

DEC - 1 1999

510(k) SUMMARY

K 99 3890

**MODEL DS-181
NONINVASIVE BLOOD PRESSURE MEASUREMENT SYSTEM**

1. **COMPANY INFORMATION.** *Name:* Nihon Seimitsu Sokki Co., Ltd ("Nissei").
Address: 2508-13 Nakago, Komochi-Mura, Kitagunma-Gun, Gunma-Ken, 377-0293, Japan
Phone: (011) 81-279-20-2311 *Contact:* Mr. I.Ishii, Quality Assurance Director
2. **DEVICE IDENTIFICATION.** *Trade Name:* Model DS-181 Digital Blood Pressure Monitor
Common Name and Classification Name: Noninvasive Blood Pressure Measurement System, 74 DXN
3. **PREDICATE DEVICE.** Model EBM-2050 Unisonic Electronic Digital Blood Pressure Monitor, Nihon Seimitsu Sokki Co., Ltd. - K850316, SE decision 4/16/85.
4. **DEVICE DESCRIPTION.** *General:* The Nissei Model DS-181 is an automatic sphygmomanometer intended for measurement, including self-measurement by the patient, of blood pressure and heart rate. The method of operation is the oscillometric method and the site of measurement is the brachial artery in the arm. The system is microprocessor controlled and includes an air pump for automatic inflation; fuzzy logic to regulate opening cuff pressure, circuitry to detect and process minute pressure oscillations; an electromagnetic deflation-rate control valve, a six-digit LCD display of systolic and diastolic pressure readings and heart rate; a memory function that stores the seven most recent measurement results plus the computed average of the stored readings; error displays; a standard arm cuff, and an optional large arm cuff.
Operation: If occlusion of the systolic pulse is not achieved by initial pressurization, cuff pressure is automatically increased incrementally until a proper systolic measurement can be obtained. The device employs a pressure measurement algorithm designed to detect, filter, process, and store pressure readings. An error message is presented whenever improper measurement procedures might result in inaccurate readings. If cuff pressure starts to exceed 330 mmHg, cuff pressure is exhausted automatically and an error signal is presented. .
Power: The Model DS-181 is powered by four AA-size batteries. Power is shut down automatically if the unit remains idle for a period of approximately three minutes. An optional AC adaptor is also available.
5. **INTENDED USES.** The Model DS-181 system is indicated for the noninvasive measurement of systolic and diastolic blood pressure and determination of heart rate in adult patients, age 18 and above. The product is recommended for use by patients capable of understanding written and/or oral directions in a home care environment.

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- 6. COMPARISON WITH PREDICATE DEVICE.** The Model DS-181 system has been compared with the Nissei Model EBM-2050 Unisonic Electronic Digital Blood Pressure cleared under 510(k) No. K850316. The intended use of the two systems is the same. The principle of operation (oscillometric measurement) and many operating features are identical. The principal differences are that the DS-181 incorporates features designed to enhance measurement reliability--fuzzy logic circuitry and an electromagnetic deflation control valve--as well as a memory function not found in the predicate device. The hour and minute clock function in the predicate device is not included in the subject device. It is concluded that there are no technologic differences between the subject and predicate devices that raise new questions concerning either safety or effectiveness.
- 7. PERFORMANCE DATA.** The measurement performance of the DS-181 system has been evaluated in clinical studies conducted in accordance with ANSI/AAMI Standard SP10-1992 and found to comply fully with the accuracy criteria established in the standard. Safety testing including electrical characteristics of the system and components, life testing over 10,000 operational cycles, intra-device variability, environmental integrity under various operating and storage conditions including high and low altitude extremes, and resistance to vibration and shock has been conducted with satisfactory results. Similarly, electromagnetic compatibility has been evaluated and found to comply with all relevant standards. Software verification and validation have been performed. It is concluded that the subject device complies with all applicable safety and performance standards.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert D. Waxham
Submission Correspondent for
Nihon Seimitsu Sokki Co., LTD.
222 Institute Street
Smithfield, VA 23430-1136

Re: K993890
Digital Blood Pressure Monitor, Model DS-181
Regulatory Class:II(2)
Product Code: DXN
Dated: November 15,1999
Received: November 16,1999

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 Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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.

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This letter will allow you to continue 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) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style and is positioned above the printed name.

Celia M. Witten, Ph.D., M.D.
Acting Director
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K993890

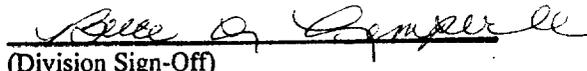
Device Name: **Model DS-181 Digital Blood Pressure Monitor**

Indications For Use:

The DS-181 system is intended for the noninvasive measurement of systolic and diastolic blood pressure and determination of heart rate in adult patients, i.e., age 18 and above.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K993890

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

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