

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

A. 510(k) Number:

k091296

B. Purpose for Submission:

This submission is for a modification to a previously cleared device (k070559). This glucose meter accessory is intended to transmit data to compatible access points such as a personal computer or cellular phone with Bluetooth capability.

C. Manufacturer and Instrument Name:

Manufacturer: Polymap Wireless, LLC.

Instrument Names: Polytel GMA models PWR-08-06, PWR-08-07, and PWR-08-09

D. Type of Test or Tests Performed:

Not applicable.

E. System Descriptions:

1. Device Description:

The Polytel PWR-08-06 GMA is a battery-powered, plug-in accessory to the Lifescan OneTouch Ultra, OneTouch Ultra 2, OneTouch UltraMini, and OneTouch Select Blood Glucose Monitors. The Polytel PWR-08-07 GMA is a battery-powered, plug-in accessory to the Bayer Contour Blood Glucose Monitors. The Polytel PWR-08-09 GMA is a battery-powered, plug-in accessory to the Abbott FreeStyle Freedom Lite and FreeStyle Lite Blood Glucose Monitors. Each of these devices acts as a remote unit to transmit data from the meter to a compatible access point, such as a Nokia Model N73 cell phone. The GMA plugs into a port on the glucose meter. In the case of the PWR-08-06, when a glucose reading is taken and the strip withdrawn from the meter, unit turns on automatically, accepts the data, and transmits it wirelessly to the compatible Access Point. The Access Point then sends the encrypted data via cell or land telephone lines to a computer server. Due to the electrical design of the Bayer and Abbott glucose meters, both the PWR-08-07 and PWR-08-09 require the user pressing a button to initiate data transmission.

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 Polytel 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 BlueCore4-Ext radio chip with 1MB of flash memory.

The GMA will be sold both through approved groups who can offer service support and OTC. 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 contact the user, answer questions about the GMA, 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 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 applicant's Hazard Analysis and Software Development processes for this line of product types:
Yes____X____ or No_____

F. Regulatory Information:

1. Regulation section:
21 CFR § 862.1345
2. Classification:
Class II
3. Product code:
NBW
4. Panel:
Chemistry (75)

G. Intended Use:1. Indication(s) for Use:

The Polytel GMA (models PWR-08-06, PWR-08-07, and PWR-08-09) are remote communications link devices intended to be used to wirelessly transmit glucose meter readings from a compatible Blood Glucose Monitor to a compatible cellular phone, such as the Nokia N73 or access point, such as the Polytel APT. The receiving device, in turn, sends the readings to the healthcare provider in another location. The device does not send any real-time alarms. Clinical judgment and experience are required to check and interpret the information delivered.

2. Special Conditions for Use Statement(s):

For prescription and over-the-counter use.

H. Substantial Equivalence Information:1. Predicate Device Name(s) and 510(k) numbers:

k061328 – eSan, Ltd. Think Plus (t+) diabetes management system

k070559 – Polymap Wireless LLC Polymap PWR-08-03

2. Comparison with Predicate Device:

Similarities			
Item	Device	eSan Predicate	PWR-08-03 Predicate
Users	Patient & Healthcare provider	Patient & Healthcare provider	Patient & Healthcare provider
Site of use	In the home	In the home	In the home
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	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	Wired connection between glucometer and device. Wireless connection between glucometer and access point
Monitoring Devices	Blood Glucose Meter	Blood Glucose Meter	Blood Glucose Meter
Power	Battery	Battery	Battery
Alarms	None	None	None

Differences			
Item	Device	eSan Predicate	PWR-08-03 Predicate
Intended Use/indications	Transmit data between a monitoring device and enabled cell phone or other compatible device	Transmit data between monitoring devices and enabled cell phone	Transmit data between a monitoring device and enabled cell phone or other compatible device
Prescription/OTC	Prescription/OTC	OTC	Prescription Sold through approved groups who set up the system
Data Transmission	Residential telephone lines or cellular connections	Cellular Connections	Residential telephone lines or cellular connections
Patient interactions	PWR-08-06: None PWR-08-07, PWR-08-09: press button to start transmission	Press button to start the data transmission	None
Wireless link	Class II Bluetooth radio	Class II Bluetooth radio	Class I Bluetooth radio
Storage	Fits inside original zippered case	Not addressed	Fits inside original zippered case
Range	10 meters	10 Meters	100 Meters

I. Special Control/Guidance Document Referenced (if applicable):

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems, 2004
- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests, 2005
- 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 user study was performed and found to be acceptable under k070559. A new user study is not required under this submission because the modifications made to the device are not expected to affect user functions.

Reading level analyses were performed for the user manuals. All are below an 8th grade level.

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.