11. Premarket Notification [510(k)] Summary

Submitted By: Welch Allyn, Inc.
4341 State Street Road
P.O. Box 220
Skaneateles Falls, NY 13153-0220

Phone: 315 685 3694
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Contact: Christopher Klaczyk,
Regulatory Affairs Manager

Common Name: Medical Device Software for interpretive and stress testing electrocardiographs, and diagnostic spirometry

Trade Name: Welch Allyn CardioPerfect Workstation software (with)

CardioPerfect Workstation Resting ECG Module
CardioPerfect Workstation ST ECG Module
CardioPerfect Workstation SpiroPerfect Module
CardioPerfect Workstation ABP Module

Classification:
LOS: None
DSI: 21 CFR 870.1025
DXN: 21 CFR 870.1130
BZG: 21 CFR 868.1840

Predicate Device: ECG-resting, CardioPerfect with Means, K962854
ECG-stress, CardioPerfect ST, K935732
Caird Technology Spirometer, K971336

Description: CardioPerfect Workstation software is used to create a computer platform on which ECG, ABP, & Spirometry applications can operate within inherent capabilities of an off-the-shelf desktop or laptop personal computer utilizing a Windows or DOS based operating system.

Indications for use:

CardioPerfect Workstation Software Version 1.5.0 and Accessories Product

The CardioPerfect Workstation software and associated accessories are indicated for the acquisition, analysis, formatting, display, printing and storage of certain physiologic signals, as identified below, for the purpose of assisting the clinician in the diagnosis and monitoring of various diseases and/or treatment regimens. The CardioPerfect Workstation software also provides non-diagnostic functions such as patient management, data security, search tools for patient and/or test records and support for exporting data to Electronic Medical Record systems.

The CardioPerfect Workstation and associated accessories are intended for use by or on the order of a physician in a hospital or clinic setting. The product is designed for use on both adult and pediatric patients, subject to any specific contraindications identified below.

Electrocardiograph – Stress

Using the optional ECG module and associated accessories the user can acquire, view, store and print ECG waveforms. Indications for electrocardiography range from routine screening of cardiac health in the physician office environment to directed diagnostic differentiation in a hospital cardiology department.

Electrocardiograph – Resting

The same as defined for stress ECG plus the ability to use optional algorithms (MEANS) to generate measurements, data presentations, graphical presentations and interpretive statements on an advisory basis for patients sixteen (16) years of age and above. These are presented for review and interpretation by the clinician.

Ambulatory Blood Pressure

Using the optional ABP module and associated accessories the user can acquire, retrieve, view, store and print patient ambulatory blood pressure history. Indications for ambulatory blood pressure measurement (as listed in Journal of Hypertension 2003, 21:821-848, E. O'Brien et. al.) include, but are not limited to, the following:

- suspected "white coat" hypertension
- Suspected nocturnal hypertension
- To establish dipper status
- Resistant hypertension
- Elderly patient
- To monitor antihypertensive drug treatment
- Type 1 diabetes
- Hypertension of pregnancy
- Evaluations of hypotension
- Autonomic failure
- Masked hypertension

Spirometry

Using the optional spirometry module and associated accessories to acquire, view, store and print measures and waveforms of pulmonary function. Normal values and comparative results are not calculated for children under the age of six. Indications for spirometry include, but are not limited to, the following:

- 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 bronchodilator

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2005

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

Re: K052158
Trade Name: CardioPerfect Workstation Software
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II (two)
Product Code: BZG
Dated: August 5, 2005
Received: August 9, 2005

Dear Mr. Klaczyk:

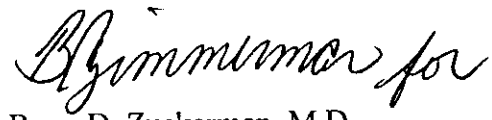
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-0295. 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.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

10. Statement of Indications For Use

510(k) Number: K052158

Device Name: CardioPerfect Workstation, Software Version 1.5.0 and Accessories Product.

CardioPerfect Workstation Software Version 1.5.0 and Accessories Product

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- Shortness of breath
- Chronic cough
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- Assist in the diagnosis of Bronchitis
- Assist in the diagnosis of Asthma
- Wheezing
- Assist in the monitoring of bronchodilator

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 k052158