K092061

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510(k) Summary

As Required by 21 section 807.92 (c)

1- Submitter Name: Genexel Medical Instrument Inc
FDA Registration number 8043684

2- Address: 111 Yangjae-dong, Seocho-gu
Seoul, Republic of Korea

MAR 2 6 2010

3- Phone: (82) 2-575-1141

4- Fax: (82) 2-575-1688

5- Contact Person: Mr Jonathan Seo

6- Date summary prepared: July 3, 2009

7- Official Correspondent: Mansour Consulting LLC

8- Address: 845 Aronson Lake Ct. Roswell, GA 30075 USA

9- Phone: 678-908-8180

10- Fax: 678-623-3765

11- Contact Person: Jay Mansour, President

12- Device Trade or Proprietary Name: FORECARE ADVANCED SPORT WRIST BLOOD PRESSURE MONITOR, MODEL FP-0217

13- Device Common or usual name: Digital Blood Pressure Monitor

14- Device Classification Name: Non Invasive blood pressure measuring system

15- Substantial Equivalency is claimed against the following device:
510K #K012054 Full Auto Wrist Digital Blood Pressure Monitor, Model SE-312, manufactured by Genexel Medical Instrument Inc, formerly Sein Electronics

16- Description of the Device:

FORECARE ADVANCED SPORT WRIST BLOOD PRESSURE MONITOR, MODEL FP-0217 is intended to measure systolic and diastolic pressure and pulse rate of adults in a home care environment using wrist 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 of FP-0217 has power button, mode button, memory button and liquid crystal display ("LCD") for displaying systolic pressure, diastolic pressure, pulse rate and date. FP-0217 has memory capacity to store the 58 most recent measurement results.

The device measures blood pressure through the use of an automatic inflating cuff. 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 cuff automatically deflates with stepwise pressure drop of 5~6 mmHg per 2 pulses during blood pressure measurement.

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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.

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

This device is an over the counter device, and its intended use is to measure systolic and diastolic pressure and pulse rate of adults, using wrist cuff and oscillometric method of measurement.

18- Safety and Effectiveness of the device:

This device is safe and effective as the predicate device cited above.

19- Summary comparing technological characteristics with predicate device:

Comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution is included within this submission. Also, Equivalency overview chart path is attached. Indeed, this device is **SUBSTANTIALLY EQUIVALENT** to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR 2 6 2010

Genexel Medical Instrument Inc.
c/o Mr. Jay Mansour
Mansour Consulting LLC
845 Aronson Lake Court
Roswell, GA 30075

Re: K092061
Trade Name: Forecare Advanced Sport Wrist Blood Pressure Monitor, Model FP-0217
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: February 24, 2010
Received: February 26, 2010

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 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,

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): K092061

Device Name: Forecare Advanced Sport Wrist Blood Pressure Monitor, Model FP-0217

Indications For Use:

This device is an over the counter device, and its intended use is to measure systolic and diastolic pressure and pulse rate of adults, using wrist 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 K092061