

**"510(k) SUMMARY"**  
**Summary of Safety and Effectiveness**

Submitter's Name & Address: Welch Allyn Inc.  
 4341 State Street Road  
 Skaneateles Falls, New York 13153

Contact Person & Telephone: Zoran I. Psenicnik  
 (315) 685-4400

Date Summary Prepared: Friday, November 06, 1998

Device Name: Classification Name - Monitor, Cardiac (including cardiometer and rate alarm)  
 Common/Usual Name - Vital Signs Monitor  
 Proprietary Name - Atlas Vital Signs Monitor

Predicate Device: Welch Allyn Inc., Clinical Vital Signs Monitor model 52STP-E1 (ref. 510(k) #K951193), BCI International Inc., Capnocheck Plus model 9004 (ref. 510(k) #K970209, and the Datascope Corp., Passport Monitor Model XG (ref. 510(k) #K911598).

Device Description, Intended Use & Effectiveness:

The Atlas Monitor (including model numbers 200, 210, and 220) is a multi-parameter device used to monitor human physiological vital signs. It combines a CRT to display ECG and CO<sub>2</sub> waveforms and LED's for other numeric values. An optional printer is available on models 200 and 210 and it comes standard for 220 model.

The indications for use for the Atlas Monitor, include the monitoring of the following human physiological vital signs:

- Blood Oxygenation** (SpO<sub>2</sub>) measurement
- ECG** waveform derived from 3 or 5 Lead measurement
- Respiration** rate/waveform derived from ECG or CO<sub>2</sub>
- Temperature** measurement via YSI 400 series probes
- Non Invasive Blood Pressure** (NIBP) measurement
- CO<sub>2</sub>**, Endtidal sidestream/waveform
- Heart Rate** derived from selected source (ECG, SpO<sub>2</sub>)

The target populations are adult and pediatric populations. The monitor is intended for use within the healthcare facility setting.

**Technological Characteristics:**

See attachment "III" for a comparison of the Atlas Monitor to the predicate devices.

**Safety:**

The system conforms to the following general safety standards:

EN60601.1	Medical Electrical Equipment, Part 1: General requirements for Safety, Amendment 1 (1991), Amendment 2 (1995)
EN60601.1.2	Medical Electrical Equipment, Part 1: General requirements for safety 2: Electromagnetic Compatibility - Requirements and tests
CE Mark	Conforms with provisions of European Council Directive 93/42/EEC concerning medical devices

The system also conforms to the following specific safety standards:

EN60601.2.27	Medical Electronic Equipment, Part 2: Particular Requirements for Safety - Specifications for Safety of Electrocardiographic Monitoring Equipment
EN60601.2.30	Medical Electronic Equipment, Part 2: Particular Requirements for Safety - Specifications for Safety of Automatic Cycling Indirect BP Monitoring Equipment

**Summary of Effectiveness:**

The design of this device utilizes currently available technology found in many legally marketed devices. Completed design reviews and scheduled testing ensured that the Atlas Monitor performs within the environment(s) for which it is to be marketed. The safety testing is compliant with the indicated standards. The software design and development (including verification and validation testing) was performed using FDA's Reviewers guidance of Medical Device Software Submissions, May 29 1998 and internal company requirements. On the basis of these results and the above referenced testing it is our determination that the device is safe, effective and performs within its design parameters as well as the legally marketed predicate devices. Welch Allyn Inc. will not market this device if it does not completely meet its design intent and safety functions.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL -8 1999

Mr. Zoran Psenicnik  
WelchAllyn, Inc.  
4341 State Street Road  
Skaneateles Falls, NY 13153

Re: K984033  
Atlas Monitor  
Regulatory Class: II (two)  
Product Code: DRT  
Dated: April 12, 1999  
Received: April 14, 1999

Dear Mr. Psenicnik:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): \_\_\_\_\_

Device Name: Welch Allyn Atlas Monitor

**Indications For Use:**

The indications for use for the Atlas Monitor, model numbers 200, 210, and 220, include the monitoring of the following human physiological vital signs:

- Blood Oxygenation** (SpO<sub>2</sub>) measurement
- ECG** waveform derived from 3 or 5 Lead measurement
- Respiration** rate/waveform derived from ECG or CO<sub>2</sub>
- Temperature** measurement via YSI 400 series probes
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- Heart Rate** derived from selected source (ECG, SpO<sub>2</sub>)

The target populations are adult and pediatric populations. The monitor is intended for use within the healthcare facility setting.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
for PBT 7/2/09  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K984033

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)