K973061

510(k) SUMMARY

Citizen Watch Company, Ltd MAR 13 1998
CH-601A and CH-601B
Digital Wrist Sphygmomanometers

SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON AND DATE PREPARED

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Date Prepared: August 15, 1997

NAME OF DEVICE

Trade Name: CH-601A and CH-601B Digital Wrist Sphygmomanometers
Common Name: Wrist Sphygmomanometer (blood pressure meter)
Classification Name: Noninvasive blood pressure measuring system, per 21 C.F.R. § 870.1130

PREDICATE DEVICES

(1) Omron HEM-605 Digital Wrist Sphygmomanometer

INTENDED USE

The Citizen CH-601A and CH-601B digital wrist sphygmomanometers are intended to be used for the oscillometric measurement of systolic and diastolic blood pressure and pulse. They are intended to be sold over-the-counter.

DEVICE DESCRIPTION

The Citizen Ch-601A and CH-601B digital wrist sphygmomanometers are small hand-held noninvasive blood pressure measurement systems that measure systolic and diastolic blood pressure and pulse from the user's left wrist. The units are contained in a hard plastic housing that contains a user interface panel and an adjustable wrist cuff. 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 measures blood pressure through the use of an automatically-inflating wrist cuff. The cuff automatically deflates during blood pressure measurement. The only difference between the CH-601A and the CH-601B is that the CH-601B has a memory function which displays the last blood pressure readout (but not the last pulse) when the system is turned on.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Both the Citizen Sphygmomanometers and the Omron predicate device measure the diastolic and systolic blood pressure from the left wrist using oscillometric methods. Both systems are microcomputer controlled, digital, auto-inflate, wrist sphygmomanometers. The Omron predicate device does not have any more memory function.

Like the Omron predicate, the Citizen sphygmomanometers display systolic and diastolic pressure ranges from 0 and 280 mm Hg. Both devices have a blood pressure measurement accuracy of the greater of $\pm$ 3mm Hg or $\pm$ 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 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 $\pm$ 5% of the measured pulse frequency. Citizen submitted laboratory testing data to establish the accuracy of its Sphygmomanometers for comparison to the Omron predicate device.

Both the Citizen and the Omron devices utilize an auto-inflate wrist cuff system for blood pressure measurement. The Citizen and Omron devices are designed to measure blood pressure and pulse from the left wrist. The wrist cuff for both systems is designed to accommodate wrists with a circumference of between 135 mm and 195 mm. The wrist cuff on the Citizen device and the predicate device are both adjusted by velcro. Inflation of the wrist cuff for the Citizen devices and the Omron predicate are accomplished with an electric 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. The operating environment for the Citizen sphygmomanometers and the Omron predicate are also the same: 50°F and 104°F and 30% to 85% relative humidity. Although the Citizen devices use two "LR03" size batteries, the Omron predicate device uses 2 "AAA" batteries. Any minor differences in the appearance, technology, or manufacture of the Citizen devices and the predicate device do not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Citizen Watch Co., Ltd.
c/o Mr. Joseph D. Edmondson, Jr.
Foley & Lardner
3000 K Street, N.W.
Suite 500
Washington, DC 20007

MAR 13 1998

Re: K973061
CH-601A and CH-601B Digital Wrist Sphygmomanometer
Regulatory Class: II (Two)
Product Code: DXN
Dated: December 12, 1997
Received: December 15, 1997

Dear Mr. Edmondson:

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 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 (Premarket 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" (21 CFR 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/dsmamain.html."

Sincerely yours,

Thomas J. Callahan

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

Enclosure

STATEMENT OF INDICATIONS FOR USE

The Citizen CH-601A and CH-601B digital wrist sphygmomanometers are intended to be used for oscillometric measurement of systolic and diastolic blood pressure and pulse and are intended to be sold over-the-counter.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K973061