

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

A. 510(k) Number:

k080538

B. Purpose for Submission:

New submission for the addition of whole blood glucose data acquisition and transmission to previously cleared blood pressure data acquisition and transmission device (k060504).

C. Measurand:

Whole blood glucose

D. Type of Test:

The IDEAL LIFE Pod is a wireless modem accessory that wirelessly receives data from IDEAL LIFE devices and transmits the data to the IDEAL LIFE website. The IDEAL LIFE database is updated securely with the user's information, which is available for review via secure Internet access. Using the Pod, an individual can more easily view and track their blood pressure (cleared under k060504), blood glucose, and/or body weight (510(k) exempt) information.

E. Applicant:

Ideal Life Inc.

F. Proprietary and Established Names:

Ideal Life POD (Model ILP 0001)

G. Regulatory Information:

1. Regulation section:

21CFR Sec.- 862.1345-Glucose test system

21CFR Sec.-862.2100 - Calculator/data processing module for clinical use

2. Classification:

Class 2

3. Product code:

NBW - System, Test, Blood Glucose, Over the Counter

JQP-Calculator/Data Processing Module, For Clinical Use

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indication(s) for use below.

2. Indication(s) for use:

The IDEAL LIFE Pod™ receives data wirelessly from IDEAL LIFE devices to transmit over the Internet or common telephone lines from the user's home. The Pod is an optional accessory to IDEAL LIFE devices, including the GlucoManager™, the BP-Manager™ and/or the Body Manager™. The Pod is intended to aid people at home and health care professionals to review and evaluate historical blood glucose, weight and blood pressure test results, to support effective health care management.

The IDEAL LIFE Pod makes no interpretation, evaluation, medical judgment or recommendations for treatment. This device is not intended as a substitute for medical care.

3. Special conditions for use statement(s):

For over the counter use

4. Special instrument requirements:

IDEAL LIFE GlucoManager (k080283) glucose meter

I. Device Description:

The IDEAL LIFE Pod is used to upload the data stored in the memory of various IDEAL LIFE devices to the IDEAL LIFE website via a common telephone line or via the Internet. Two modes of transmission of data are possible: (1) via the telephone line which connects to an RJ11 jack on the IDEAL LIFE Pod, or (2) via the Internet through the Ethernet cable attached to the RJ45 jack on the IDEAL LIFE Pod.

J. Substantial Equivalence Information:

1. Predicate device name(s):

IN TOUCH Diabetes Management Software System
Ideal Life POD (Model ILP 0001A Version 1)

2. Predicate 510(k) number(s):

k984527 and k060504

3. Comparison with predicate:

	Predicate 1 K984527, IN TOUCH Diabetes Management Software System	New Device IDEAL LIFE POD (Model ILP 0001A Version 2)	EQUIVALENT OR DIFFERENT Impact on S&E
Indication for Use	The IN TOUCH Diabetes Management Software System is intended for use in home and clinical settings to aid people with diabetes and health care professionals in the	The IDEAL LIFE Pod™ receives data wirelessly from IDEAL LIFE devices to transmit over the Internet or common telephone lines from the user's home. The Pod is an	Same as Predicate 1,

	review, analysis, and evaluation of historical blood glucose test results to support effective diabetes management. It is intended for use as an accessory to LifeScan Brand blood glucose monitoring systems with data management capabilities.	optional accessory to IDEAL LIFE devices, including the GlucoManager™, the BP-Manager™ and/or the Body Manager™. The Pod is intended to aid people at home and health care professionals to review and evaluate historical blood glucose, weight and blood pressure test results, to support effective health care management. The IDEAL LIFE Pod makes no interpretation, evaluation, medical judgment or recommendations for treatment. This device is not intended as a substitute for medical care.	
	Predicate 1 K984527, IN TOUCH Diabetes Management Software System	New Device IDEAL LIFE POD (Model ILP 0001A Version 2)	EQUIVALENT OR DIFFERENT
Intended Use	Blood Glucose Analyzer	Blood Glucose Analyzer and Physiological Signal Transmitter	Equivalent
Users	General adult population	General adult population	Equivalent
Prescription Status; Environment of Use	Non-prescription Use in a clinical or non-clinical environment	Non-prescription Use in a clinical or non-clinical environment	Equivalent
Part of a System	Use with LifeScan Brand blood glucose monitors	Use with IDEAL LIFE BP-Manager™, Gluco-Manager™, Body Manager™	Equivalent
Purpose of the System	Transmission of information, access to Internet-based database and personal data management system, ability to view data and graphical analysis of the data, enter personal information and reminders (diet and exercise, medications, notes), enter alert levels.	Same	Equivalent
	Predicate 1	New Device	EQUIVALENT

	K984527, IN TOUCH Diabetes Management Software System	IDEAL LIFE POD (Model ILP 0001A Version 2)	OR DIFFERENT	
Display	N/A	Same as previous Pod	different from Predicate 1	
Automatic	Automatic after connection	Same	Equivalent	
Communication method from device	Hard wire connection of blood glucose monitor directly to personal computer	Same	different from Predicate 1	
Power Source	N/A	Same		
Operating Temp/Humidity		Same		
Storage Temp/ Humidity		Same		
Console Wt.		Same		
Size		Same		
Connectors		Same Same RJ45 jack for Ethernet cable connection for data transmission		Different – RJ11 new adapter
		Predicate 2 K060504 IDEAL LIFE POD (Model ILP 0001A Version 1)	New Device IDEAL LIFE POD (Model ILP 0001A Version 2)	EQUIVALENT OR DIFFERENT Impact on S&E
Indication for Use	The IDEAL LIFE POD™ is an optional accessory to the IDEAL LIFE BP-MANAGER™ and is a transmitter that is intended to transmit data obtained by the IDEAL LIFE BP-MANAGER™ to the internet via common telephone lines from the user's home setting. The IDEAL LIFE POD™ is an optional accessory designed to assist in the management of user information. This device makes no interpretation, evaluation, medical judgments or recommendations for treatment. Clinical judgment and experience are required to check or interpret information transmitted. This device is	The IDEAL LIFE Pod™ receives data wirelessly from IDEAL LIFE devices to transmit over the Internet or common telephone lines from the user's home. The Pod is an optional accessory to IDEAL LIFE devices, including the GlucoManager™, the BP-Manager™ and/or the Body Manager™. The Pod is intended to aid people at home and health care professionals to review and evaluate historical blood glucose, weight and blood pressure test results, to support effective health care management. The IDEAL LIFE Pod makes no interpretation, evaluation, medical judgment or recommendations for treatment.	Same as Predicate 1, Different (Expanded) from Predicate 2) Does this impact S&E? No, because testing has demonstrated that new device meets Intended Use.	

	not intended as a substitute for medical care.	This device is not intended as a substitute for medical care.	
	Predicate 2 K060504 IDEAL LIFE POD (Model ILP 0001A Version 1)	New Device IDEAL LIFE POD (Model ILP 0001A Version 2)	EQUIVALENT OR DIFFERENT
Intended Use	Physiological Signal Transmitter	Blood Glucose Analyzer and Physiological Signal Transmitter	Equivalent
Users	General adult population	General adult population	Equivalent
Prescription Status; Environment of Use	Non-prescription Use in a non-clinical environment	Non-prescription Use in a clinical or non-clinical environment	Equivalent
Part of a System	Use with IDEAL LIFE BP-Manager™	Use with IDEAL LIFE BP-Manager™, Gluco-Manager™, Body Manager™	Equivalent
Purpose of the System	Same	Same	Equivalent
	Predicate 2 K060504, IDEAL LIFE POD (Model ILP 0001A Version 1)	New Device IDEAL LIFE POD (Model ILP 0001A Version 2)	EQUIVALENT OR DIFFERENT
Display	3-LED's	Same as previous Pod	Equivalent to Predicate 2, different from Predicate 1
Automatic	Automatic after connection	Same	Equivalent
Communication method from device	Wireless RF protocol	Same	Equivalent to Predicate 2, different from Predicate 1
Power Source	AC Adapter or AA batteries	Same	
Operating Temp/Humidity	10°C to 40°C/below 85% RH	Same	
Storage Temp/ Humidity	-5°C to 50°C/below 90% RH	Same	
Console Wt.	142 g. without batteries	Same	
Size	120mm W x 105mm D x 30mm H	Same	
Connectors	AC adapter jack for electrical power RJ11 jack (telephone line transmission)	Same Same RJ45 jack for Ethernet cable connection for data transmission	

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

- ISO 15197; In vitro diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus, 2003
- ANSI/AAMI/ ISO 14971, Medical Devices – Application of risk management to medical devices, 2007.
- ANSI C63.4; Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz, 2003.

L. Test Principle:

The IDEAL LIFE Pod accessory to a compatible glucose meter the IDEAL LIFE Gluco-Manager Model GMM 0001, which uses specific test principles, the subject of k080283.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
see above associated device
 - b. *Linearity/assay reportable range:*
see above associated device
 - c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
see above associated device
 - d. *Detection limit:*
see above associated device
 - e. *Analytical specificity:*
see above associated device
 - f. *Assay cut-off:*
see above associated device
2. Comparison studies:
 - a. *Method comparison with predicate device:*
see above associated device
 - b. *Matrix comparison:*
Not Applicable
3. Clinical studies:
 - a. *Clinical Sensitivity:*
Not Applicable
 - b. *Clinical specificity:*
Not Applicable
 - c. *Other clinical supportive data (when a. and b. are not applicable):*
User testing of the POD was conducted to determine:
 1. If the POD and Gluco-Manager are easy to use and function as planned when the user is provided only the instructions and materials that would be available if a person were to purchase the devices; and

2. To verify that test data transmitted with (a) the POD connected via the RJ-11 telephone jack, and (b) the POD connected via the RJ-45 Ethernet cable are user friendly and provide the expected Gluco-Manager output on the Internet.

The goal was to select subjects who have never used these devices, who have varying educational levels, and who range in age from 18 to 70+ years. Twenty (20) subjects were enrolled in this study.

Inclusion Criteria:

1. Male and female patients aged 18 to 70+ years.
2. Subjects must be able to read English and must be physically able to conduct the test by themselves.
3. Subjects must have some familiarity with computers, as the use of the two devices with a computer and Internet-based system is central to the study.
4. Subjects must agree to sign the Informed Consent document.
5. Subjects will not be paid for their participation in this study.

Exclusion Criteria:

1. Subjects who have used either of these IDEAL LIFE devices before will be excluded from the trial.

Evaluation

Each Study Subject was provided with the following:

- One POD
- One Gluco-Manager
- One Ethernet cable
- One telephone cable
- Pod and Gluco-Manager Instruction Manuals
- Written Instructions
- Survey parts 1 and 2

Study Subjects were instructed to follow the Instruction Manual(s) to set up the Gluco- Manager and Pod. The Instruction Manuals provide a toll-free number to register the Pod and to receive a user name and password. If the Study Subject asked questions of IDEAL LIFE staff at the time that the toll-free telephone number is called for product registration, questions will be allowed as this will be standard procedure during actual device use.

Seven data sets are preloaded in the Gluco-Manager and the subjects transmitted preloaded data using the Modem/RJ-11 jack setup and then view their data on the Internet. After this process was completed, Part 2 of

the evaluation was completed to evaluate the usability of the devices and the accuracy of the data transmitted. At the end of the user questions, the subjects were directed to repeat this process using the Ethernet connection. Subjects transmitted preloaded data using the Ethernet/RJ-45 jack setup and then viewed their data on the Internet. After this process was completed, Part 3 of the evaluation was completed to evaluate the usability of the devices and the accuracy of the data transmitted.

Descriptive statistics were used to analyze the mean and standard deviation of VAS scores, as well as the coefficient of variation (SD/Mean). Comments of study subjects were analyzed to determine if changes to the Instruction Manual or the device are required or would be beneficial. A log of telephone calls and questions was maintained for the same purpose. Adverse events, if any, were processed according to IDEAL LIFE MDR Reporting Procedure 902P.

Applicant's Analysis and Conclusions

The Pod is a "Plug-N-Play" device that is, by design, simple to set up and to use. Validation and Verification testing conducted by IDEAL LIFE engineers during development and prior to finalizing the software and hardware design, including this Usability Test and one smaller previous test. The user test was designed to test the usability of the Pod with the Gluco-Manager for naive users, to reflect initial operation by a new purchaser of the devices and identify potential design flaws in actual use situations.

Average scores for all questions were below "2" on a scale of 1 to 10, 1 being the most favorable response. All open comments were positive.

In conclusion, the positive response to this user test and a previous usability test indicates that there are no areas of concern about the usability of the device by the intended users.

4. Clinical cut-off:
Not Applicable
5. Expected values/Reference range:
See above associated device

N. Instrument Name:

Ideal Life POD (Model ILP 0001)

O. System Descriptions:

1. Modes of Operation:

The device is for data transmission the communication of the Pod with compatible IDEAL LIFE devices is shown using wireless Bluetooth technology. After the data from these devices is transmitted to the Pod, the Pod acts like a modem to communicate through the user's telephone line cord (using the LINE connector, white in the photo below) or over the Internet (using the Ethernet connector via an RJ45 connector, red in the photo below).

Model	IDEAL LIFE Model ILP 0001, Version 2
Display	3 LED's
Power Source	AC adapter
Operating Temperature/Humidity	10°C to 40°C / <85% relative humidity
Storage Temperature/Humidity	-5°C to 50°C / <90% relative humidity
Console Weight	Approximately 142 g without batteries
Outer Dimensions	Approximately 120mm W × 105mm D × 30mm H
Connectors	AC adapter jack for electrical power; USB port
	RJ11 jack marked "line" for telephone line transmission of data to IDEAL LIFE
	RJ11 jack marked "phone" for connection of user's telephone
	RJ45 jack for Ethernet cable connection for transmission of data over the Internet
Frequency Range	2400 to 2483.5 MHz
Channel Band Width (99%)	840 kHz
Conducted Output Power	1.28 dBm

2. Software:

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

Yes or No

3. Specimen Identification:

Glucose meter controlled, by time and date stamp

4. Specimen Sampling and Handling:

Not Applicable

5. Calibration:
Not Applicable

6. Quality Control:
Not Applicable

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:

The applicant performed the following two sets of test scripts:

Dial up connection

This test script was to ensure that “Gluko-Manager” (GMM) readings are correct and can be displayed on the Ideal life Website. POD-2N dial up connection was used to transmit readings to the Ideal Life DB. This Test Case was a combination of Hardware Test for the device “Gluko-Manager” (GMM) and System Test for the Web-Based Application.

All executed Test Cases have the status - PASS

Internet connection

This test script was to ensure that “Gluko-Manager” (GMM) Readings are correct and can be displayed on the Ideal life Website. POD-2N internet connection was used to transmit readings to the Ideal Life DB. The Test Case was a combination of Hardware Test for the device Gluko-Manager” (GMM) and System Test for the Web-Based Application.

All executed Test Cases have the status - PASS

Q. Proposed Labeling:

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

R. Conclusion:

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