NOV 10 2011 K111932

510(K) Notification	510 (k) SUMMARY	positive ID
Section: 5		
Doc # NA		
Confidential		

Section 5 510(k) SUMMARY

Date Prepared: June 30, 2011

Company Name and Address:

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Contact person: Triana Dorland

Device Name:

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.

Classification Name:

Classification:

Glucose Test System 21 CFR 862.1345 Product code: NBW

Class II

Predicate Devices:

1) MedApps Remote Patient Monitoring System, K062377, Product Code: NBW

2) IDEAL LIFE Pod, K080538, Product Code: NBW, JQP

Indications 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.

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)

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.

Summary of Characteristics Compared to Predicate Devices:

The Intended Use and Indications for Use of the predicate devices and the iglucose™ System are virtually the same and all are intended for over the counter use. Intended users are home users and health care providers.

The operation of the subject device is similar to the predicate devices in that the user connects the device to a compatible glucose meters and then initiates the transmission of glucose readings from the glucose meters to a central database. The user or healthcare provider can then access and view glucose readings using a web-based application. The features of the method of operation are described in the table below.

Attribute	**MedApps Remote Patient Monitoring System** **K062377**	**IDEAL LIFE Pod** **K080538**	**Subject Device (iglucose™ System)**
Connection to glucose meters	Wirelessly Bluetooth	Wirelessly	Data cable
Compatible glucose meters	510(k) cleared	Same	Same
Data Collection Software Functionality	Transmit data from sensor device to Central Database	Same	Same
Transmission to database	Cellular technology	Telephone Line	Same (as MedApps Predicate device)

The underlying technology of the iglucose™ System is similar to that of the predicate devices in that they all connect to compatible glucose meters and transmit the glucose readings to a secure central database. They each transmit data using wired or wireless telecommunication. The transmitted data can then be accessed and reviewed by users and healthcare providers. All devices supply historical readings, reports and graphs to the user.

Minor Differences:

There are four minor differences between the iglucose™ and the two predicate devices: 1. Connection to the glucose meters, 2. Power source, 3. Type of telecommunications technology used to communication method with central server and 4. Method of outbound communication of information. These are described in the table below.

Attribute	**MedApps Remote Patient Monitoring System** **K062377**	**IDEAL LIFE Pod** **K080538**	**Subject Device (iglucose™ Solution)**
Connection to glucose meters	Bluetooth and Cellular Technology	Short Range Radio System using Bluetooth and wired SmartCable	Data cable
Power source	Wall power plug for hub (120 VAC/50-60)	Wall power plug for Pod.	Wall power plug (100 to 240 VAC/ 50-60) and rechargeable battery in iglucose™
Type of Telecommunications Technology used; Communication method with central server.	Cellular Technology (Cell phone with embedded cellular module).	Telephone line (Pod with embedded modem)	Cellular Technology (iglucose™ device with embedded cellular module)
Method of Outbound communication of information	Stored in repository database for access by the healthcare provider and Interactive Voice Response System	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.

Summary of Testing:

Software:

Validation was performed as an output requirement from the analysis that led to the software being established as a Moderate Level of Concern. Some examples of testing performed: Home Page, Registration, Log-in Procedure, Administrative Area, device interfacing and data transmission. All tests passed.

Firmware:

Validation was performed as an output requirement from the analysis that led to the device being established as a Moderate Level of Concern. Some examples of testing performed: Power and initialization, network communication, glucose meters connection, battery testing. Also, integration testing was performed in order to test the interoperability and function of the device. All tests passed.

Mechanical:

Durability testing was performed on the power cord and data cable, and all tests passed.

Usability Study:

A usability validation was conducted in May, 2011. Eighteen users with Type 1 or Type 2 diabetes participated in the study. The test goals for the iglucose™ System usability study were to validate: the effectiveness of the user manual, creating accounts, logging in, connections, viewing the readings, and to verify that the validation success criteria were met.

Overall the usability test was successful, and demonstrated that the iglucose™ System is easy to use and safe for the purpose for which it is intended.

Conclusion:

Results of software, firmware and mechanical testing indicate the device performs as expected, and meets all its specification requirements. Usability testing demonstrates the device is easy to use and safe for its intended purpose.

PositiveID Corporation believes that based on the indications for use, descriptive information, and test results provided in this submission, the iglucose™ System has been shown to be

equivalent in technology, method of operation, functional performance and indications for use to its predicate devices, and is safe for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

PositiveID Corporation
c/o Edward Valdez
Quality Systems Manager
1690 S. Congress Avenue, Suite 200
Delray Beach, FL 33445

NOV 10 2011

Re: k111932
Trade/Device Name: iglucose System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system.
Regulatory Class: II
Product Code: NBW, JQP
Dated: October 11, 2011
Received: October 17, 2011

Dear: Mr. Valdez:

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 such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 4 INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: iglucose™ System

Indications 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.

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Prescription Use _____ AND/OR Over-The-Counter Use __X__

21 CFR Part 801 Subpart D 21 CFR 801 Subpart C

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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