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EXHIBIT 2
510K Summary

Nihon Seimitsu Sokki Co. Ltd (Nissei)
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Contact: I. Ishii, Chief Engineer

1. **Identification of the device**
Proprietary-Trade Name: Model DS-1862 Digital Blood Pressure Monitor
Classification Names: DXN, SYSTEM, MEASUREMENT, BLOOD-PRESSURE, NON-INVASIVE,
Common/Usual Name: Noninvasive Blood Pressure Measurement System

2. **Equivalent legally marketed devices**
This product is similar in function and design to predicate Nihon Seimitsu Sokki Co., Ltd. (Nissei) DS-181, K993890

3. **Indications for Use (intended use).** The DS-1862 Digital Blood pressure Monitor 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. The product is recommended for use by patients capable of understanding written and/or oral directions in a home care environment.

4. **Description of the Device** The Nissei Model DS-1862 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, an eleven-digit LCD display of systolic and diastolic pressure readings and heart rate; a memory function that stores the thirty most recent measurement results for two patients 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-1862 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. Safety and Effectiveness, comparison to predicate device

The results of bench and user testing indicate that the new device is as safe and effective as the predicate device.

6. Comparison matrix – new vs. Predicate device

Designation	Nihon Seimitsu Sokki Co., Ltd. (Nissei) DS-181, K993890	Nihon Seimitsu Sokki Co., Ltd. (Nissei) DS-1862
Operating Principle	Oscillometric method	SAME
Indication for use	For the noninvasive measurement of systolic and diastolic blood pressure and determination of heart rate in adult patients, i.e. age 18 and above.	SAME
Display	7 Digit LCD	11 Digit LCD
Measurement Range	Sys 50-250 mm Hg (cuff press.) Dia 40 to 180 mm Hg Pulse rate 40 to 160 pulse/min	SAME
Accuracy	±3 mm Hg (cuff press.) ±5% of reading (pulse rate)	SAME
Cuff arm circumference	230 to 320 mm	170 to 350 mm
Power supply	Four AA size batteries	SAME
External dimensions	160mm W x 100mm D x 52mm H	163mm W x 180mm D x 83mm H
Memory	7 Measurement results, Computation of the average of stored data.	30 Measurement results x 2, Computation of the average of stored data.
Weight	265 g. w/o batteries	420 g. w/o batteries

7. Conclusion

After analyzing both bench and clinical testing data, it is the conclusion of Nissei that the "DS-1862" Digital Blood Pressure Monitor is as safe and effective as the predicate device, has essentially no significant technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Nihon Seimitsu Sokki Co. Ltd.
c/o Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
P.O.Box 7007
Deerfield, IL 60015

Re: K040309
Trade Name: Digital Blood Pressure Monitor, Model DS-1862
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: 74 DXN
Dated: February 03, 2004
Received: February 09, 2004

Dear Mr. Kamm:

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 (301) 594-4648. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K040309

Device Name: **Nissei Model DS-1862 Blood Pressure Monitor**

Indications For Use: For the noninvasive measurement of systolic and diastolic blood pressure and the determination of heart rate in adult patients, i.e. age 18 and above, in a homecare environment. Patients should be capable of understanding the instructions for use.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vodnel

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040309