

510(k) Summary

As Required by 21 section 807.92 (c)

- 1- Submitter Name:** Sein Electronics Co., Ltd
2- Address: 133-3, Pyungchon-dong, Anyang-city, Kyunggi-do, Korea
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5- Contact Person: Tae young Choi
6- Date summary prepared: August 1, 2005
7- Official Correspondent: Mansour Consulting LLC
8- Address: 1308 Morningside Park Dr. Alpharetta, GA 30022 USA
9- Phone: 770-777-4146
10- Fax: 678-623-3765
11- Contact Person: Jay Mansour, President
12- Device Trade or Proprietary Name: BLOOD GLUCOSE AND BLOOD PRESSURE MONITOR SYSTEM, MODEL BGP-100
13- Device Common or usual name: Blood Glucose Monitor, Blood glucose test strips, quality control material, and Blood Pressure Monitor
14- Device Classification Name:
 System, test, blood glucose, over the counter
 Glucose oxidase, glucose
 Single (specified) analyte controls
 System, measurement, blood-pressure, non-invasive
15- Substantial Equivalency is claimed against the following device:
 Blood Pressure Monitor, Model SE-311, manufactured by Sein Electronics Co., Ltd. 510k #K042138
 Clever Chek TD-3213, 510k# K042795
 One Touch Ultra Blood Glucose monitoring system, 510k #K002134

16- Description of the Device:

BGP-100 Sein Blood Glucose & Pressure Monitor system BGP-100 combines the function of a blood glucose monitoring system and a blood pressure meter in one unit. Supplies with the meter are test strips, lancets, lancing device, storage case and control solution. The blood glucose monitoring system is turned on by strip insertion; Once the user confirms that the numerical code on the display, and strip bottle all match, a test strip is inserted into the meter and glucose testing can proceed. The user then supplies finger-tip blood or control solution to the strip and the meter starts the measurement, which is completed in 5 seconds. Sein Electronics Co.,Ltd has provided instructions and illustrations explaining, that the blood drop will be pulled into the strip sample entry by capillary action until meter beeps and the result will be show on liquid crystal display ("LCD") after 5 seconds. Results are automatically stored in the meter's memory for tracking purposes. The capacity of memory is 150 blood glucose values and average value of past 14 days or 30days. Control Solution is sold separately from the kit. BGP-100 adopts the wrist type cuff for blood pressure meter part. The cuff and control unit are combined into a single wrist-mounted assembly. The user interface panel has power switch, mode switch, memory switch, for blood pressure meter part and LCD for displaying the systolic blood pressure, diastolic blood pressure, pulse rate, date and time. This device has the memory function that permits memory and display of the 60 most recent measurement results. User should wrap the pressure cuff around the wrist with the palm facing up and pushes the "Power" button. The cuff will be full with appropriate air pressure automatically. Pressurization is automatically governed. If the initial inflation pressure (180mmHg) is inadequate for measurement, i.e. lower that the patient's systolic pressure, the pump will automatically re-pressurize to a preset level (30 mmHg) above the initial level. Symbols in the LCD indicate pressurization status at all times. The air of cuff is automatically deflated during blood pressure measurement. No special training beyond basic ability to follow instruction is required. Since the products are designed for home use, detailed instructions on avoidance of practices that adversely affect the accuracy of measurements are included in the instruction manual.

17- Intended use of the device: (refer to FDA form attached)

The BGP-100 blood glucose and blood pressure measurement system consists of a meter with wrist cuff and test strips. The system is intended for use in the quantitative measurement of glucose in whole blood taken from the fingertip. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes mellitus, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. It is not intended for use on neonates. Also the system measures systolic and diastolic blood pressure and pulse rate from adult's wrist in the home care environment. The device employs a wrist cuff and the oscillometric method of measurement.

18- Safety and Effectiveness of the device:

This device is safe and effective as the predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14- Summary comparing technological characteristics with predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached. Indeed, this device is **SUBSTANTIALLY EQUIVALENT** to the predicate device. Refer to the explanations/details within the main submission.

FDA file reference number	510k # K042138	510k # K042795 and 002134
TECHNOLOGICAL CHARACTERISTICS	Comparison result	
Indications for use	IDENTICAL	Identical
Target population		Identical
Design		SIMILAR
Materials		
Performance		
Sterility		
Biocompatibility		
Mechanical safety		
Chemical safety		
Anatomical sites		
Human factors		
Energy used and/or delivered		
Compatibility with environment and other devices		
Where used		
Standards met		
Electrical safety		
Thermal safety		
Radiation safety		

Refer to the submission for more details.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 7 2005

Sein Electronics Co., Ltd.
c/o Mr. Jay Mansour, MSQA, BE, LA, RAC
President
Mansour Consulting LLC
1308 Morningside Park Drive
Alpharetta, GA 30022

Re: k052108
Trade/Device Name: Blood Glucose and Blood Pressure Monitor System,
Model BGP-100
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA, JJX, DXN
Dated: October 26, 2005
Received: October 31, 2005

Dear Mr. Mansour,

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

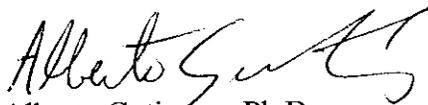
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. 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/industry/support/index.html>.

Sincerely yours,



Alberto Gutierrez, Ph.D.

Director

Division of Chemistry and Toxicology

Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052108

Device Name: Blood Glucose and Blood Pressure Monitor System, Model BGP-100

Indications For Use:

The BGP-100 blood glucose and blood pressure measurement system consists of a meter with wrist cuff and test strips. The system is intended for use in the quantitative measurement of glucose in whole blood taken from the fingertip. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes mellitus, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. It is not intended for use on neonates.

Also the system measures systolic and diastolic blood pressure and pulse rate from adult's wrist in the home care environment. The device employs a wrist cuff and the oscillometric method of measurement.

Prescription Use
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
 (21-CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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