

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

A. 510(k) Number:

k073231

B. Purpose for Submission:

Modification to previously cleared device to enable radio frequency transmission of blood glucose results to compatible Medtronic MiniMed devices such as the Paradigm REAL-Time insulin infusion pumps and the Guardian REAL-Time glucose monitor.

C. Measurand:

Whole blood glucose

D. Type of Test:

Quantitative (glucose oxidase)

E. Applicant:

LifeScan, Inc.

F. Proprietary and Established Names:

OneTouch UltraLink Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1345 Glucose Test System

2. Classification:

Class II

3. Product code:

NBW – System, Test, Blood Glucose, Over the Counter
CGA – Glucose Oxidase, Glucose

4. Panel:

75, Clinical Chemistry

H. Intended Use:

1. Intended use(s):

See Indications for Use below

2. Indication(s) for use:

The OneTouch UltraLink Blood Glucose Monitoring System is intended to be used for self-testing outside the body (*in vitro* diagnostic use) for the quantitative measurement of glucose in fresh capillary whole blood obtained from the finger, forearm or palm. The OneTouch UltraLink System is intended for use by people with diabetes in a home setting and by healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control.

The OneTouch UltraLink Blood Glucose monitor may be used to transmit glucose values to appropriate MiniMed Paradigm and Guardian REAL Time devices using radio frequency communication.

3. Special conditions for use statement(s):

- Not for neonatal use
- Not for screening or diagnosis of diabetes mellitus
- Alternative site testing is for use at times of steady state only
- For Over-the-Counter use
- Not for use in critically ill patients or those in hyperosmolar state

4. Special instrument requirements:

One Touch UltraLink Blood Glucose Meter

I. Device Description:

The One Touch UltraLink Blood Glucose Monitoring System consists of the OneTouch UltraLink blood glucose meter, OneTouch Ultra test strips, and OneTouch Ultra control solutions.

J. Substantial Equivalence Information:

1. Predicate device name(s):

OneTouch Ultra 2 Blood Glucose Monitoring System

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

k053529

3. Comparison with predicate:

Similarities		
Item	Subject Device	Predicate
Detection method	Amperometry	same
Enzyme	Glucose oxidase	same
Calibration	Plasma equivalent	same
Reaction time	5 seconds	same
Measurement range	20-600 mg/dL	same
Hct range	30-55%	same

Differences		
Item	Device	Predicate
Radio Frequency (RF) communication	yes	no
Backlight on meter display	no – removed to preserve adequate power supply for RF feature without largely increasing meter dimensions	yes

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

ISO 14971, Medical devices, Application of risk management to medical devices

ISO 10993, Biocompatibility evaluation of medical devices – Part 1: Evaluation and Testing

IEC 61010-1, Safety requirements for electrical equipment for measurement, control and laboratory use; Part1, General requirements

IEC 61010-2-101, Safety requirements for electrical equipment for measurement, control and laboratory use; Part2-101, Particular requirements for in vitro diagnostic (IVD) medical equipment

IEC 60529, Degrees of protection provided by enclosures (IP Code)

IEC 61326, Electrical equipment for measurement, control and laboratory use – EMC requirements

CLSI EP6-A, Evaluation of the linearity of quantitative measurement procedures: A

statistical approach

L. Test Principle:

To perform a test, the test strip is inserted into the monitor. A drop of blood is applied to the end of the strip and automatically drawn into the sample chamber. Glucose measurement is based on electrical current caused by the reaction of glucose in the sample with the reagents contained on the strip. The current resulting from this enzymatic reaction is proportional to the glucose concentration in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Repeatability was assessed by assaying venous blood samples adjusted to 5 glucose concentrations (40, 100, 130, 200 and 300 mg/dL). A total of 500 repetitions were run on each of 2 test strip lots on 10 meters (10 repetitions per meter, per interval). The mean, SD and %CV were calculated for each lot at each glucose level. All SD and %CV results were within the sponsor's acceptance limit of 5mg/dL and 5% respectively.

Intermediate precision was assessed by assaying 200 repetitions of each of 3 levels of control material (40, 120, and 350 mg/dL) on 2 test strip lots and 10 meters, over a period of 11 days by 8 operators. All SD and %CV results were within the sponsor's acceptance limit of 5mg/dL and 5% respectively.

b. Linearity/assay reportable range:

Unpooled venous blood collected from nine donors was adjusted to 7 glucose levels (20, 100, 200, 300, 400, 500, and 600mg/dL). Each concentration was measured with 16 replicates on each of 2 test strip lots and run on 8 meters over a period of 3 days. The results were as follows:

$$\text{Lot 1} \quad y = 0.02009x + 0.451, r^2 = 0.999$$

$$\text{Lot 2} \quad y = 0.02014x + 0.405, r^2 = 1.000$$

	Target value	Average YSI	Average plasma equivalent YSI	Average plasma equiv UltraLink	SD
Lot 1	20	22.79	25.24	25.43	2.13
	100	101.48	112.39	107.81	3.27
	200	201.42	223.09	220.81	11.53
	300	301.61	334.07	340.10	16.36
	400	405.01	448.63	452.19	20.28
	500	510.63	565.59	575.72	24.39
	600	604.32	669.32	668.96	26.57
Lot 2	20	22.79	25.24	25.39	2.15
	100	101.48	112.39	108.54	3.71
	200	201.42	223.09	220.98	11.71
	300	301.61	334.07	342.38	17.10
	400	405.01	448.63	452.33	21.21
	500	510.63	565.59	572.63	27.66
	600	604.32	669.32	664.01	27.73

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Established in predicate submission (k053529)

d. *Detection limit:*

Established in predicate submission (k053529) as 20 – 600 mg/dL

e. *Analytical specificity:*

Established in predicate submission (k053529)

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

The sponsor conducted a study to demonstrate equivalence between the proposed device and the predicate (Ultra 2 System meter). A total of 400 venous whole blood samples were adjusted to 5 glucose levels (20, 70, 240, 450, and 600 mg/dL) and tested on 16 subject and 16 predicate devices. The sponsor's acceptance criteria was that the mean bias difference of the UltraLink from the Ultra 2 would be within 3 mg/dL or 4%, whichever was greater, with 95% confidence. The results were as follows:

Glucose level	bias from Ultra 2
20	0.09 mg/dL
70	-0.62 mg/dL
240	-0.38 %
450	-0.27 %
600	-0.28 %

The sponsor also conducted a system accuracy study, comparing the UltraLink System to the YSI 2300 Analyzer. In this study, two samples from each of 103 subjects, ranging from 47- 402 mg/dL were tested with 3 test strip lots on 12 meters over 12 days. The results, presented in the format recommended by ISO 15197, were as follows:

For glucose concentrations < 75 mg/dL:

within \pm 5 mg/dL	within \pm 10 mg/dL	within \pm 15 mg/dL
61%	94.4%	100%

For glucose concentrations \geq 75mg/dL:

within \pm 5%	within \pm 10%	within \pm 15%	within \pm 20%
34.7	68.3	91.3	98.8

b. Matrix comparison:

The alternative sampling site performance from the palm and forearm was established in predicate submission (k053529).

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):

A lay user performance study was conducted with 93 subjects at two study sites. The subjects were briefed on the study procedures and requirements but received no training or instruction on the use of the UltraLink System other than copies of the device labeling. The subjects obtained their own fingerstick samples and ran the test, and then the healthcare professionals obtained a second fingerstick sample. The range of samples tested was 60-398 mg/dL. The results were as follows:

Lay user vs YSI $y = 0.986x - 6.04, r = 0.974$
HCP vs YSI $y = 0.985x - 4.44, r = 0.978$

The results, presented in the format recommended by ISO 15197, were as follows:

For glucose concentrations < 75 mg/dL:

	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
lay	50.0%	100%	100%
HCP	33.3%	66.7%	100%

For glucose concentrations ≥ 75 mg/dL:

	within $\pm 5\%$	within $\pm 10\%$	within $\pm 15\%$	within $\pm 20\%$
lay	34.3	63.5	86.2	95.6
HCP	34.6	72.0	90.7	98.4

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The labeling presents expected blood glucose levels for people without diabetes as follows: (referenced from Joslin Diabetes Manual)

before breakfast	70-105 mg/dL
before lunch or dinner	70-110 mg/dL
1 hour after meals	< 160 mg/dL
2 hours after meals	< 120 mg/dL
between 2 and 4 am	> 70 mg/dL

N. Instrument Name:

OneTouch UltraLink Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

Each test strip is single use and must be replaced with a new strip for each additional reading

2. Software:

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

Yes ___X___ or No _____

3. Specimen Identification:

There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

This device is intended to be used with capillary whole blood from the finger, palm, and forearm. Since the whole blood sample is applied directly to the test strip, there are no special handling or storage issues.

5. Calibration:

A calibration code is provided with each batch of test strips and is entered into the meter to calibrate the meter for that batch. No further calibrations are required of the user.

6. Quality Control:

A Glucose control solution at a normal concentration is provided by the sponsor and should be used with this device. An acceptable range for the control is printed on the test strip vial. The user is instructed to contact the Customer Help line if control results fall outside these ranges. An additional level of control (high) is available by calling the Customer Help line.

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

Not applicable.

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.