SEP 26 2002

K022084

510(k) Summary of Safety and Effectiveness

May 28, 2002

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

Telephone: (315) 685-4602
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Contact: Shawn Earle, Senior Quality Engineer

Device Name:

Trade Name: Atlas Monitor
Common Name: Vital Signs Monitor
Classification Name: Cardiac Monitor (including cardiotachometer and rate alarm)

Predicate Device:

The predicate device for the Atlas Monitor is the Atlas Monitor cleared for market under 510(k) submission K984033, except for the improved SpO_2 channel. The predicate device for the improved SpO_2 channel in the Atlas Monitor is the Nellcor model N-395 pulse oximeter cleared for market under 510(k) submissions K991823 and K993637.

Device Description:

The Atlas Monitor is a multi-parameter device used to monitor human physiological vital signs. It combines a CRT to display ECG and CO_2 waveforms and LED's for other numeric values. There are (3) different models available.

FEATURES	MODEL 200	MODEL 210		MODEL 220	
ECG	Yes	Yes		Yes	
SpO_2 Nellcor MP506	Yes	Yes	No	Yes	No
SpO_2 Nonin	No	No	Yes	No	Yes
NIBP	Yes	Yes		Yes	
Temperature	No	Yes		Yes	
Impedance Respiration	No	Yes		Only if $ETCO_2$ is not running	
$ETCO_2$	No	No		Yes	
Printer	Option	Option		Standard	
Battery Backup	Not Available	Standard		Standard	
RS423 I/O	Not Available	Standard		Standard	

The ECG front end will meet all applicable AAMI and harmonized EU standards (see safety reference section for particular standards). The Atlas Monitor will provide a 5 wire front end and will be compatible with both a 3 wire and 5 wire cable. Diagnostic (0.05Hz to 100Hz) and monitor (0.5Hz to 40Hz) bandwidth will be provided. The corresponding ECG waveform is displayed on the CRT. User can select which lead the monitor is displaying. If optional printer is installed that waveform can be printed.

The SpO_2 value is obtained by the measurement of the red and infrared light absorbed by the patient's tissue. A probe, consisting of a detector and emitter, is placed on a patient at a point where profusion of a body part is close to the skin surface, like a hand digit. The changes in absorption are used to determine oxygen saturation and heart rate. The pulse signal graph LED bar indicates the relative strength of the pulses detected by the SpO_2 module. The control board requires a single voltage input and generates all the necessary internal voltages. Communication to the Atlas Main board is via an internal serial communication interface. The SpO_2 capability in Atlas is obtained by the utilization of OEM modules.

The OEM SpO_2 modules are manufactured by:

OEM P/N: MMONX75	Nonin Medical, Inc. 2605 Fernbrook Lane North Plymouth, MN 55447-4755
OEM P/N: MP205	Nellcor Puritan Bennett, Inc. 4280 Hacienda Drive Pleasanton, CA 94588-2719

The NIBP portion of the Atlas monitor utilizes the oscillometric method of blood pressure determination. In this method, the patient's arm is compressed and blood flow occluded through the use of a cuff and bladder combination. Each time the patient's heartbeats, a slight variation of pressure occurs in the cuff. The cuff pressure is decreased in a step fashion. The device measures and catalogs the pressure pulses at each step in cuff pressure. The patient's systolic and diastolic pressures are determined through the examination of these pulses.

The temperature portion of the Atlas monitor uses well established precision YSI 400 probes to monitor surface temperature of a patient. The YSI probes work on the principle of interchangeable thermistors (NTC Type) that exhibits a steep drop in resistance as temperature changes, providing high sensitivity to temperature changes. Welch Allyn, Inc. does not manufacture probes but it does recommend use of YSI 400 probes manufactured by:

YSI Inc
1700/1725 Brannum Lane
PO Box 279
Yellow Springs, OH 45387

The impedance respiration feature utilizes the ECG lead set and patient surface ECG electrodes, together with additional electronics processing. The respiration rate in breaths/minute is displayed in numerical format on the CRT.

The end tidal CO_2 ($ETCO_2$) measurement is performed by utilizing an OEM PCB from:

Pryon Corporation
N93 W14575 Whittaker Way
Menomonee Falls, WI 53051

The Pryon side stream CO_2 control board (LC101) is designed to acquire CO_2 data utilizing an on board pump to aspirate a patient gas sample. Employing a proprietary side stream sensor, the C-cap bench, Patient waveform is obtained. The sensor is based on single beam single frequency and dual thermopile detector. The control board requires a single voltage input and generates all the necessary internal voltages. The control board outputs the CO_2 waveform and performs all calculations for CO_2 data and respiration rate. Communication to the Atlas main board is via an internal serial communication interface.

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_2) measurement
- ECG waveform derived from 3 or 5 lead measurement
- Respiration rate/waveform derived from ECG or CO_2
- Temperature measurement via YSI 400 series probes
- Non-Invasive Blood Pressure (NIBP) measurement
- CO_2 End-Tidal sidestream/waveform
- Heart Rate derived from selected source (ECG, SpO_2)

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

Technological Comparison to the Predicate Device:

The Atlas Monitor is the same as the Atlas Monitor cleared for market under 510(k) submission K984033. The improved SpO_2 channel in the Atlas Monitor is a replacement for the SpO_2 channel currently in the Atlas Monitor. Nellcor Puritan Bennett manufactures the SpO_2 channel currently in the Atlas Monitor. The improved SpO_2 channel is substantially equivalent to the SpO_2 channel in the Nellcor model N-395 pulse oximeter. The Nellcor model N-395 was cleared for market under 510(k) submissions K991823 and K993637.

Summary of Performance Testing:

The Atlas Monitor and associated accessories have been tested and found to comply with the recognized national and international performance, safety and electromagnetic compatibility standards for medical devices and product specifications listed in the Atlas labeling.

A risk analysis, identifying potential hazards and documenting mitigation of the hazards, has been developed and verified/validated as part of Welch Allyn, Inc. product development procedures. Welch Allyn, Inc. Quality System conforms to 21 CFR 820 and is certified to ISO 9001 and EN46001.

Conclusions:

As stated above, Welch Allyn, Inc. conclusion is that the Atlas Monitor is safe, effective, comply with the appropriate medical device standards and equivalent to the Atlas Monitor currently on the market.

This 510(k) Summary of Safety and Effectiveness may be copied and submitted to interested parties as required by 21 CFR 807.92

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2002

Mr. Shawn Earle
Senior Quality Engineer
Welch Allyn, Incorporated
4341 State Road Street
Skaneateles, New York 13153

Re: K022084
Trade/Device Name: Atlas Monitor, Models 200, 210, 220
Regulation Number: 870. 2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: August 29, 2002
Received: September 3, 2002

Dear Mr. Earle:

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,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

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

Telephone: (315) 685-4602
Fax: (315) 685-4091

501(k) Number: K022084

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K022084