

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

A. 510(k) Number:

k070559

B. Purpose for Submission:

New submission for a glucose meter accessory to transmit data to compatible access points such as a personal computer or cellular phone with Bluetooth capability.

C. Manufacturer and Instrument Name:

Polymap Wireless

Polymap PWR-08-03

D. Type of Test or Tests performed:

Not Applicable

E. System Descriptions:

1. Device Description:

The Polymap PWR-08-03 is a battery-powered, plug-in accessory to the LifeScan OneTouch Ultra Blood Glucose Monitor. It acts as a remote unit to transmit data from the meter to a compatible access point, such as a Nokia Model 6620 cell phone or other compatible access point. The PWR-08-03 plugs into a port on the glucose meter. When a glucose reading is taken and the strip withdrawn from the meter, the PWR-08-03 turns on automatically, accepts the data, and transmits it wirelessly to the compatible Access Point. The Access Point may display the data and/or send the encrypted data via cell or land telephone lines to a computer server.

The access point can be a compatible cell phone, personal computer, or other device having Bluetooth capability. This allows glucose readings to be monitored from a remote location. The glucose readings transmitted by the Polymap glucose accessory are intended to be used for monitoring and historical trending. Clinical judgment and experience are required to check and interpret the information delivered. The unit does not transmit any alarms.

The device hardware platform is a Cambridge Silicon Radio BC02-Ext chip with XAP2 processor. The programming language used is C.

The PWR-08-03 will be sold only through approved groups who can offer service support. It will be advertised: to physicians; in a variety of publications, and; on the Polymap website which will direct interested users to contact one of the approved support groups that Polymap has identified. Users may contact Polymap directly, or go to the Polymap website. A support technician from one of the approved groups will visit the user, answer questions about the PWR-08-03, validate that it works properly with the user's particular access point, and validate accurate data transmission to the monitoring site.

2. Principles of Operation:
Not Applicable
3. Modes of Operation:
Transmits data over a wireless Bluetooth link from a Lifescan OneTouch Ultra Blood Glucose Monitor to a compatible server.
4. Specimen Identification:
Glucose meter generated – unique unit ID
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 Sec.- 862.1345-Glucose test system.
2. Classification:
Class II
3. Product Code:
NBW - SYSTEM, TEST, BLOOD GLUCOSE, OVER THE COUNTER
4. Panel:
Chemistry (75)

G. Intended Use:

1. Indication(s) for Use:
The Polymap PWR-08-03 is a remote communications link intended to be used to wirelessly transmit glucose meter readings from a Blood Glucose Monitor to a compatible access point or cellular phone, such as the Nokia 6620. The device does not send any real time alarms. Clinical judgment and experience are required to check and interpret the information delivered.
2. Special Condition for use Statement(s):
Prescription use

H. Substantial Equivalence Information:

1. Predicate device name(s) and 510(k) numbers:
e-San Bluetooth Cradle - k052343
2. Comparison with Predicate Device:

	Predicate	Polymap PWR-08-03
Intended Use/ indications	Transmit data between monitoring devices and enabled cell phone	Transmit data between a monitoring device and enabled cell phone or other compatible device
Users	Patient & Healthcare provider	Patient & Healthcare provider
Site of use	In the home	In the home
Prescription	OTC	Sold through approved groups who set up the system
System description	Transmitting device that sends data from a glucose meter to an access point	Transmitting device that sends data from a glucose meter to an access point
Connection	Wired connection between glucometer and device. Wireless connection between glucometer and access point	Wired connection between glucometer and device. Wireless connection between glucometer and access point
Data Transmission	Cellular connections	Residential telephone lines or cellular connections
Patient interactions	Press button to start the data transmission	None
Monitoring devices	Blood Glucose Meter	Blood Glucose Meter
Wireless link	Class II Bluetooth radio	Class I Bluetooth radio
Power	Battery	Battery
Range	10 Meters	100 Meters
Alarms	None	None

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

- IEC 60601-1-1:2000, Medical Electrical Equipment - Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems.
- IEC 60601-1-2:2001 Medical Electrical Equipment - Part 1-2: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests
- ISO 14971:2000, Medical devices - Application of risk management to medical devices

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 Usability study was conducted to answer the following questions:

- 1. Can users understand and follow the Instructions for Use and successfully set up and use the product in actual use? Do any outstanding usability issues affect device performance?
- 2. Does the configured glucose meter result match the transmitted data?
- 3. Are all data transmitted, e.g., test results, date, time, etc., accurate?

The study demonstrates users are able to successfully follow the Instructions for Use and use the device. No outstanding usability issues were discovered. In addition, the PWR-08-03 accurately transmits the glucose readings and other pertinent information such as date and time. Placing the Lifescan OneTouch Ultra glucose meter into the carrying pouch and attaching the PWR-08-03 lead to it does not impede or interfere with use of the meter.

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.