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510(k) SUMMARY

Citizen Watch Company, Ltd.
CH-502A and CH-502B
Digital Finger Sphygmomanometers

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Name of Device and Name/Address of Sponsor

CH-502A and CH-502B Digital Finger Sphygmomanometers

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Classification Name

Noninvasive blood pressure measuring system.
21 C.F.R. § 870.1130.

Predicate Devices

(1) Omron HEM-815F Digital Finger Sphygmomanometer (K894563)

Intended Use

The Citizen CH-502A and CH-502B finger sphygmomanometers are intended to be used for the oscillometric measurement of systolic and diastolic blood pressure and pulse.

Technological Characteristics and Substantial Equivalence

The Citizen devices are auto-inflate digital readout finger sphygmomanometers. The only difference between the CH-502A and the CH-502B is that the CH-502B has a memory function which displays the last blood pressure readout when the system is turned on. Both the Citizen Sphygmomanometers and the Omron predicate device measure the diastolic and systolic blood pressure from the index finger using oscillometric methods. Both systems are microcomputer controlled, digital, auto-inflate, finger sphygmomanometers.

Like the Omron predicate, the Citizen sphygmomanometers display systolic and diastolic pressure ranges between 0 and 280 mm Hg. Both devices have a blood pressure measurement accuracy of the greater of ± 3mm Hg or ± 2% of the reading. The pulse measurement range of the Citizen devices and the Omron predicate are also the same, from 40 to 200 pulses/minute. The accuracy of the pulse measurements for both the Citizen sphygmomanometers and the Omron predicate device are ± 5% of the measured pulse frequency.

Both the Citizen and the Omron devices utilize a finger cuff system for blood pressure measurement. The Citizen and Omron devices are designed to measure blood pressure and pulse from the left index finger. The finger cuff for both systems is designed to accommodate fingers with a circumference of between 2 inches to 3 inches. The finger cuff on the Citizen device and the predicate device are both adjusted by an adjustment slide. Inflation of the finger cuff for the Citizen devices and the Omron predicate are accomplished with an electrical pump and pressure is released during deflation by an automatic air-release valve.

The Citizen devices, like the Omron predicate, have a "POWER" switch, a "START" switch, and an LCD display. Both the Citizen and the Omron devices have an automatic power off feature if the device is not used for three minutes. The operating environment for the Citizen sphygmomanometers and the Omron predicate are also the same: 50 °F to 100 °F and 30% to 85% relative humidity. The overall dimensions of the Citizen devices and the Omron predicate are also substantially equivalent. The Citizen devices measure 150 mm X 94.5 mm X 34 mm; the Omron device measures 146 mm X 87 mm X 43 mm.

Although the Citizen devices use four "AAA" size batteries, the Omron predicate device uses 2 "AA" batteries. Additionally, the CH-502B has a memory function which displays the last blood pressure and pulse reading when the device is turned on. The Omron predicate does not have this feature. These minor differences in the technological principles of the Citizen devices and the predicate device do not raise any new questions of safety or effectiveness.

Device Description

The Citizen CH-502A and CH-502B finger sphygmomanometers are small hand-held noninvasive blood pressure measurement systems that measure systolic and diastolic blood pressure and pulse from the user's index finger. The units are contained in a hard plastic housing that contains a user interface panel and a finger cuff size adjuster slide. The user interface panel has a power switch, a start switch, and a liquid crystal display ("LCD") for displaying the systolic and diastolic blood pressure and pulse.

The device is initially turned on by pressing the "POWER" switch. When the unit is on, the system equalizes the pressure inside the unit to the atmospheric pressure. The system is then initialized, the LCD displays a pressure reading of "0," and three short buzzes are heard which signal that the system is ready for use.

To begin a measurement, the user's left index finger is inserted into the finger chamber from the end of the device with the control panel. The cuff size adjuster slide is pulled until the user's left finger is held secure in the cuff. The start switch is then pressed. The finger cuff is then inflated until it reaches a pre-set pressure value at which time the pump is stopped. The automatic pressure deflation unit then deflates the pressure in the finger cuff and pump circuit at a constant rate. The deflation occurs during blood pressure measurement after the inflation is complete. The deflation occurs until the pulse and blood pressures (systolic and diastolic) are measured.

The buzzer sounds at every sensing of the user's pulse and then displays the systolic and diastolic pressure and then alternates to display the pulse rate. The device can then be shut down by pressing the "POWER" switch or by waiting three minutes for it to automatically shut down.

The Citizen sphygmomanometers display certain error messages under specified conditions. First, if the system can not obtain an accurate blood pressure measurement due to undue user movement, or over-tightening or under-tightening of the finger cuff, the LCD will display "Err" to notify the user that the measurement should be repeated. Second, if the pulse could not be accurately measured the LCD will display "PUL Err" which notifies the user that the pulse measurement should be repeated. Third, the LCD will display "BT" when the batteries become too weak to provide proper operation of the device. If this message appears, the manual instructs the user to replace the batteries. Finally, if some other system error occurs which prevents accurate blood pressure or pulse measurements the LCD displays "--- ---." If this message appears, the user manual instructs the user to have the unit repaired or replaced.