K024005

FEB 1 2 2003

Section 1 – Revised 510(k) Summary

[As described in CFR 807.92]

Submitter's Name & Address

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B. Other Contact Persons

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C. Device Name

Proprietary Name: Welch Allyn Vital Signs Monitor
Common Name: Vital Signs Measurement Device
Classification Name: Noninvasive Blood Pressure Measurement System

D. Device Classification

Class II (CFR21 870.1130 Noninvasive Blood Pressure Measurement System).

E. Predicate Device

Welch Allyn Vital Signs Monitor
Welch Allyn, Inc.
510(K) Document Control Number K951193

F. Description of the Device

The Welch Allyn Vital Signs Monitor is designed to non-invasively and automaticallymeasure systolic and diastolic blood pressure, pulse rate, temperature and oxygen saturation (SpO2) for adult and pediatric patients. **THE**

WELCH ALLYN VITAL SIGNS MONITOR IS NOT INTENDED TO BE USED ON NEONATAL PATIENTS. All blood pressure, pulse, temperature and SpO2 values are displayed on large, easy-to-read displays, and may be printed via an integrated thermal printer, as desired.

The rechargeable battery and wide variety of mounting accessories make the Welch Allyn Vital Signs Monitor convenient for many locations. The operator may choose any combination of simultaneous measurement modalities. This flexibility, combined with features such as programmable alarms and automatic blood pressure cycles, makes the Welch Allyn Vital Signs Monitor ideal for a wide variety of patient monitoring needs.

The Welch Allyn Vital Signs Monitor is intended for use in a wide variety of health care settings. This includes hospital departments, as well as patient transport within the hospital environment. The Welch Allyn Vital Signs Monitor is also intended for use in alternate care settings, such as physician offices, freestanding ambulatory care and surgery centers, health clinics and nursing homes. The Welch Allyn Vital Signs Monitor may also be used during patient transport within any of these alternate care environments.

The Welch Allyn Vital Signs Monitor is not intended for the monitoring of patients during transport external to the health care environment (eg. ambulance, helicopter transport). The Welch Allyn Vital Signs Monitor is not intended for use in environments, which are not supervised by a health care practitioner.

H. Intended Use

The Welch Allyn Vital Signs Monitor is intended for monitoring of blood pressure, pulse rate, temperature and oxygen saturation (SpO_2) of adult and pediatric patients. The device is not designed, sold or intended for use except as indicated.

The Welch Allyn Spot Check Device is not designed for use with neonates. To ensure pediatric blood pressure accuracy and safety, note that the Welch Allyn Small Child cuffs are the smallest cuffs approved for use with young children and infants. The circumference of the child's arm must fit within the range markings on the cuff.

The Welch Allyn Spot Check Device should not be used on patients who are linked to heart/lung machines.

I. Technological Similarities and Differences

The Welch Allyn Vital Signs Monitor and the Welch Allyn Vital Signs Monitor with MP506 Pulse Oximeter OEM Module are essentially the same device. Welch Allyn has added the new SpO2 module from Nellcor (The MP506 (same as in the N-595 Pulse Oximeter mad ey Nellcor)) to the Vital Signs Monitor. This is an upgraded SpO2 module that was cleared by the FDA 510(k) K012891. The Vital

Signs Monitor was cleared by the FDA 510(k) K002530.

In regards to the change in the SpO2 module for to the Vital Signs Monitor, the basic fundamental technology is the same. A sensor is placed on the finger, toe, ear lobe, or forehead and a microprocessor interprets the amount of red and infra-red light that is passing through the tissue and calculates Specific Oxygen (SpO2) of the blood.

J. Testing for Equivalence

Equivalence to the legally market predicate device was determine through the means of verification and validation testing. The following testing was conducted on the VSM with MP506:

Verification: 3 test were conducted on the VSM 506

1) Software system level functional tests
2) Pre-scan IEC60601-1-2 testing at a third party test house
3) Nellcor compliance testing (whereby Nellcor tested our VSM with their MP506 to their standards).

The full protocols were tested on the VSM with MP506 and these tested were used to show that Welch Allyn implemented correctly the new MP506 SpO2 module.

Validation: 4 test were conducted on the VSM with MP506

1) Software system level functional tests
2) Accuracy test
3) Usage test
4) Basic functional tests

The full protocols were tested on the VSM with MP506 and these tests were used to show that the Welch Allyn VSM meet the customer requirements.

K. 510(k) Summary Conclusions

Based on the following, it is our conclusion that the new Welch Allyn Vital Signs Monitor with MP506 Pulse Oximeter OEM module is substantially equivalent to the Welch Allyn Vital Signs Monitor.

- The features and intended use has not changed
- The Vital Signs Monitor with MP506 Pulse Oximeter OEM module has passed all the safety and effectiveness testing.
- The fundamental technology of the Welch Allyn Vital Signs Monitor with MP506 Pulse Oximeter OEM module has not changed from that of the Welch Allyn Vital Signs Monitor cleared under K951193.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 2 2003

Mr. David Klementowski
Corporate Regulatory Affairs Manager
Welch Allyn, Incorporated
4341 State Street Road
Skaneatels Falls, New York 13153

Re: K024005
Trade/Device Name: Welch Allyn Vital Signs Monitor
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQN, DQA
Dated: January 29, 2003
Received: January 30, 2003

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), please contact the Office of Compliance at (301) 594-4646. 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 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,

Susan Runner

Susan Runner, DDS, MA
Interim 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 Statement.

510(k) Number: Unknown

Device Name: Welch Allyn Vital Signs Monitor

Indications for use: The Welch Allyn Vital Signs Monitor is intended for monitoring of blood pressure, pulse rate, temperature and oxygen saturation (SpO_2) of adult and pediatric patients. The device is not designed, sold or intended for use except as indicated.

**** The Welch Allyn Vital Signs Monitor is not designed for use with neonates.*** To ensure pediatric blood pressure accuracy and safety, note that the Welch Allyn Small Child cuffs are the smallest cuffs approved for use with young children and infants. The circumference of the child's arm must fit within the range markings on the cuff.

** The Welch Allyn Vital Signs Monitor should not be used on patients who are linked to heart/lung machines.*

(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: K024005