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

A. **510(k) Number:**
k091229

B. **Purpose for Submission:**
New submission for an accessory Data Management Software application for glucose meters

C. **Manufacturer and Instrument Name:**
EPS Bio Technology Corp.
GlucoManager Data Management Software

D. **Type of Test or Tests performed:**
Glucose data transmission

E. **System Descriptions:**

1. Device Description:
The GlucoManager Data Management Software enables users the ability to export data from the EasyMax N (k083099) glucose meter to a computer via a RS232 Cable. The GlucoManager Data Management Software enable users in review, analysis and evaluation of historical blood glucose test results to support diabetes management. The device is not intended to provide any diagnosis based upon patient results.

2. Principles of Operation:
Not Applicable

3. Modes of Operation:
Not Applicable

4. Specimen Identification:
Not Applicable

5. Specimen Sampling and Handling:
Not Applicable

6. Calibration:
Not Applicable

7. Quality Control:
Not Applicable

8. Software:

The GlucoManager Data Management Software is compatible with Microsoft® Windows® Vista, XP, Windows 2000, Windows 98,Windows Me operating systems
Hardware specifications:
- Intel(or Compatible) Pentium II 300 MHz processor or higher
- 32 Megabytes (MB) or greater of available random access memory (RAM)
- 20 MB of free hard disk space minimum
- An available Bluetooth module for glucose meter connection
- Compact disk (CD) drive
- Mouse

- 800 x 600 (or higher) resolution monitor
- EPS RS232 Download Cable

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

F. Regulatory Information:

1. Regulation Section:
   21CFR §862.1345 -Glucose test system.
   21CFR §-862.2100 - Calculator/data processing module for clinical use.
2. Classification:
   Class 2 and 1 respectively
3. Product Code:
   NBW, JQP
4. Panel:
   Chemistry (75)

G. Intended Use:

1. Indication(s) for Use:
   The GlucoManager Data Management Software (GDMS) is intended for use in home and clinical settings to aid people with diabetes and their health care professionals in the review, analysis and evaluation blood glucose test results to support effective diabetes management. The device is not intended to provide any diagnosis based upon patient results.
2. Special Condition for use Statement(s):
   Compatible meters: EasyMax N (k083099) meter

H. Substantial Equivalence Information:

1. Predicate device name(s)and 510(k) numbers:
   LifeScan's, In Touch Diabetes Management Software k984527
2. Comparison with Predicate Device:

Similarities

Element of Comparison	LifeScan IN TOUCH® Diabetes Management Software (k984527)	EPS GlucoManager Data Management Software (GDMS)
About User		
- Intended Use (S)	IN TOUCH® Diabetes Management Software can help healthcare professionals and people with diabetes monitor blood glucose levels. You and your healthcare professional can use IN TOUCH Software to plan meals, exercise, lifestyle, and medication	The GlucoManager Data Management Software (GDMS) is intended for use in home and clinical settings to aid people with diabetes and their health care professionals in the review, analysis and evaluation blood glucose test results to support

Element of Comparison	LifeScan IN TOUCH® Diabetes Management Software (k984527)	EPS GlucoManager Data Management Software (GDMS)
	to help control diabetes. IN TOUCH Diabetes Management Software lets you track and review blood glucose test results. This helps you keep your blood glucose levels stable.	effective diabetes management. The device is not intended to provide any diagnosis based upon patient results.
- Single User Use	Single and Multi-Patient	Single Patient
About Installation		
- Computer System Requirement	* A supported blood glucose meter, * CD-Rom drive * 100~200 MB minimum of free hard disk space while installation, 100 MB after installation * 128 MB minimum of free RAM, * Video monitor and adapter with at least 800 x 600 pixels and 256 colors, * Available 9-pin or 25-pin COM or USB port. * Operating system of Microsoft® Windows® 98, Windows® 2000 Professional, Windows® XP Home and Professional	* EasyMax N Blood Glucose Meter, * Compact Disk (CD) drive * 20 MB or greater of free hard disk space, * 32 MB or greater of free RAM, * 800 x 600 (or higher) resolution monitor, * Available 9-pin RS232 serial port. * Operating system of Microsoft® Windows® Me, Windows 98, Windows® 2000, Windows® XP, Windows® Vista
- Installation of Program	Installed using CD	Installed using CD
- Language Capabilities	English, Spanish	English
- Ability to Uninstall Program	Yes	Yes
- Ability to Link to Different Database Versions	Yes	Yes
- Technical Support	Yes	Yes, Customer Service Center Toll-Free Number: 1-866-203-2761
About Transmission		
- Auto-detect COM Port	Yes	Yes
- Cable Availability	Serial Cable, Cable available separately.	Serial Cable, Cable available separately.
- Capable of Uploading Data from Various	Software driver must be uploaded on the device or installed on PC.	Software driver must be uploaded on the device or installed on PC.

Element of Comparison	LifeScan IN TOUCH® Diabetes Management Software (k984527)	EPS GlucoManager Data Management Software (GDMS)
Devices		
About Operation		
- Ability to Access Program via Icon or Explorer	Yes	Yes
- Viewing the User's Manual	Yes, link provided via icon	Yes
- Copy Database to Separate File	Yes	Yes
- Copy Saved Database Back to Achieve Database	Yes	Yes
About Personal Settings		
- Unit of Blood Glucose	Choice of mg/dL or mmol/L	Pre-Set to mg/dL
About Report		
- Report Types	Logbook, Line Graph, Average Readings.	Log Book, Glucose Trend, Average Day, Average Week
About Modifying Results		
- Downloaded Results Cannot Be Edited or Deleted	Yes	Yes
- Ability to Modify Meter Average Results	No	No
About Patient and Therapy Management		
- Required Information on Use (Patient) Enter	No required information	No use (patient) enter

Differences

Element of Comparison	LifeScan IN TOUCH® Diabetes Management Software (k984527)	EPS GlucoManager Data Management Software (GDMS)
About Operation		
- Ability to Clear Meter Results in Memory and Set Mater Clock to a Specific Date and Time	Yes	No
- Ability to Email Report	Yes	No

Element of Comparison	LifeScan IN TOUCH® Diabetes Management Software (k984527)	EPS GlucoManager Data Management Software (GDMS)
from PC Directly from Program		
About Personal Settings		
- Ability to Display 12 or 24 Hour Clock Format and Change Date Format	Yes, mm/dd/yy or dd/mm/yy.	No
- Ability to Synchronize Meter Clock to PC Upon Download	Yes	No
- Ability to Personalize Target Ranges	Yes	No
- Ability to Set Default Target Range	Yes	No
- Ability to Enter Hypoglycemic Range	Yes	No
- Ability to Enter Insulin Regiment	Yes	No
- Ability to Set Default Favorite Report	Yes	No
- Ability to Default to Manufacturer Settings	Yes	No
About Report		
- Report Types	Data List, Data Statistics, Within Target, Standard Day, Histogram Chart, 14 Days Summary, Glucose & Insulin	No
About Modifying Results		
- Manual Entry	Yes	No
- Ability to Input Additional Information	Yes, insulin doses, carb data, exercise data, health notes, comments.	No
- Ability to Specify Complications Associated with Diabetes by Patient	Yes	No
- Specifying / Entering Medications / Insulin	Yes, up to three different medicines, insulin types	No

Element of Comparison	LifeScan IN TOUCH® Diabetes Management Software (k984527)	EPS GlucoManager Data Management Software (GDMS)
- Deleting Results, Patients and All Accompanying Records	Yes, only manual entry results may be deleted.	No
About Patient and Therapy Management		
- Search Patient Capability	Yes	No
- Diabetes Control	Yes, including insulin list, exercise, carbohydrate	No
- Doctor Information and Diabetes Educator Information	Yes, one doctor may be entered. one diabetes educator may be entered.	No
- Ability to Limit Result Selection by Last Transfer	Yes, with the exception of the In TOUCH Ultra.	No

I.   Standard/Guidance Document Referenced (if applicable):
IEC 62304:2006 Medical device software – Software life cycle process
ISO 14971:2007, Medical Devices – Application of Risk Management to Medical Devices

J.   Performance Characteristics:
   Glucose meter specific
   1.   Analytical Performance:
        a.   *Accuracy:*
             Not Applicable
        b.   *Precision/Reproducibility:*
             Not Applicable
        c.   *Linearity:*
             Not Applicable
        d.   *Carryover:*
             Not Applicable
        e.   *Interfering Substances:*
             Not Applicable
   2.   Other Supportive Instrument Performance Data Not Covered Above:

        To determine the accurate data transmission from the meter to PC, the sponsor demonstrated the performance of the GlucoManager Data Management Software to meet the evaluation protocol and acceptance criteria stated below.

Each test-set consisted of randomly selecting one of the ten glucose meters and conducting data transmission. The process was repeated until all the glucose meters were tested. All stored test results in glucose meters were recorded before conducting the data transmission. Acceptance criteria were that the transmitted data will not be different from the previous recorded data.

To determine the repeatability of data transmission from the meter to PC, the sponsor demonstrated the performance of the GlucoManager Data Management Software to meet the evaluation protocol and acceptance criteria stated below.

One glucose meter with 480 stored test results transmitted complete data set 100 times. Acceptance criteria were that the transmitted data will not be different from the previous recorded data. This protocol did not have any incorrect data.

A User acceptance Study using 106 subjects was conducted to evaluate the GlucoManager Data Management Software with the following objectives:

- To evaluate design and ease-of-use
- To document participant feedback on the features / functions
- To document Observer feedback on participant performance
- To validate that the user instructions are accurate and easy to follow
- To evaluate participant ratings with respect to features / functions
- To report any discrepancies (bugs/error messages) found during the evaluation

The subjects (Users) were required to have a minimum of basic computer skills and feel comfortable using a Windows-based Operating System.

Conclusions were based on the subjects' ability to demonstrate by usage and evaluation (rating) of features/functions (recorded as responses to 19 feature/function tests), their understanding of the applications of the software, their understanding of how to use the software, their comprehension of the contents of the instructions for use, as well as user assessment of ease-of-use based on a separate questionnaire.

Performance of each User was recorded and evaluated by EPS study administrators (Observers), who are familiar with proper use of GlucoManager Data Management Software. Observers rated each subject's performance using four general questions.

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.