

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

**A. 510(k) Number:**

k123136

**B. Purpose for Submission:**

New 510(k) for Diabetes Data Manager for use with Genesis Health Technologies Blood Glucose Meter TD-4123 with cellular module cleared under k121224

**C. Manufacturer and Instrument Name:**

Genesis Health Technologies  
Genesis Health Record System

**D. Type of Test or Tests performed:**

Diabetes data management system

**E. System Descriptions:**

Device Description:

The Genesis Health Record System (GHRS), an internet browser-based software system, is an optional accessory to the Genesis Blood Glucose Monitoring System (Genesis BGMS) that aids in diabetes care and management. The GHRS receives test results from the Genesis Blood Glucose Meter (Genesis BGM) via secure cellular transmission over the Verizon wireless network, and stores these results in a secured database.

Principles of Operation:

Once a patient's glucose measurement is taken, the cellular module automatically searches for and connects to the Verizon cellular network and uploads the test result to the patient's account. After the reading is successfully uploaded to the patient's account of the upload is confirmed to the device and patient.

Once uploaded to the secured database, an individual patient's results can only be viewed by that patient and by additional person(s) authorized by that patient. The Genesis BGMS and GHRS are not intended to provide automated treatment guidance or decisions, nor are they to be used as a substitute for professional healthcare judgment.

Modes of Operation:

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 X or No \_\_\_\_\_.

**Specimen Identification:**

Specimen identification is based on time and date of testing.

**Specimen Sampling and Handling:**

Data transmission from glucose meters using capillary whole blood samples

**Calibration:**

Glucose meter specific. See statement below under section J.

**Quality Control:**

Glucose meter specific. See statement below under section J.

**Software:**

FDA has reviewed the applicant's Hazard Analysis and software Documentation: Yes  or No

**F. Regulatory Information:**

Device Name	Product Code	Classification	Regulation	Panel
Glucose Test System	NBW: Blood Glucose Test System, Over-the- Counter	Class II	21 CFR § 862.1345	Clinical Chemistry (75)
Calculator/Data Processing Module for Clinical Use	JQP: Calculator/ Data Processing Module for Clinical Use	Class I	21 CFR § 862.2100	Clinical Chemistry (75)

**G. Intended Use:**1. **Indication(s) for Use:**

The Genesis Health Record System is an accessory to the Genesis Health Technologies Blood Glucose Meter, Model TD-4123 to assist in the review and evaluation of blood glucose test results and related information to aid in diabetes management. It is indicated for use by adult diabetic patients for use in the home and by healthcare professionals in the professional setting. The System is not intended to provide automated treatment guidance or decisions. The System is not indicated for the diagnosis or screening of diabetes.

2. **Special conditions for use statement(s):**

Prescription and Over the Counter Use

**H. Substantial Equivalence Information:**

1. Predicate device name(s) and 510(k) numbers:  
PC Care by i-SENS k100937
2. Comparison with Predicate Device:

<b>Substantial Equivalence Information</b>		
<b>Feature</b>	<b>Candidate Device: GHRS</b>	<b>Predicate Device: PC Care by i-SENS K100937</b>
Intended Use	The Genesis Health Record System is an accessory to blood glucose meters to assist in the review and evaluation of blood glucose test results and related information to aid in diabetes management. It is indicated for use by adult diabetic patients for use in the home and by healthcare professionals in the professional setting. The System is not intended to provide automated treatment guidance or decisions. The System is not indicated for the diagnosis or screening of diabetes.	Same
<b>Major Features of Device</b>		
Transfer data from a blood glucose meter to a database	Automatically, from device to a remote database wirelessly over a secure cellular network using CDMA technology.	Automatically from device to PC via a special USB cable

<b>Substantial Equivalence Information</b>		
<b>Feature</b>	<b>Candidate Device: GHRS</b>	<b>Predicate Device: PC Care by i-SENS K100937</b>
Data can be analyzed by user to display trends in graph form. Multiple types of reports can be displayed	Logbook, Logbook summary, Test history in graph formats, Trends over specified date range	Same
Data is stored in a Database	In a remote server	On the local PC
Results and reports can be shared with others	Authorized users can log on to MYGHR website and view results	Reports can be attached to email or printed out.
Parameters can be customized	Target ranges, dates various health parameters	Same
Installation of Program	Not required Site is internet based and accessed through a web browser	Installed using a CD
Computer System Requirements	Device using Windows, Mac, iPhone, Android or similar OS, with one of the following approved browsers installed: Internet Explorer 9 Mozilla Firefox 12 Apple iOS 5 Apple Safari 5.1 Google Chrome 19 Android Internet Browser 2.3	CPU: Minimum 300 MHZ Intel Pentium 2 Windows 95, Windows 98, Windows ME, Windows 2000, Windows XP, Windows Vista and Windows 7 Minimum free hard disk space: 60MB RAM 128MB or higher USB port required PC Care USB Cable Mouse and Keyboard Video monitor with 1024x768 pixel screen minimum and 256 colors CD-Rom drive optional printer
Access to DMS	Accessed via internet on any PC with internet connection and approved browser	From personal computer via program
Indication time of test	Describes tests: Normal (in-between meals), Before Meal, After Meal, Control Solution	Same

<b>Substantial Equivalence Information</b>		
Feature	Candidate Device: GHRS	Predicate Device: PC Care by i-SENS K100937
User Manual	Accessed online	On program installation CD

**I. Standard/Guidance Document Referenced (if applicable):**

- ISO 14971:2007 Medical devices - Application of risk management to medical devices
- IEC 62304:2006 Medical device software - Software life cycle processes
- IEC 60601-1-2 Medical Electrical Equipment- Part 1-2: General Requirements for Safety- Collateral standard: Electromagnetic Compatibility

**J. Performance Characteristics:**

The performance characteristics listed below as applicable, are presented in the specific glucose clearance under k121224.

- Analytical Performance:
  1. The performance characteristics listed below as applicable, were presented in the specific glucose meter clearance under k121224
    - a) *Accuracy:*  
See above statement under section J(1).
    - b) *Precision/Reproducibility:*  
See above statement under section J(1).
    - c) *Linearity:*  
See above statement under section J(1).
    - d) *Carryover:*  
See above statement under section J(1).
    - e) *Interfering Substances:*  
See above statement under section J(1).
  2. Other Supportive Instrument Performance Data Not Covered Above:
    - a) A human factors study was performed to assess usability of the GHRS system and data. Testing was conducted with 25 test patient users, 25 Genesis Health Technologies Blood Glucose Meter, Model TD-4123, and 4 healthcare professionals. Patients used the meter with control-solution only.

Another phase of testing was continued over a 3-week period in a simulated-use environment. Patients were asked to use the system as

they typically would in a real-world scenario. Patients were asked to take “sample” readings (using control solution) three times per day. 20 of the patients tested over a five day period, and 5 of the patients tested over a 3-week period. Patients were asked to complete a set of tasks in the online MyGHR system similar to those performed in the initial test session. Patients were asked to provide feedback on the system and submit the feedback at the end of the testing period.

At the end of the study, the meters were collected from the test patients by MyGHR employees. At this point, the data history on the meters was compared with the data stored in the MyGHR system (using the GHR-Admin portal). A comparison of the data, including reading type, glucose value, and reading date/time was tabulated to ensure 100% accuracy of the data uploaded from each meter.

These studies confirm that adults with average education and computer skills and no prior knowledge of the system can safely and accurately use the GHT BGM Meter (GHT-BGM-TD-4123) and the GHRs online web-based portal without direct instruction or training. The testing also confirmed that the meters and patients can be managed by healthcare professionals to track and view patient glucose readings and reports, and perform account and profile management. The study confirmed that the system is 100% accurate with respect to data accuracy and integrity when used by patients in an intended use environment.

- b) Bench Testing was performed using control solutions tested 20 times to automatically transmit data after each measurement on each of 2 Genesis Health Technologies Blood Glucose Meters, Model TD-4123 over the cellular network to 2 test account logins on the GHRs. All data fields, such as result, time, date, meter ID, including report and graphs were 100% accurate.
- c) Software documentation was reviewed and demonstrated that the device was developed under appropriate software lifecycle processes.
- d) Genesis Health Technologies Blood Glucose System owner’s manual cleared under k121224 was modified only to include information and instructions for the Genesis Health Record System. The sponsor provided the results of a Flesch-Kincaid readability assessment which indicated a Grade Level Score 6.6 of Genesis Health Technologies Blood Glucose System owner’s manual. The sponsor also provided the results of a Flesch-Kincaid readability assessment with Grade Level Score 9.4 obtained for the Genesis Health Record System owner’s manual.

- e) The sponsor provided a statement of conformity to IEC 60601-1-2, Medical Electrical Equipment- Part 1-2 and provided testing laboratory certification to Emission Test Compliance to Electromagnetic Environment-Guidance.

**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.