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

A. 510(k) Number:
k111932

B. Purpose for Submission:
New submission for an accessory data management software application for cleared glucose meters.

C. Manufacturer and Instrument Name:
PositiveID Corporation
iglucose System

D. Type of Test or Tests performed:
Diabetes data management system

E. System Descriptions:

1. Device Description:
   The iglucose™ System is designed to assist individuals with diabetes with their record keeping management, by automatically tracking and storing historical blood glucose readings. It has been developed for home or health care facility settings as an aid in supporting diabetes management. iglucose™ is designed to connect to glucose meters and automatically transmit blood glucose reading(s) to a secure database. Users can then utilize the iglucoe™ diabetes management portal (web-based application) to view their blood glucose readings as well as to generate and display reports. At the user's discretion, authorized individuals can also view blood glucose readings and reports.

   More specifically, the iglucose™ System is comprised of the following:
   • iglucose™ Device
   • Secure Database
   •iglucose™ Diabetes Management Portal (web-based application)

2. Principles of Operation:
   The iglucose™ device is approximately the size of a cell phone and has a rechargeable battery. It connects to compatible FDA cleared glucose meters via a data cable and extracts data from a glucose meter. It then wirelessly (via the cellular network) transmits data (blood glucose readings, date and time) from a glucose meter to a secure database. Software used for the database enables the data to be viewable in an organized manner via the iglucose™ diabetes management portal (web-based application). At the user's discretion, the data can be communicated via email, SMS text message and/or fax.

Data can be displayed in a logbook form. In addition, data can be displayed and trended in reports that are in tabular and graphical formats such as line graphs, pie charts and histograms.

3. 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 ___ .
4. Specimen Identification:
   Meter controlled download to data manager
5. Specimen Sampling and Handling:
   Not Applicable
6. Calibration:
   Not Applicable
7. Quality Control:
   Not Applicable
8. Software:

   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 II and I respectively
3. Product Code:
   NBW - System, Test, Blood Glucose, Over the Counter
   JQP - Calculator/Data Processing Module, for Clinical Use
4. Panel:
   Chemistry (75)

G. Intended Use:

1. Indication(s) for Use:
   The iglucose™ System collects and transmits stored data from a variety of FDA cleared blood glucose meters such as the LifeScan® OneTouch® and Home Diagnostics™ True™ monitoring systems to a secure database via wireless cellular technology. Subsequently, blood glucose data can then be reviewed

through a web portal as an aid in supporting diabetes management. It is intended to be used in a home or health care facility settings.

The iglucose™ System does not measure, interpret or make decisions on the data that it conveys, nor is it intended to provide automated treatment decisions, or to be used as a substitute for professional healthcare judgment. All medical diagnosis and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.

2. Special Condition for use Statement(s):
   Over The Counter (OTC)

H. Substantial Equivalence Information:

1. Predicate device name(s)and 510(k) numbers:
   IDEAL LIFE Pod, k080538

2. Comparison with Predicate Device:

Attribute	**IDEAL LIFE Pod K080538**	**Subject Device (iglucose™ System)**
Indication(s) for Use / Intended Use	Same	The iglucose™ System collects and transmits stored data from a variety of FDA cleared blood glucose meters to a secure database via wireless cellular technology. Subsequently, blood glucose data can then be reviewed through a web portal as an aid in supporting diabetes management. It is intended to be used in a home or health care facility settings.
Connection to glucose meters	Wirelessly Short Range Radio System using Bluetooth and wired SmartCable	Data cable
Compatible glucose meters	Same	Same
Data Collection Software Functionality	Same	Same
Transmission to database	Telephone Line	Wireless Cellular
Power source	Wall power plug for Pod.	Wall power plug (100 to 240 VAC/ 50-60) and rechargeable batteryin iglucose™

Attribute	IDEAL LIFE Pod K080538	Subject Device (iglucose™ System)
Type of Telecommunications Technology used; Communication method with central server.	Telephone line (Pod with embedded modem)	Cellular Technology (iglucose™ device with embedded cellular module)
Method of Outbound communication of information	Data is viewed in a web-based application, sent via email. SMS text and fax.	Data is viewed in a web-based application, sent via email, SMS text and fax. No voice Response System.

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

IEC 60601-1-1:2000, Medical electrical equipment -- Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems.

J. Performance Characteristics:

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:
   A Human Factors study of 22 participants was performed to verify ease of use, label comprehension, meter data transfer in the hands of lay users. Additionally, meters are bench tested to verify data transfer compatibly and accuracy.

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**.**