K080177
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5. 510(K) Summary

This document was prepared in accordance with 21 CFR 807.92.

MAY - 9 2008

Section (a)

(1) **Name of the submitter:** Nihon Seimitsu Sokki Co., Ltd.

Address of the submitter: 2508-13 Nakago, Shibukawa, Gunmma 377-0293, Japan

Telephone number of the submitter: 81-279-20-2311

Contact person: Mitsuo Kanai

Date of documentation: January 22, 2008

(2) **Trade name of the device:** Wrist Blood Pressure Monitor, Model WS-1100/WS-1100PV

Common name: Blood pressure monitor

Classification: Class II, 74 DXN, 21 CFR 870.1130 – Cardiovascular devices panel

(3) **The predicate devices:** Nissei Model WS-500 Digital Wrist Blood Pressure Monitor, K003444

Digital Blood Pressure Monitor, Model DS-1901, K071384

Microlife Wrist Watch Blood Pressure Monitor, Model BP3AX1-4U, K061403

(4) **Description of the device:**

Wrist Blood Pressure Monitor, Model WS-1100/WS-1100PV is an automatic sphygmomanometer to be used in a homecare environment. Blood pressure, systolic and diastolic, and pulse rate are measured in the wrist artery using the oscillometric method. WS-1100/WS-1100PV is a single-mounted device of the main unit and the cuff unit. ABS and PMMA are used for the outer housing of the main unit and the Lenticular image is printed as the positioning guide to remind the user to take correct posture for blood pressure measurement. The preformed cuff unit, which is applicable to wrist circumference approximately between 4.9 and 8.5 inches (between 125 and 215 mm), includes the inflatable bladder and the nylon shell. The device consists of the microprocessor, the

pressure-frequency converter, the operation keys, the pump, the electromagnetic deflation control valve (ECV) and the display. The device is powered by two AAA alkaline batteries. The cuff, wrapped over the user's wrist, is inflated and deflated during the course of a measurement. Circuits within the cuff sense the oscillations in pressure against the cuff produced by the expansion and contraction of the arteries in the wrist in response to each heart beat. The amplitude of each pressure waves is measured, converted to millimeters of mercury, and displayed on the LCD as a digital value.

Measured blood pressure values are classified against the guideline by World Health Organization or equivalent guidelines and the classified levels are displayed in the reading display. The device compares the measured blood pressure value to the individual target value set by the user and flashes the value when it exceeds the target value.

The device also compares the longest and the shortest time intervals of the detected pulse waves to the mean time interval and flashes heart mark to indicate the detection of irregular pulse rhythm when the difference of the time intervals is over 25 %.

The user of WS-1100/WS-1100PV can choose to save the measurement results in either one of two memory banks, each of which has the capacity for sixty readings, or not to save the results at the end of a measurement. The results are saved along with the date and time of the measurement and the user can review the saved readings. The device also has feature to display the saved readings taken in the morning and the evening separately. The user can also review the saved readings on a personal computer by downloading saved readings using the designated USB cable included in the product package. The application software is downloaded over the internet.

(5) Intended use of the device:

The WS-1100/WS-1100PV system is intended for noninvasive measurement of systolic and diastolic blood pressures and determination of pulse rate in adults in a homecare environment.

The device features include the display of irregular pulse rhythm detection, the classification display of measured blood pressure values against the guideline by World Health Organization or equivalent guidelines, the personal setting for individual blood pressure target values, the two memory banks to save the measurement results with date and time of measurement and the transferring the saved results to personal computers.

The subject device is basically a modification of the Nissei Model WS-500 Digital Wrist Blood Pressure Monitor, K003444, to include the product features of Digital Blood Pressure Monitor, Model DS-1901, K071384 and Microlife Wrist Watch Blood Pressure Monitor, Model BP3AX1-4U, K061403. Although the specified age of intended patient population is not exactly the same due to the amendment of SP-10, one of the consensus standard for the non-invasive blood pressure monitors, the intended use of the predicate device, Nissei Model WS-500, to measure blood pressure and pulse rate in adults, is the principal intended diagnostic use of the device shared by the other two predicate devices, Model DS-1901 and Model BP3AX1-4U. These two devices, however, have extra indications for use, which are more related to product features than the scientific technology. The intended use of the subject device also includes these extra indications and further indications related to product features in the principle intended use. Therefore the difference of the intended use is not critical to the intended diagnostic use and does not affect the safety and effectiveness of the device.

(6) Technological characteristics of the subject device and the predicate device:

The predicate device which the subject device is to be compared to in respect of the substantial equivalency of technological characteristics is Nissei Model WS-500 Digital Wrist Blood Pressure Monitor.

The subject device and Nissei Model WS-500 are automatic blood pressure monitor with the main unit and the inflatable cuff unit singly-mounted and powered with two AAA batteries, operated by the user with push button controls. With both devices, blood pressure is taken at the wrist, using the oscillometric method.

The subject device and the predicate mainly uses the same materials for the outer housing of the main unit and the surface of the cuff unit, where become in contact with the users. ABS is used for the upper and bottom cases of the main unit and Nylon is for the surface of the cuff unit. The only difference is the material used for the display panels. While the display panel of the predicate device is made of polycarbonate (PC), that of the subject device is made of polymethyl methacrylate (PMMA). PMMA is new with the subject device when compared to the predicate device. PMMA, however, is used with one of the other predicate device, Model DS-1901, which is also our product, as well the material is used in as wide range of fields and applications as the PC, the material used with the predicated device.

The subject device and the predicate device share the same principal design construction and the same energy source and mainly use the same materials. Although the materials used for the display panels raise the difference between two devices, it neither raises new questions regarding the safety and the effectiveness of the subject device nor affects the substantial equivalency of the device.

Section (b)

The predicate devices were tested to evaluate their safety and effectiveness, including electrical safety, electromagnetic compatibility, environmental safety and clinical performance, in accordance with IEC60601 and ANSI/AAMI SP-10 standards. With the clinical studies performed with the subject device, however, there is a difference in the test protocol when it is compared to that of the predicate device, Nissei Model WS-500. The protocol for the predicate device states to exclude patients with wrist circumference greater than 20.5 cm while the exclusion criteria for wrist circumference is changed to 21.5 cm (8.5 inches) with the subject device. This is to expand the applicable wrist circumference range of the subject device.

The subject device was also tested and fulfilled the requirements from these standards. Although there is a difference in test protocol as described above, it is concluded that the subject device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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c/o Mr. Koji Kobo
c/o Cosmos Corporation, Tokyo Office
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Re: K080177
Wrist Blood Pressure Monitor, Model WS-1100, WS-1100PV
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II (two)
Product Code: DXN
Dated: April 24, 2008
Received: April 28, 2008

Dear Mr. Kobo:

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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080177

510(K) Number: K080177

Device Name: Wrist Blood Pressure Monitor, Model WS-1100/WS-1100PV

Indications for Use:

WS-1100/WS-1100PV system is intended for noninvasive measurement of systolic and diastolic blood pressure and determination of pulse rate in adults in a homecare environment.

The device features include the display of irregular pulse rhythm detection, the classification display of measured blood pressure values against the guideline by World Health Organization or equivalent guidelines, the personal setting for individual blood pressure target values, the two memory banks to save the measurement results with date and time of measurement and the transferring the saved results to personal computers.

Prescription Use_____ AND / OR Over-The Counter Use ____X____

(Per 21 CFR 801.109 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K080177