

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE**

A. 510(k) Number:

k080853

B. Purpose for Submission:

For the addition of a USB cable to transmit data to a PC from a previously cleared glucose meter configured with a blood pressure (BP) monitor system (k052108). The meter and BP monitor remain the same.

C. Manufacturer and Instrument Name:

Genexel-Sein, Inc., DUO-CARE Blood Glucose and Blood Pressure Monitor System

D. Type of Test or Tests Performed:

Whole blood glucose and Blood Pressure

E. System Descriptions:

1. Device Description:

This device combines the functions of a blood glucose meter and a blood pressure measurement system in one unit. Supplied with the meter are the test strips, lancets, lancing device, control solutions and storage case. To measure blood glucose, the user inserts a test strip. A numerical code appears on the screen and the user compares this number to the number located on the test strip bottle to ensure the two numbers match. Once the user confirms that the code number in the meter matches the strip bottle, glucose testing can proceed. The sponsor has provided instructions and illustrations explaining that the blood drop will be pulled into the strip sample entry by capillary action and that the confirmation window must be completely filled with blood to obtain an accurate result. Results are stored in the meters memory for tracking purposes. The controls can be purchased separately.

To measure blood pressure, the user is instructed to wrap the cuff around the left wrist with the palm facing up approximately ¼ to ½ inch below the ball of the thumb. The user is instructed not to move or talk during the measurement. The sponsor has also provided instructions and illustrations explaining that the user must be sitting and the blood pressure cuff must be at the same level as the user's heart to obtain an accurate reading. Results are stored in the meters memory for tracking purposes.

2. Principles of Operation:

Glucose: the glucose oxidase in the strip reacts with the glucose in the sample to produce an electrical current proportional to the glucose concentration. The meter measures the current and converts it to the corresponding glucose concentration in

mg/dL or mmol/L.

Blood pressure: the pressure sensor in the cuff detects small changes in pressure and converts them to electrical signals. The meter analyzes the signals and converts them to standard measurements of pulse rate and systolic and diastolic blood pressure.

3. Modes of Operation:

Each test strip is single use and must be replaced with a new strip for additional readings. There are no disposable components used to measure blood pressure. Data is transmitted to a PC utilizing a USB cable.

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes X or No _____

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

Yes ____ or No X

4. Specimen Identification:

There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

5. Specimen Sampling and Handling:

This device is intended to be used with capillary whole blood from the finger only. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

6. Calibration:

Each bottle of test strips has a code number which is used to calibrate the meter. The user confirms that the code number on the test strip bottle matches the code number in the instrument. If they are different then the user changes the number by depressing the code key on the meter until the correct number is displayed. No further calibrations are required of the user.

7. Quality Control:

The sponsor is providing a high and low glucose control solution with this device. To mark the test result as a control the user is instructed to press and hold the C button for three seconds. Check will appear on the display. This prevents control results from being stored in the internal memory. An acceptable range for each control level is printed on the test strip vial label. If control results fall outside

these ranges, the user is referred to a list of troubleshooting steps and the customer care line.

8. Software:

FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

Yes or No

F. Regulatory Information:

1. Regulation section:

21 CFR §862.1345, Glucose Test System

21 CFR §862.1660, Quality Control Material (assayed and unassayed)

21 CFR §870.1130, Noninvasive blood pressure measurement system

2. Classification:

Class II (Glucose Test System)

Class I, reserved (Assayed Quality Control Materials)

Class II (Blood Pressure Measurement System)

3. Product code:

NBW, CGA – Glucose Test System

JJX – Single (specified) analyte controls (assayed and unassayed)

DXN – Blood Pressure Measurement System

4. Panel:

75, Clinical Chemistry – Glucose Test System and Quality Control Material

74, Cardiovascular – Blood Pressure Measurement System

G. Intended Use:

1. Indication(s) for Use:

The DUO-CARE 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.

The system included optional accessory software that is installed on the users' computers for data management purposes.

2. Special Conditions for Use Statement(s):

This device is not intended for use on neonates nor to screen for diabetes.
For in vitro diagnostic over-the-counter and professional use

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

Genexel-Sein (formerly Sein) Blood Glucose and Blood Pressure Monitor System, Model BGP-100 k052108

2. Comparison with Predicate Device:

FDA file reference number	501(k) # k052108
Technical Characteristics	Comparison result
Indications for use	Identical
Target population	
Design	
Materials	
Performance	
Sterility	
Biocompatibility	
Mechanical safety	
Chemical safety	
Anatomical sites	
Human factors	
Energy used and/or delivered	Identical
Compatibility with environment and other device	
Where used	
Standards met	
Electrical safety	
Thermal safety	
Radiation safety	

I. Special Control/Guidance Document Referenced (if applicable):

None referenced

J. Performance Characteristics:

1. Analytical Performance:

- a. *Accuracy:*
Provided in k052108
 - b. *Precision/Reproducibility:*
Provided in k052108
 - c. *Linearity:*
Provided in k052108
 - d. *Carryover:*
Provided in k052108
 - e. *Interfering Substances:*
Provided in k052108
2. Other Supportive Instrument Performance Data Not Covered Above:
The expected values provided in the package insert are referenced from: Krall, L.P. and Beaser, R.S.: Joslin Diabetes Manual, Philadelphia: Lea and Febiger (1989), 138.

The normal fasting adult glucose range for a non-diabetic is 70 -110 mg/dL. One-hour after a meal, normal blood glucose results should be less the 160 mg/dL. A medical professional should determine the range that is appropriate for diabetes patients.

Saved data on the DUO-CARE - Date, Time, Systolic Pressure, Diastolic Pressure, Heart Rate and Glucose were transmitted and compared to captured data. Data were 100% accurately transmitted. Additionally a user study was conducted to demonstrate stored data on the DUO-CARE could be uploaded onto a PC. The study evaluated loading necessary software on to a PC, connecting the USB cable, transferring data to the PC, and viewing data on the PC, using only the instruction manual.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.