510(k) Summary

[per 21 CFR 807.92]

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Trade Name: Model: ProBP™ 2000,
Welch Allyn 901123 Digital Blood Pressure Device

Common Name: Blood pressure device

Classification Name: System, Measurement, Blood pressure, Noninvasive
(Class II, Cardiovascular, 21 CFR 870.1130, Product Code: DXN)

Predicate Device: Transtek Blood Pressure Monitor, TMB-1591-A
510(k) Number: K161886
(Class II, Cardiovascular, 870.1130, DXN)

Description of the Subject Device:

The device is designed to measure the systolic and diastolic blood pressure and heartbeat rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the arm.

This device is designed for professional use, in other words, it is a professional BP device that only for trained users such as nurses, clinicians, and medically qualified personnel.

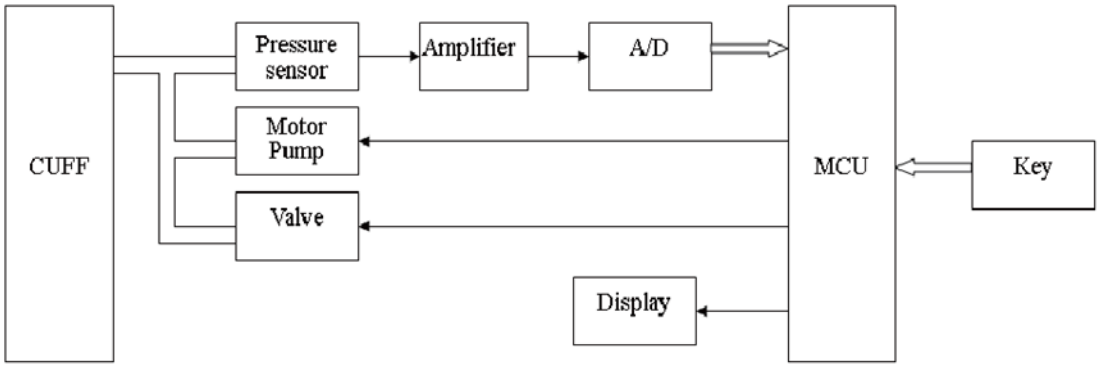
The measurement method for determining the systolic and diastolic pressure is similar with the ausculatory method but uses an electronic pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating heartbeat rate. This well-known technique for measuring blood pressure is called the “Oscillometric method”.

The device includes the main unit and cuff unit. The main unit consists of the microprocessor, the pressure sensor, the operation key, the pump, the electromagnetic deflation control valve and the LCD. ABS is the plastic used in the outer housing. The device comes with one standard Reusable-11 Welch Allyn FlexiPort cuff. Other size cuffs can be ordered as needed for arm circumferences ranging from 15cm to 55cm. This device is equipped with the same wireless radio (Bluetooth) as supplied with the predicate device cleared in K161886, TMB-1591-A.

The subject device does not incorporate any software to support the BT wirelessly transmit function. In other word, ProBP 2000 has BT module but disabled the Bluetooth functionality. And Welch Allyn does not provide an application to receive data utilizing BT.

The subject device does not have any externally-facing electronic interfaces.

The device's block diagram



Refer to above chart, the operational processes as following,

* The patient prepared according to the device's guidance. The user (trained operator, such as nurse) places the CUFF wrapped on the proper position of the patient's upper arm.
* The user presses the Key to power the device for measuring.
* The MCU sends a signal to activate Motor Pump to inflate the CUFF.
* During the inflation, the Pressure sensor measures the pulse waveform of the pressure change.
* The waveform is amplified by the Amplifier for subsequent processing.
* The analog signal of waveform is converted into a digital signal through the A/D (Analog/Digital) module.
* The MCU analyzes and calculates the digital signal by a specific algorithm and outputs the value of blood pressure and pulse rate.
* After the measurement is completed, the Motor Pump is controlled by MCU to stop inflating. And a signal from MCU is sent to the Valve to deflate the CUFF.
* The device stores the measurement data in the ROM, and directly shows the Systolic/Diastolic blood pressure (Arabic numerals + mmHg) & Pulse rate (Arabic numerals + Pul/min) on the LCD Display, available for user to read and record.
* The device is powered by either four AA alkaline batteries or an optional AC to DC power supply. These options are identical to the predicate device TMB-1591-A (K161886).

Principle and Measurement Algorithm of the Device:

The subject device uses the Oscillometric Measuring method to detect blood pressure. The device detects blood pressure measurement on the inflation. Before every measurement, the unit establishes a "zero pressure" equivalent to the air pressure. Then it starts inflating the cuff with the inflation rate 7mmHg/s, meanwhile, the device detects pressure oscillations generated by beat-to-beat pulsatile. Then the measurement finishes, and the device starts deflating. Deflation occurs in step intervals based on the cuff pressure. The deflation step range is about 6-12 mmHg. Higher cuff pressure corresponds to the larger pressure deflation step.

The oscillometric algorithm in the device measures pulse heights at various cuff pressures throughout the cycle. Those pulse heights are used to build a patient specific pulse envelope as taught by standard oscillometric technique. That pulse envelope is used to calculate systolic and diastolic blood pressure.

The algorithm in the device detect erroneous readings by checking for inconsistencies in the data measured. This can be strange shapes to the pulse profile, large changes in rate of inflation, and wide variances in pulse heights and rates. If one of those conditions is detected, the device switches to the deflation algorithm. The deflation algorithm uses comparisons between multiple pulses to filter out erroneous pulses caused by motion. It also ensures that the pulse profile is of a reasonable shape.

The signal is picked up by the transducer then converted to a digital value via the Analog-to-Digital converter. The digital value is fed into the MCU and MCU will calculate the blood pressure and heart rate measurement values according to built-in algorithms.

The values calculated by the algorithm are displayed to the user on the correct section of the screen for the values. Digits are displayed on individual 7 segment areas specifically designed to display digits. The areas where the readings are displayed are labeled as to which reading is being displayed in those segments.

The accuracy of the device's algorithm has been validated through bench testing including testing to the blood pressure standard, IEC 80601-2-30. The device was also clinically tested and met the accuracy requirements of ISO 81060-2.

Indications for Use:

The Welch Allyn ProBP 2000 Digital blood pressure device is intended for use in measuring blood pressure and heart rate in patients at least 3 years of age or older with arm circumferences between 15 cm to 55 cm (approximately 5.9 to 21.7 inches).

The Welch Allyn ProBP 2000 automatically measures systolic and diastolic pressure and pulse rate. The device is intended to be used by clinicians and medically qualified personnel.

Contraindications:

This device is not intended for use on neonates, infants, or children under the age of 3 years. The effectiveness of this device has not been established in pregnant, including pre-eclamptic, patients.

Technological Characteristics:

The subject device is modified based on the predicate device. Model 2000 essentially the same device and has the same technical characteristics as the marketed devices cleared in K161886. They use the same oscillometric blood pressure algorithm. The form factor and device material are the same.

The differences between the subject device and predicate device are as following.

1) The proposed device is for use by clinically trained professionals (Rx), rather than by patients for self-monitoring (OTC) as stated in the cleared device indications;
2) The subject device is intended for patients at least 3 years of age or older with arm circumferences between 15 cm to 55 cm (approximately 5.9 to 21.7 inches), while the predicate device is intended for use in adult patient populations with arm circumferences between 15 cm to 54 cm (approximately 6 to 21 inches);
3) The subject device BP hose is not detachable from the device. The cuff connection is Welch Allyn FlexiPort design which is inherently compliant to IEC 80369-5 because the inner-fluid pathway of the FlexiPort connector is greater than 8.5 mm. Model 2000 is exempt from the requirements of IEC 80369-1:2010 – small-bore connectors for liquids and gasses in healthcare applications because there are no connectors accessible to the user in normal use with a diameter less than 8.5mm.
4) The subject device modified the range of arm circumferences from 15~54cm to 15~55cm;
5) The proposed device uses Welch Allyn FlexiPort Blood Pressure Cuffs (K070060);

6) Differs from the predicate device, ProBP 2000 device does not have wirelessly transmission functionality.
7) The subject device is not contraindicated for "…any person who is connected to a wearable or implantable electronic device or instrument, such as a pacemaker or defibrillator." We have no evidence to support this patient demographic should be contraindicated. We performed a literature review and found no evidence that any person who is connected to a wearable or implantable electronic device or instrument, such as a pacemaker or defibrillator should be contraindicated. We did however add a note in the directions for use stating the device has not been evaluated for this demographic. "Note This device has not been evaluated for any person who is connected to a wearable or implantable electronic device or instrument, such as a pacemaker or defibrillator."

Performance Tests

We conducted design verification and design validation activities to demonstrate that these proposed devices met all design specifications as are Substantially Equivalent to the predicate device.

The results show that the subject devices conform to the following standards:

Biocompatibility Testing

The Welch Allyn FlexiPort Blood Pressure Cuffs used with these devices were tested for biocompatibility in compliance to ISO 10993-1 and cleared in 510(k) (K070060).

Software Verification and Validation Testing

The software of proposed devices was verified and validated in compliance to IEC 62304 Edition 1.1 2015-06. Medical Device Software - Software life cycle processes.

Clinical Validation

This device was tested to ISO 81060-2 Second edition 2013-05-01 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type.

The study population consisted of 88 qualified healthy subjects ranging in age of 3~12 years (35 pediatric) & 12~75 years (53 adults / adolescents), and gender of 39 males & 49 females, of any racial / ethnic background. All data's mean error and standard deviation of differences for systolic, diastolic pressure is not over the limits of ISO 81060-2:2013, and the accuracy of subject device is better than predicate device. No adverse effect and/or complication is found in this study.

Non-Clinical Tests

These devices were tested / assessed to evaluate its safety and effectiveness based on below standards:

Standard	***Version***	***Title***
IEC 60601-1	3ED 2005, AMD 1 2012	Medical electrical equipment - Part 1: general requirements for basic safety and essential performance
IEC 60601-1-2	4 ED 2014	Medical electrical equipment - Part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests
IEC 80601-2-30	1.1 ED 2013	Medical electrical equipment - Part 2-30: particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN/ISO 14971	2007	Medical devices - Application of risk management to medical devices

IEC 60601-1-6	2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62366	2014	Medical devices - Application of usability engineering to medical devices

Device Comparison:

The subject device is very similar to the predicate device (K161886). They have the identical technology principle, blood pressure algorithm, energy source; and have the same appearance and mechanical architecture. Also, they have very similar intended use, performance specifications, software and functions.

The subject device's clinical use is modified to professional use that different from the home use of the predicate device. The indications for use and contraindications for the subject devices have been modified to be suitable for a trained clinician, and to match the target patient populations, at least 3 years of age or older. This subject device is set-up to use Welch Allyn FlexiPort BP Cuffs (K070060) for arm circumferences from 15~54 to 15~55 cm. Correspondingly, the hose connection fitting (FlexiPort) was designed to be applied for these Cuffs.

The subject device ProBP 2000 does not provide wireless transmission functionality.

For above mentioned modifications / differences, we implemented as much as required performance tests, validations, evaluation, to ensure subject device is safe and effective. These bench tests' results proved that the subject device met all requirements of statutory standards. The clinical validation shows the subject device complied with the specific standard, and the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.

In addition, the predicate device's contraindication of "This device is contraindicated for any person who is connected to a wearable or implantable electronic device or instrument" was added when the parent predicate device embedded wireless module. At that time we did not find any evidence of risk to those persons who are connected to wearable or implantable electronic device or instrument. We added this contraindication only because of precautionary motive. From our experiences, industry practices, and those market wireless devices' 510(k) records, still no risk be found, and this (similar) contraindication is not required. Thus, we remove it in this submission and added a note in the DFU, Directions For Use, indicating that "This device has not been evaluated for any person who is connected to a wearable or implantable electronic device or instrument, such as a pacemaker or defibrillator."

Conclusion:

Based on the information presented in this 510(k) premarket notification submission, the subject device is considered substantially equivalent. This subject device is as safe and effective as the currently marketed predicate device TMB-1591-A (K161886). The differences between the indications for use and contraindications, hardware, and mechanical aspects of the proposed device and the predicate device were successfully tested with the relevant standards and FDA guidance, and do not affect equivalent safety and effectiveness or raise new questions of safety or effectiveness.