embolus
- thoracic, abdominal, or cerebral aneurysms (danger of rupture due to increased thoracic pressure)
- presence of an acute disease process that might interfere with test performance (e.g., nausea, vomiting)
- recent eye (for example, cataract), thoracic and abdominal surgery
- chest and abdominal pain

The electrocardiograph has no known contraindications.

Technological Characteristics:

The subject device has the same technological characteristics and indications for use as the predicate. The hardware, software, and mechanical aspects of the CP150 have been updated to current technology equivalent to the cleared devices (CP150™ Electrocardiographs, K131573, S.E. dated July 3, 2013 and Medikro Spirometer, K133428, S.E. dated May 21, 2014) as described below. Modifications were made to the CP150 in order to provide an interface to receive, convert, and display measurements from the optional Medikro Spirometer. The modifications include:

- Hardware Interface
  - Creation of connectors between Medikro Spirometer and CP150 Spiro
- Software Interface
  - Software changes to receive flow data
  - Software changes to enable conversion of flow data to parameter measurements (e.g., FVC, FEV1, PEF, etc.)
  - Software changes to allow user setting the spirometer configurations and conduct the spirometry tests.
  - Software changes to display the parameter measurements of spirometry test
  - Software changes to allow for printing and saving spirometry tests

Non-Clinical Tests:

The Welch Allyn CP150™ Electrocardiograph with Spirometry Option was tested to evaluate its safety and effectiveness based on the following standards:

Standard	Version	Title
ISO 14971	2007/2007	Medical Devices – Application of Risk Management to Medical Devices
IEC 60601-1	3rd Edition 2005	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1-2	2007	Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
IEC 62304	2006	Medical Device Software - Software Life Cycle Processes
IEC 60601-2-25	2nd Edition 2011-10	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
ANSI/AAMI EC11	1991 (R2007)	Diagnostic electrocardiographic devices
ATS/ERS	2005	ATS/ERS Task Force Standardisation of Lung Function Testing: Standardisation of spirometry

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 11, 2014

Welch Allyn
c/o Mr. Kevin Crossen
Director, Regulatory Affairs
4341 State Street Road
P.O. Box 220
Skaneateles Falls, New York 13153

Re: K141582
Trade/Device Name: Welch Allyn CP150 Electrocardiograph with Spirometry Option
Regulation Number: 21 CFR 870.2340 and 21 CFR 870.1840
Regulation Name: Electrocardiograph And Diagnostic Spirometer
Regulatory Class: Class II
Product Code: DPS and BZG
Dated: June 11, 2014
Received: June 13, 2014

Dear Mr. Crossen:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

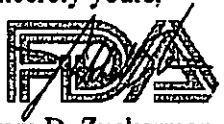
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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

Enclosure

K141582

Indications for Use

510(k) Number (if known): K141582

Device Name: Welch Allyn CP150™ Electrocardiograph with Spirometry Option

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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)

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