

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

**A. 510(k) Number:** k031260

**B. Analyte:** whole blood glucose

**C. Type of Test:** Quantitative, utilizing Glucose Dehydrogenase technology.

**D. Applicant:** TheraSense, Inc.

**E. Proprietary and Established Names:**

FreeStyle Blood Glucose Monitoring System

FreeStyle Tracker Diabetes Management System

**F. Regulatory Information:**

1. Regulation section:

21 CFR 862.1345 Glucose Test System

21 CFR 862.1660 Quality Control Material

2. Classification:

Class II, Class I

3. Product Code:

NBW, System, Test, Blood Glucose, Over The Counter

LFR, Glucose Dehydrogenase, Glucose

JJX, Single (Specified) Analyte Controls, Class I

4. Panel:

Chemistry (75)

**G. Intended Use:**

5. Indication(s) for use:

**FreeStyle Blood Glucose Monitoring System**

The ThereSense, Inc. FreeeStyle Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not

intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

**FreeStyle Tracke Diabetes Management System**

The TheraSense, Inc. FreeStyle Tracker Diabetes Management System is intended for use in the quantitative measurement of glucose in whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

Additionally, the TheraSense, Inc. FreeStyle Tracker Diabetes Management System is intended for use in home and clinical settings to aid people with diabetes and healthcare professionals in the review, analysis, and evaluation of historical blood glucose test results to support an effective diabetes management program.

The ThereSense, Inc. FreeStyle Blood Glucose Monitoring System, and FreeStyle Tracker Diabetes Management System is specifically indicated for use on the finger, forearm, upper arm, thigh, calf and hand.

6. Special condition for use statement(s):

Provides plasma equivalent results.  
Not Intended for use on neonates.

7. Special instrument Requirements:

N/A

**H. Device Description:**

The FreeStyle Blood Glucose Monitoring System comprises an electronic biosensor glucose reagent test strip, a handheld meter, a quality control solution, a complete Owner's Booklet and Quick Reference Guide. A lancing device, lancets and a logbook for recording test results are also included with the system.

**I. Substantial Equivalence Information:**

1. Predicate device name(s):

The predicate devices are the TheraSense, Inc. FreeStyle Blood Glucose Monitoring System and the TheraSense, Inc. FreeStyle Tracker Diabetes Management System

2. Predicate K number(s):

FreeStyle Blood Glucose Monitoring System (K992684)  
(K000582)  
(K012014)

FreeStyle Tracker Diabetes Management System (K020866)

3. Comparison with predicate:

All attributes of device to remain the same, only the labeling is to be modified.

**Tracker Blood Glucose Monitoring  
Features Comparison to Predicate**

	<b>Tracker System</b>	<b>FreeStyle System Predicate Device</b>
<b>Device Name &amp; Manufacturer</b>	TheraSense, Inc.	Same
<b>Device Description</b>	Glucose Test System	Same
<b>510(k) Number</b>	K020866	K992684, K000582, K012014, K994433
<b>Regulatory Class</b>	II; 75 LFR	Same
<b>Device Classification</b>	21 CFR 862.1345	Same
<b>Intended Use</b>	Quantitative glucose measurement in whole blood for self monitoring in diabetics.	Same as K992684, K000582, and K012014
<b>Enzyme</b>	Glucose Dehydrogenase	Same
<b>Reagent Form</b>	Test Strip	Same
<b>Detection Methodology</b>	Electrochemical	Same
<b>Recommended Sample</b>	Capillary whole blood	Same
<b>Minimum Sample size</b>	300 nanoliters (0.3 microliters)	Same
<b>Calibration</b>	Test Strip Plasma equivalent	Same
<b>Sample Application</b>	Whole blood applied to a test strip that is external to the meter	Same
<b>Result Range</b>	20 to 500 mg/dL (1.1 – 27.8 mmol/L)	Same
<b>Test Time</b>	Average of 15 seconds	Same
<b>Assay Method</b>	Coulometric Electrochemical Sensor	Same

	<b>Tracker System</b>	<b>FreeStyle System Predicate Device</b>
<b>Measurement Units</b>	Either mg/dL or mmol/L	Same
<b>Memory</b>	250 most recent blood glucose and control solution tests	Same
<b>Automatic Shut-off</b>	2 minutes after last user action	Same
<b>Power Source</b>	2 replaceable AAA batteries, or rechargeable PDA battery	Two AAAA replaceable batteries
<b>Battery Life</b>	2-4 weeks	1,000 tests
<b>Operating Temperature</b>	50 – 95 degrees F	Same
<b>Operating Relative Humidity</b>	5-90 %	Same
<b>Hematocrit</b>	30-60 %	Same
<b>Wiping Required?</b>	No	No
<b>Timing Required?</b>	No	No
<b>Date / Time Stamp?</b>	Yes	Yes
<b>Communication</b>	PDA	Serial Port
<b>Dimensions</b>	85.0 x 54.5 x 20.0 mm Module only	97 x 52 x 25 mm
	150.0 x 77.0 x 24.0 mm Module and PDA	n/a
<b>Weight</b>	Approx. 40 grams Module only	Approx. 60 grams
	Approx. 1140 grams Module and PDA	n/a
<b>Data Management Capability</b>	Yes, Tracker Data Management Software	Yes, Connect Data Management Software

**J. Standard/Guidance Document Referenced (if applicable):**

NCCLS EP-7; AdvaMed Points to Consider for Glucose Monitoring Devices  
Intended for Alternative Site Testing

**K. Test Principle:**

The user obtains a blood sample using a conventional lancing technique. The user inserts a test strip into the meter, which turns the meter on. When the strip is touched to the blood drop, the sample chamber on the strip is filled by capillary action in approximately 2 seconds. The blood sample volume required is approximately 0.3 microliters (300 nanoliters), which can be obtained from the finger or other areas of

the body such as the arm. Test results are displayed in about 15 seconds. The time required to display test results varies depending on the blood glucose concentration (approximately 15 to 45 seconds).

The glucose in the blood sample reacts with the glucose Dehydrogenase enzyme to yield gluconolactone, and produces a small electrical current. This current is measured by the FreeStyle meter and displayed as a glucose level.

#### L. Performance Characteristics (if/when applicable):

The performance of the FreeStyle Test Strips has been tested both in laboratory and clinical studies. The testing range of the FreeStyle System is 20 mg/dL to 500 mg/dL (1.1 to 27.8 mmol/L).

##### 1. Analytical performance:

###### a. Precision/Reproducibility:

Within-lot and within-vial precision of FreeStyle test strips was measured with venous blood samples in the laboratory. The pooled precision data for fifty-four test strip lots (n= 5,184) is shown in the tables below:

##### Within-Lot Precision

Average Glucose Concentration (mg/dL)	43	194	380
SD (mg/dL)	2.4	6.2	13.7
CV (%)	5.6	3.2	3.6

##### Within-Vial Precision

Average Glucose Concentration (mg/dL)	43	194	380
SD (mg/dL)	1.8	3.6	7.4
CV (%)	4.1	1.8	2.0

Variability in blood test from strip to strip was 5.6% or less.

###### b. Linearity/assay reportable range:

The established linearity and reportable range was cleared with submission K020866, which received clearance on 11 June 2002.

###### c. Traceability (controls, calibrators, or method):

Cleared with K020866

###### d. Detection limit

20 – 500 mg/dL

1.1 – 27.8 mmol/L

###### e. Analytical specificity:

Cleared with K020866.

f. *Assay cut-off:*  
N/A

2. Comparison studies:

a. *Method comparison with predicate device:*

The accuracy of the FreeStyle system was tested by comparing blood glucose results obtained by study subjects with those obtained using a YSI Model 2300 Glucose Analyzer. The results below were obtained from subjects with Type 1 or Type 2 diabetes. The regression statistics are derived from a plot of the FreeStyle arm data versus YSI capillary data.

Slope =	0.931
y-intercept	+ 8.1 mg/dL
Correlation coefficient (R)	0.969
Number of samples tested in duplicate	197
Range tested	51 to 487 mg/dL

b. *Matrix comparison:*  
N/A

3. Clinical studies:

a. *Clinical sensitivity:*  
N/A

b. *Clinical specificity:*  
N/A

c. *Other clinical supportive data (when a and b are not applicable):*

A clinical study was conducted to compare glucose readings using blood from the finger and blood from the palm. Forty-four subjects with type 1 diabetes were given a glucose challenge to raise glucose to a hyperglycemic state and then given subcutaneous insulin to reduce glucose to a normal or hypoglycemic state. Three subjects were excluded from the data analysis because they did not achieve the glucose rate of change required by the protocol. The differences between readings from the finger and palm sites for all glucose levels and for low glucose levels are summarized below.

	Range (mg/dL)	Number of test pairs	Average difference	Standard Deviation
All test	43 – 477	1309	-2.1%	12.7%
Low Glucose	43 – 69	72	4.9 mg/dL	9.0 mg/dL

Physiologic differences in the circulation between the finger or palm and other test sites like the forearm, upper arm, thigh, calf and hand, may result in differences in blood glucose measurements from the other test sites and your finger or palm. Differences in blood glucose measurements between the other test sites and your finger or palm may be observed in finger or palm blood samples sooner than flood samples from the forearm

and other alternate sites. Vigorous rubbing of the alternate test sites before lancing will help to minimize the difference between finger and alternate site test results. Refer to the Owners Booklet for complete information about testing your blood glucose.

4. Clinical cut-off:  
N/A

5. Expected values/Reference range:

#### **Normal Glucose Values**

The normal fasting glucose range for a non-diabetic adult is 70 to 110 mg/dL (3.9 to 6.1 mmol/L) 3. Burtis CA Ashwood ER eds: Teitz Textbook of Clinical Chemistry. 2<sup>nd</sup> Edition W.B. Saunders. Philadelphia. 1994. P. 2190 One to two hours after meal, normal glucose values should be less than 120 mg/dL (6.7 mmol/L) 4. Krall LP and Beaser T: Joslin Diabetes Manual. Lea and Febiger. Philadelphia 1989 p. 138. Consult your physician or healthcare professional for the target glucose values that are right for you.

#### **Low Glucose Values**

The FreeStyle Meter displays results between 20 and 500 mg/dL (1.1 and 27.8 mmol/L). If your result is lower than 20, “Low” (LO) will appear on the meter display. This indicates severe low blood sugar (hypoglycemia). **You should immediately treat low blood sugar as recommended by your healthcare professional.**

#### **High Glucose Values**

If your test result is above 500 mg/dL (27.8 mmol/L) “High”(HI) will appear on the meter display screen. This indicates severe high blood sugar (hyperglycemia). **You should immediately treat low blood sugar as recommended by your healthcare professional.**

#### **Unexpected Results**

Low or high blood sugar readings can indicate a potentially serious medical condition. If your blood sugar is unusually low or high, or if you do not feel the way your results indicate, repeat the test with a new test strip. If your reading is not consistent with your symptoms or if your blood glucose result is less than 60 mg/dL (3.3 mmol/L) or higher than 240 mg/dL (13.3 mmol/L), you should contact your healthcare professional and follow his or her treatment advice.

#### **M. Conclusion:**

Based upon review of the information and labeling provided, this device is Substantially Equivalent to 21 CFR 862.1345, 75 NBW, System, Test, Blood Glucose, Over the Counter and 75 LFR Glucose Dehydrogenase, Glucose.