3/5/99

510(k) SUMMARY K981702

MODEL WS-300 AUTOMATIC DIGITAL ELECTRONIC WRIST BLOOD PRESSURE MONITOR

1. **COMPANY INFORMATION.** *Name:* Nihon Seimitsu Sokki Co., Ltd.
   Address: 2509-13 Nakago, Komochi-Mura, Kitagunma-Gun, Gunma-Ken 377-02, Japan
   Phone: (011) 81-278-20-2311 *Contact:*

2. **DEVICE IDENTIFICATION.** *Trade Name:* Model WS-300 Automatic Digital Electronic Wrist Blood Pressure Monitor *Common Name:* Digital Wrist Blood Pressure Monitor
   Classification Name: Noninvasive Blood Pressure Measurement System, 74 DXN

3. **PREDICATE DEVICE.** Nihon Seimitsu Sokki Co., Ltd.: Model WS-200 Automatic Digital Electronic Wrist Blood Pressure Monitor, K952494, SE decision 12/28/95.

4. **DEVICE DESCRIPTION.** *General:* The WS-300 system is an automatic sphygmomanometer intended for measurement of blood pressure at the wrist using the oscillometric method. The entire system, including the cuff, is a single wrist-mounted unit. The system is microprocessor controlled and includes an air pump, an electromagnetic valve to regulate deflation rate, circuitry to detect and process minute pressure oscillations, an LCD display of systolic and diastolic pressure readings followed by heart rate, and pushbutton controls. A memory circuit stores the seven most recent measurements for comparison.
   Operation: The WS-300 system employs a pressure measurement algorithm designed to detect, filter, process, and store pressure readings. The algorithm has been evaluated for the ability to detect and compensate for artifacts and to yield reliable readings in the presence of cardiac arrhythmias. The electromagnetic deflation control valve maintains the deflation rate at a constant 4 mmHg/sec irrespective of differences in wrist size which would otherwise cause variation in the deflation rate.
   Power: The unit is powered by two AA-size batteries and contains an indicator to alert the operator when battery charge is weak.

5. **INTENDED USES.** The WS-300 system is intended for the noninvasive measurement of systolic and diastolic blood pressure and determination of heart rate in adult patients. The product is recommended for use by patients with labile blood pressure or known hypertension in a home care environment as an adjunct to medical management.

6. **COMPARISON WITH PREDICATE DEVICE.** The Model WS-300 is a modification of the previously approved Model WS-200 Wrist Blood Pressure Monitor. The intended use of the two systems is the same. The principle of operation (oscillometric measurement), the measurement algorithm, and many operating features are identical. The Model WS-300 differs from the WS-200 in that it is constructed as a single unit rather than with a separate cuff, in that includes an electromagnetic deflation rate control valve which insures a constant deflation rate in contrast to the variable deflation speed that occurs with the predicate device, and in that it requires two rather than four 1.5V batteries for power.

7. **PERFORMANCE DATA.** The measurement performance of the two systems has been compared by injecting identical pulse wave data, and excellent agreement between results calculated by the subject device and the predicate device were demonstrated. Safety testing including maximum cuff pressure, stability under various operating and storage conditions, vibration and shock, and electromagnetic compatibility has been conducted, resulting in the determination that the subject device complies with all relevant safety standards. The results of performance tests showed the WS-300 to comply with measurement accuracy and cuff deflation requirements as stated in ANSI/AAMI Standard SP10-1992. Software validation testing was performed and reported in accordance with applicable FDA guidance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 1999

NIHOM SEIMITSU SOKKI CO., LTD
c/o Mr. Robert D. Waxham
Submission Correspondent
Waxham Medical Writing
222 Institute Street
Smithfield, VA 23430

Re: K981702
Automatic Digital Electronic Wrist Blood Pressure Monitor
Regulatory Class: II (Two)
Product Code: 74 DXN
Dated: December 4, 1998
Received: December 7, 1998

Dear Mr. Waxham:

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 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). 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" (21CFR 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/dsma/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

510(k) Number (if known): K981702

Device Name: Model WS-300 Automatic Digital Electronic Wrist Blood Pressure Monitor

Indications For Use:

The WS-300 system is intended for the noninvasive measurement of systolic and diastolic blood pressure and determination of heart rate in adult patients. The product is recommended for use by patients with labile blood pressure or known hypertension in a home care environment as an adjunct to medical management.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elena Mendez

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K981702

Prescription Use_____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)