JUN 2 7 2002

V. 510(k) Summary

[As described in CFR 807.92]

Submitted by:	Welch Allyn Inc. 4341 State Street Road Skaneateles Falls, NY 13153
Contact Person:	David Klementowski Corporate Regulatory Affairs Manager
Date Prepared:	20 May 2002
Proprietary Name:	Welch Allyn ABPM 6100
Common Name:	Ambulatory Blood Pressure Monitor
Classification Name:	Class II 870.1110 Blood Pressure Computer
Predicate Devices:	Pressure Trak System Model 222-B SunTech Medical Instruments 510(k) Document Control Number *K010622* Welch Allyn Ambulatory Blood Pressure Monitor Welch Allyn, Inc. 510(k) Document Control Number *K925899*

Description of the Device:

The Welch Allyn ABPM 6100 is a microprocessor based ambulatory blood pressure monitor that uses an oscillometric step deflation technique to determine blood pressure. An internal electric pump is used to inflate the cuff and two valves control deflation. During cuff deflation, small cuff pressure changes (resulting from arterial blood pressure pulses) are analyzed by the microprocessor, in order to determine the blood pressure. The Welch Allyn ABPM 6100 has the ability to make blood pressure determinations at predetermined intervals (normally from a schedule determined by the physician), or on demand (by using the stop/start key). Each reading is stored in memory, allowing the physician to download all the results obtained during the study period after the study has concluded to be analyzed by PC software. The readings can be displayed on the LCD or the LCD can be disabled to prevent the patient from seeing the readings (see attachment I for photographs of the device).

Intended Use

The Welch Allyn ABPM 6100 is a non-invasive oscillometric ambulatory blood pressure monitor that is to be used with ABPM 6100 Software, a PC based computer program. The ABPM 6100 is capable of recording and displaying up to 250 measurements of systolic and diastolic blood pressure and heart rate. It is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure adult or pediatric patients systolic and diastolic blood pressures over an extended period of time. The system is only for measurement, recording, and display. It makes no diagnosis.

Action Taken to Comply with Section 514 of the Act

The agency has recognized the following standards:

a) EN60601-1
b) EN60601-1-1
c) EN60601-1-2
d) EN60601-2-30
e) AAMI SP10

The Welch Allyn ABPM 6100 meets the requirements called out in these standards. Evidence of compliance is on file at Welch Allyn and is available for review upon demand.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 7 2002

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

Re: K021756
Trade Name: Welch Allyn ABPM 6100
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: June 18, 2002
Received: June 19, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021756

III. Indications for Use Statement

510(k) Number: Unknown

Device Name: Welch Allyn ABPM 6100

Indications for use: The Welch Allyn ABPM 6100 is a non-invasive oscillometric ambulatory blood pressure monitor that is to be used with ABPM 6100 Software, a PC based computer program. The ABPM 6100 is capable of recording and displaying up to 250 measurements of systolic and diastolic blood pressure and heart rate. It is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure adult or pediatric patients systolic and diastolic blood pressures over an extended period of time. The system is only for measurement, recording, and display. It makes no diagnosis.

* - See next page for contraindications for use.

(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
and Respiratory Devices

510(k) Number K021756

Prescription Use X Or Over-The-Counter Use _____

(Per 21 CFR 801.109)