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5. 510(K) Summary

AUG 2 2012

This document was prepared in accordance with 21 CFR 807.92.

Section (a)

(1) Name of the submitter: Nihon Seimitsu Sokki Co., Ltd.
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Telephone number: 81-279-20-2311
Contact person: Mitsuo Kanai
Date of documentation: July 23,2012

(2) Trade name of the device: Blood Pressure Monitor DSK-1031
Common name: Blood pressure monitor
Classification: Noninvasive blood pressure measurement system, DXN, 870.1130, Class II

(3) Predicate devices: Model DS-181 Digital Blood Pressure Monitor, K993890/Model DSK-1011 Blood Pressure Monitor, K112691/Wrist Blood Pressure Monitor, Model WS-1100/WS-1100PV, K080177 manufactured by Nohon Seimitsu Sokki Co., Ltd. and Model HEM-789N3/BP785/BP760 Blood Pressure Monitor, K061822 manufactured by OMRON HEALTHCARE Co., Ltd.

(4) Description of the device:
Blood Pressure Monitor DSK-1031 is an automatic sphygmomanometer to be used in a homecare environment. Blood pressure, systolic and diastolic, and pulse rate are taken at upper arm non-invasively using oscillometric method, which is one of the most common methods with recent automatic sphygmomanometer that determines blood pressure and pulse rate with oscillations against cuff applied to measurement site. The device consists of the main unit and the nylon cuff that is applicable to arm circumference between 8.7 and 16.5 inches (between 220 and 420 mm) and is powered by four AA alkaline batteries or AC adaptor. The device not only determines blood pressure and pulse rate from oscillations but also analyses pulse wave and determines appropriateness of cuff application. Besides these auxiliaries, user can get pulse pressure value and blood pressure level according to WHO (World Health Organization) guideline also on the display. User can choose to activate clock function of the device to review measured readings with measurement date and time.

(5) Intended use of the device:

DSK-1031 system is intended for noninvasive measurement of systolic and diastolic blood pressure, determination of pulse rate and calculation of pulse pressure in adults in a homecare environment.

The device features include display of irregular pulse rhythm detection, classification display of measured blood pressure values against WHO guideline' display of cuff condition, display of body movement detection and two memory accounts to save measurement results.

The indication for use of DSK-1031 system is not exactly same with but similar to the predicate device, Model DSK-1011 Blood Pressure Monitor and Wrist blood Pressure Monitor, Model WS-1100/WS-1100PV. However, the fundamental intended use, which is to measure adults' blood pressure non-invasively in home care environment, remains the same. The difference between the indications for use of the subject device and the predicate device lies in supplemental product features; some features of the predicate device are not provided with the new device and some new features are introduced with the subject device. As demonstrated in relevant sections of this submission, these features are concluded not to affect the device safety and effectiveness.

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

The subject device holds the same technological fundamentals with the predicate device, Model DS-181 Digital Blood Pressure Monitor and Model DSK-1011 Blood Pressure Monitor. Both devices consist of the main unit and the cuff for upper arm and powered with four AA alkaline batteries or designated AC adaptor. The patient contacting materials used for the subject device had been used with either one of the predicate devices, Model DS-181 and DSK-1011 or WS-1100/WS-1100PV and these materials do not go through any different process from the predicate devices. The list of patient contacting materials and components is included in the relevant section of this application.

7) The following devices comparison table shouws the derails of differences between the subject device and the claimed predicats.

Device comparison table

	DSK-1031, the subject device	WS-1100/WS-1100PV	DS-181	HEM-780N3/BP785/BP760	DSK-1011	Note
510(K)No.	K112620	K080177	K993890	K061822	K112691	
Intended use	DSK-1031 system is intended for noninvasive measurement of systolic and diastolic blood pressure, determination of pulse rate and calculation of pulse pressure in adults in a homecare environment. The device features include display of irregular pulse rhythm detection, classification display of measured blood pressure values against WHO (World Health Organization) guidelines display of cuff condition, display of body movement detection and two memory account to save measurement results.	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 guideline, 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.	Noninvasive measurement of systolic and diastolic blood pressure and determination of pulse rate in adult patients, age 18 and above	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with arm circumference ranging from 9 inches to 17 inches (22cm – 42cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings. The blood pressure monitor compares average blood pressure results to pre-established AHA (American Heart Association) hypertension guideline of 135/85 mmHg. The Omron 780N3 model is not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated.	Blood Pressure Monitor DSK-1011 is intended for noninvasive measurement of systolic and diastolic blood pressure, determination of pulse rate and calculation of pulse pressure in adults in a homecare environment. The device features include display of irregular pulse rhythm detection, classification display of measured blood pressure values against WHO (World Health Organization) guidelines display of body movement detection and two memory accounts to save measurement results.	Refer to "12. Substantial Equivalence Discussion".
Operation principle	Oscillometric method	Oscillometric method	Oscillometric method	Oscillometric method	Oscillometric method	Same
Pressure indication range	3 to 300 mmHg	0 to 300 mmHg	0 to 300 mmHg	0 to 299 mmHg	3 to 300 mmHg	Same as DSK-1011.
Measurement	Upper arm	Wrist	Upper arm	Upper arm	Upper arm	Same as DS-181 and DSK-1011

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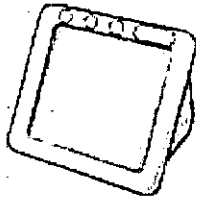
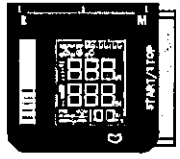
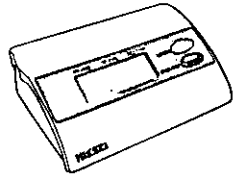
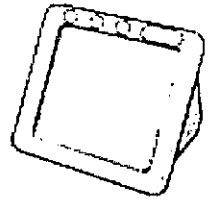
site and applicable circumference	Approximately 8.7 to 16.5 inches (220 to 420 mm)	Approximately 4.9 to 8.0 (125 to 205 mm)	Standard Approximately 9.1 to 12.6 inches (230 to 320 mm) Large Approximately 12.6 to 16.5 inches (320 to 420mm)	Approximately 9 to 17 inches (220 to 420 mm)	Standard-Large size (Approximately 8.7 to 16.5 inches; 220 to 420 mm)	
Power source	4 AA alkaline batteries or 100-240V 50/60Hz AC adaptor	2AAA alkaline batteries	4 AA alkaline batteries or 6VDC AC adaptor	4 AA batteries or 120V 60Hz AC adaptor	4 AA alkaline batteries or 100-240V 50/60Hz AC adaptor	Same as DS-181 and DSK-1011
Inflation	Automatic air pump	Automatic air pump	Automatic air pump	Automatic by electric pump	Automatic air pump	Same
Deflation	Automatic electric control valve	Automatic electric control valve	Automatic electric control valve	Automatic pressure release valve	None	Same
Exhaust	Automatic quick exhaust valve	Automatic quick exhaust valve	Automatic quick exhaust valve	Automatic quick exhaust	Automatic quick exhaust valve	Same
Illustrational image of the device						———
Display	15 digits liquid crystal display Date and time display	15 digits liquid crystal display Date and time display	7 digits liquid crystal display	13 digits liquid crystal display Date and time display	15 digits liquid crystal display Date and time display	Same as WS-1100/ WS-1100PV and DSK-1011
Device setting by the user	Date and time	Date and time Personal target limits of blood pressure values	None	Date and time TRURED™ MODE	Date and time	Same
supplemental product features	Irregular Pulse Rhythm Symbol	Irregular Pulse Rhythm Symbol	None	None	Irregular Pulse Rhythm Symbol	Body movement and Cuff winding are the same as HEM-780N3/BP785/BP760 and DSK-1011. Refer to "12.
	Body Motion Symbol	None	None	Movement Error Symbol	Body Motion Symbol	
	Cuff Symbol	None	None	Cuff Wrap Guide Symbol	None	
	WHO Classification Symbol	JNC-7 Classification Symbol	None	None	WHO Classification Symbol	
	Pulse Pressure Display	None	None	None	Pulse Pressure Display	

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		H.D.M.S Mode Exporting The Saved Readings to Your PC		Irregular Heartbeat Symbol Morning Hypertension Symbol Moring Average Symbol Evening Average Symbol Calibration Check System Blood Pressure Level Indicator		Substantial Equivalence Discussion".
Memory features	2 memory banks to save 60 measurement results with date and time, when the clock is activated; the saved readings can be intentionally deleted by the user.	2 memory banks to save 60 blood pressure and pulse rate readings each with date and time; saved reading(s) can be intentionally deleted by the user. Mode to view AM and PM readings separately Exporting saved readings to personal computers using the designated USB cable	A single memory bank to save 30 blood pressure readings; readings are deleted at battery replacement.	2 memory banks to save 100 measurement results with date and time, when the clock is activated; the saved readings can be intentionally deleted by the user.	2 memory banks to save 60 measurement results with date and time, when the clock is activated; the saved readings can be intentionally deleted by the user.	Same as DSK-1011.
Auxiliary feature	None	Position guide Lock Key	None	None	None	———
Main unit	Size: approximately W;4.5, D;2.6, H;4.5 inches Weight: approximately 8.8 oz. Material: ABS and PMMA	Approximate size: W; 2.79, D; 2.56, H; 1.18 inches Approximate weight: 4.09 oz. Material: ABS and PMMA	Approximate size: W; 6,23, D; 3.94, H; 2.05 inches Approximate weight: 9.35 oz. Material: ABS and PC	Approximate size: W; 4 7/8, D; 6 1/4 , H; 3 5/16 inches Approximate weight: 15 1/8 oz. Material: ABS and PC	Size: approximately W;4.5, D;2.6, H;4.5 inches Weight: approximately 8.8 oz. Material: ABS and PMMA	———
Cuff	Preformed nylon cuff	Preformed nylon cuff	Nylon flat arm cuff	Preformed nylon cuff	Nylon flat arm cuff	Same as WS-1100/ WS-1100PV
Reference standard(s)	IEC 60601-1:1998 + A1:1991 + A2:1995 IEC 60601-1-2, 2001 + A1:2004/IEC60601-1-2 CISPR 11:2009 + A1:2010 IEC 61000-3-2:2005+A1+A2:2009 IEC 61000-3-3:2008	IEC 60601-1:1998 + A1:1991 + A2:1995 IEC 60601-1-2, 2001 + A1:2004 CISPR 11:2003 + A1:2004 + A2:2006 IEC 61000-4-2,-3,-8 ANSI/AAMI SP –10-2002	36.202 of EN60601-1-2:1993(EMS) EN55011:3.1991(EMI)	ANSI/AAMI SP –10-2002	IEC 60601-1:1998 + A1:1991 + A2:1995 IEC 60601-1-2, 2001 + A1:2004/IEC60601-1-2 CISPR 11:2009 + A1:2010 IEC 61000-3-2:2005+A1+A2:2009 IEC 61000-3-3:2008	———

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	IEC61000-4-2:2008 IEC61000-4-3:2006+A1:2007+A2:2010 IEC61000-4-4:2004+A1:2010 IEC61000-4-5:2005 IEC61000-4-6:2008 IEC61000-4-8:2009 IEC61000-4-11:2004 ANSI/AAMI SP10:2002				IEC61000-4-2:2008 IEC61000-4-3:2006+A1:2007+A2:2010 IEC61000-4-4:2004+A1:2010 IEC61000-4-5:2005 IEC61000-4-6:2008 IEC61000-4-8:2009 IEC61000-4-11:2004 ANSI/AAMI SP10:2002	

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Section (b)

(1) Non-clinical tests

The subject device was evaluated in accordance with IEC and SP-10 not only to demonstrate the substantial equivalence but also to establish the better safety. This is why some reference standards were added to test the subject device when compared to the predicated devices. The detailed information of reference standards is provided in the relevant sections of this submission.

(2) Clinical tests

No clinical test report is submitted because differences between the subject device and the predicate devices do not affect clinical performance.

(3) Conclusions drawn from non-clinical tests

It is concluded from the non-clinical tests conducted that the subject device is not only as safe and as effective as the predicate devices but is also safer and more effective than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Nihon Seimitsu Sokki Co., Ltd.
c/o Mr. Koji Kubo
Manager
Cosmos Corporation
2F, 6-5-3 Komagome
Bunkyo-ku
Tokyo 113-0021
JAPAN

Re: K112620
Trade/Device Name: Digital Blood Pressure Monitor, Model DSK-1031
Regulatory Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: July 9, 2012
Received: July 10, 2012

Dear Mr. Kubo:

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.

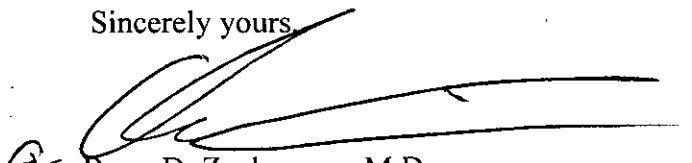
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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

Enclosure

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510(K) Number: K112620

Device Name: Blood Pressure Monitor DSK-1031

Indications for Use:

Blood Pressure Monitor DSK-1031 is intended for noninvasive measurement of systolic and diastolic blood pressure, determination of pulse rate and calculation of pulse pressure in adults in a homecare environment.

The device features include display of irregular pulse rhythm detection, classification display of measured blood pressure values against WHO (World Health Organization) guideline, display of cuff condition, display of body movement detection and two memory accounts to save measurement results.

Prescription Use_____ AND / OR Over-The Counter Use ___X___

(Per 21 CFR 801.109 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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112620