K032927

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MAY - 7 2004

510(k) Summary

As Required by 21 section 807.92 (c)

1-Submitter Name: Sein Electronics Co., Ltd
2-Address: Room #506, Youcheon Factopia, #196, Anyang 7-dong, Manan-Gu, Anyang-city, Kyunggi-do, Korea
3-Phone: (82) 31-467-2188
4-Fax: (82) 31-467-2107
5-Contact Person: Won-Ky Kim
6-Date summary prepared: September 9th, 2003
7-Device Trade or Proprietary Name: Full Auto Arm Digital Blood Pressure Monitor, Model SE-7070
8-Device Common or usual name: Blood pressure monitor
9-Device Classification Name: Non Invasive blood pressure measuring system
10-Substantial Equivalency is claimed against the following device:
Full Auto Blood Pressure Monitor, Model SE-7700H, manufactured by Sein Electronics Co., Ltd.

11-Description of the Device:

SE-7070 is intended to measure systolic and diastolic pressure and pulse rate of adults in a home care environment using arm cuff and oscillometric method of measurement.

There are no contraindications; the subject device may be employed in the care of normotensive, hypertensive, or hypotensive patents.

The user interface panel has a power switch, a mode switch, a memory switch and a liquid crystal display ("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 58 most recent measurement results.

The device measures blood pressure through the use of a automatic inflating cuff. Pressurization is automatically governed. The device has fuzzy logic function that establishes automatically initial inflation pressure according to blood pressures of patients. The cuff automatically deflates during blood pressure measurement.

The patient is responsible for applying the cuff, for initiating the measurements sequence by pressuring the "Power" button, and for recording results. The patient cannot alter bleed-down rate.

All system functions are preprogrammed. The user is cautioned in the instruction manual against attempting any programming or other modification.

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.

12-Intended use of the device:

SE-7070 is intended to measure systolic and diastolic pressure and pulse rate of adults in a home care environment using arm cuff and oscillometric method of measurement.

13-Safety and Effectiveness of the device:

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

14-Summary comparing technological characteristics with other 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 **SIMILAR** to the predicate device.

FDA file reference number	510k # K003282
Attachments inside notification submission file	510k summary print out
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Identical, except that the end user is the individual at home, not medical practitioner
Target population	Identical
Design	Similar
Materials	Similar
Performance	Similar
Sterility	Similar
Biocompatibility	Similar
Mechanical safety	Similar
Chemical safety	Not Applicable
Anatomical sites	Identical
Human factors	Similar
Energy used and/or delivered	Similar
Compatibility with environment and other devices	Similar
Where used	Identical
Standards met	Similar
Electrical safety	Similar
Thermal safety	Similar
Radiation safety	Similar

REFER TO MAIN SUBMISSION FOR COMPLETE DETAILS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 2004

Sein Electronics Co., Ltd.
c/o Jay Mansour
Mansour Consulting LLC
1308 Morningside Park Drive
Alpharetta, GA 30022

Re: K032927
Trade Name: Full Auto Arm Digital Blood Pressure Monitor, Model SE-7070
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: April 04, 2004
Received: April 12, 2004

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 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,

for 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): K032927

Device Name: FULL AUTO ARM DIGITAL BLOOD PRESSURE MONITOR, MODEL SE-7070

Indications For Use:

This device is an over the counter device, and is indicated for use to measure systolic and diastolic pressure and pulse rate of adults by the individual, in a home care environment, using arm cuff and oscillometric method of measurement

Prescription Use _____ AND/OR Over-The-Counter Use ✔
(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)

Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032927