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

A. 510(k) Number:

k103544

B. Purpose for Submission:

New device

C. Measurand:

Whole Blood Glucose

D. Type of Test:

Quantitative, amperometric method, glucose oxidase

E. Applicant:

AgaMatrix, Inc.

F. Proprietary and Established Names:

iBGStar Blood Glucose Monitoring System

iBGStar Diabetes Manager Application

BGStar Control Solutions

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
CGA	II	21 CFR 862.1345 - Glucose test system, Glucose oxidase	Chemistry (75)
JQP	I	21 CFR 862.2100 - Calculator/data processing module for clinical use	Chemistry (75)
NBW	II	21 CFR 862.1345 - System, Test, Blood Glucose, Over the Counter	Chemistry (75)
JJX	I, reserved	21 CFR 862.1660 – Quality Control Material (assayed and unassayed)	Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indications for use below.

2. Indication(s) for use:

   The iBGStar™ Blood Glucose Monitoring System is intended for the quantitative measurement of blood glucose levels in fresh capillary whole blood samples drawn from the fingertip, palms (at the base of the thumb), or forearms. It is intended to be used by a single patient and should not be used for testing multiple patients. The iBGStar™ Blood Glucose Monitoring System is intended for self testing outside the body (*In vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The iBGstar Blood Glucose Monitoring System is not for the diagnosis of, or screening for diabetes, and is not intended for use with neonates.

   BGStar™ Test Strips are for use with the iBGStar™ Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertip, palms (at the base of the thumb), or forearms. Palm and forearm testing (Alternative Site Testing) should be done only during steady-state times (when glucose is not changing rapidly).

   BGStar Control Solutions are for use with the iBGStar™ Blood Glucose Meter and iBGStar Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

   The iBGStar Diabetes Manager Application is intended for use in the home with the capability of sending glucose readings through email to an individual's healthcare professional in the review, analysis and evaluation of glucose test results to support an effective diabetes management program. It is an optional data management software accessory for use with the iBGStar Blood Glucose Monitoring System.

3. Special conditions for use statement(s):

   For prescription and over-the-counter use.

   Not for neonatal use, not for screening or diagnosis of diabetes mellitus.

   Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients.

   Alternative site testing (AST) should not be used to calibrate continuous glucose monitors (CGMs) nor for use in insulin dose calculations.

   AST testing should only be done during steady-state times (when glucose is not changing rapidly).

4. Special instrument requirements:

   The iBGStar Blood Glucose Meter

I. Device Description:

The iBGStar Blood Glucose Monitoring System (BGMS) consists of a hand-held blood glucose meter, test strips and one control material (an additional level of control material is available upon request). The meter is codeless and does not require a calibration code. The meter is turned on by strip insertion and then the user applies finger-tip/palm blood or control solution to the strip. The meter begins the assay, which completes in 4 - 12 seconds. The meter's software converts the signal generated from the test strip into a plasma equivalent glucose concentration and displays the value on the meter's LCD screen. A dock connector cover, lancing device with cap, power adapter and micro-USB to USB cable is also included.

The iBGStar Blood Glucose Meter can download test results to the iBGStar Diabetes Manager Application (or App) via the dock connector on the iPhone or iPod touch. The app can be used to store and manage patient's diabetes information, review trends, or share with patient's healthcare team.

The meter may be used with the iPod touch, 4th generation, and the iPhone 4.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Jazz Blood Glucose Monitoring System, WaveSense Diabetes Manager

2. Predicate K number(s):

   k071393, k101597

3. Comparison with predicate:

   Blood Glucose Monitoring System (meter, strips, controls):

Similarities		
Characteristic	**Predicate device (k071393)**	**Proposed Device**
Intended use	For the quantitative measurement of blood glucose levels from fresh capillary whole blood samples taken from the fingertip, palms (at the base of the thumb), or forearms	Same
Calibration	No coding required	Same
Test Principle /Enzyme	Glucose oxidase	Same
Control levels	Two levels	Same

Differences		
Characteristic	**Predicate device (k071393)**	**Proposed Device**
Backlight in meter	Yes	No
Number of results stored in meter	1865	300
Meter power source	Two CR-2032, 3 volt, lithium batteries	Polymer lithium-ion rechargeable batteries
Meter Size	L-84 mm, W-46 mm, H-19.5 mm	L-56 mm, W-24 mm, H-10 mm
Meter Weight	48g	8.5g

Data management system:

Similarities		
Characteristic	**Predicate device (k101597)**	**Proposed Device**
Intended use	Download glucose readings to a data management system to aid in the effective management of diabetes	Same
Management tools	Logbooks and trend charts	Same
Differences		
Characteristic	**Predicate device (k101597)**	**Proposed Device**
Upload to	PC (computer)	Device compatible with the iPhone operating system
Transfer of glucose readings	Cable download	Transfers to the iPhone/iPod touch automatically via the dock

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

ISO 15197:2003(E) *In vitro* diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus.

CLSI EP7-A2: *Interference Testing in the Clinical Laboratory; Approved Guideline*

IEC 61326: Electrical equipment for measurement, control and laboratory use

IEC 61000-4-2: Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques

CEI/IEC 61010-2-101: Safety requirements, Particular requirements for in vitro diagnostic (IVD) medical equipment

IEC 61010-1 Edition 2.0: Safety requirements for electrical equipment for measurement, control and laboratory use

IEC 60068-2-64: Environmental Testing Part 2 – Test methods

ISO 13484:2003 Medical devices – Quality management systems – Requirements for regulatory purposes

L. Test Principle:

The BGStar test strip contains glucose oxidase enzyme with a redox chemical mediator that produces an electrochemical signal in proportion to the glucose concentration in the blood sample. The iBGStar meter measures this signal, using dynamic electrochemistry to correct for common analytical interferences such as hematocrit.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Repeatability (between run precision) was evaluated at room temperature using venous whole blood adjusted to five different levels of glucose. Twelve iBGStar blood glucose meters were used, along with twelve individual vials of test strips, one vial being assigned to each BGMS. The glucose in a venous blood sample, having Hematocrit 42 ± 2%, was allowed to glycolyze to a low level by standing overnight. Concentrated glucose solution was added to glucose depleted blood to achieve five different blood glucose concentration levels.

Glucose conc. (mg/dL)	Meter	1	2	3	4	5	6	7	8	9	10	11	12
36	Mean	29.5	29.7	27.8	29.6	27.9	29.7	30	30.4	28.9	29.5	28.6	28.4
	SD	2.2	1.2	1.8	2.1	1.6	1.6	2.3	2.1	2.0	2.1	1.0	1.2
	CV %	7.4	3.9	6.3	7.0	5.7	5.3	7.7	6.8	6.8	7.0	3.4	4.1
79	Mean	70.8	71	70	68.7	68.6	70.8	69.8	71.4	69.4	71.4	67.9	69.7
	SD	3.8	3.3	2.1	2.4	2.1	3.0	2.1	2.3	2.4	3.5	2.1	3.6
	CV %	5.4	4.6	3.0	3.4	3.0	4.3	3.0	3.2	3.4	4.9	3.1	5.2
118	Mean	104.6	109.1	101.5	105.7	104.8	108.5	103.9	108.8	103.3	105.9	102.6	107.0
	SD	5.1	3.5	4.0	2.9	2.9	3.4	3.2	1.9	3.4	3.5	3.3	3.2
	CV %	4.8	3.2	4.0	2.8	2.8	3.1	3.1	1.7	3.3	3.3	3.3	3.0
201	Mean	179.8	183.8	179.8	181.3	183.3	188.8	174.9	187.7	180.7	186.1	176.5	186.1
	SD	5.6	6.8	6.4	5.2	4.4	5.1	6.2	2.3	5.7	4.8	3.7	5.4
	CV %	3.1	3.7	3.5	2.9	2.4	2.7	3.5	1.2	3.1	2.6	2.1	2.9
347	Mean	333.9	323.3	311.7	327.4	331.1	339.5	312.7	329.6	329.5	329	326.2	329.0
	SD	8.3	15.9	8.7	8.6	14.3	8.6	8.0	8.5	6.1	10.5	8.3	14.0
	CV %	2.5	4.9	2.8	2.6	4.3	2.5	2.6	2.6	1.9	3.2	2.5	4.3

Intermediate (day-to-day) precision of the iBGStar Blood Glucose System was determined using one lot of glucose test strips and three different levels of glucose control solutions. Three different operators collected data over a period of ten days on twelve individual iBGStar blood glucose meters. Twelve iBGStar blood glucose meters were used, along with twelve individual vials of test strips from a single lot, one vial being assigned to every BGMS. Three different operators collected data over a testing period which extended over ten separate days.

	Results from Control Solution, mg/dL								
	50 mg/dL (Level 1)			108 mg/dL (Level 2)			270 mg/dL (Level 4)		
Meter	mean	SD	CV, %	mean	SD	CV, %	mean	SD	CV, %
1	56.7	3.7	6.6	136.0	3.8	2.8	368.8	9.8	2.7
2	55.6	1.0	1.7	133.2	2.4	1.8	354.5	14.0	4.0
3	55.7	1.5	2.7	134.8	3.0	2.2	346.2	14.0	4.0
4	55.7	1.6	2.9	133.8	2.9	2.2	350.6	6.5	1.8
5	55.3	1.1	1.9	134.9	2.2	1.6	365.1	10.1	2.8
6	55.7	0.9	1.7	137.3	1.9	1.4	357.1	6.7	1.9
7	56.4	2.4	4.2	130.5	1.9	1.5	350.2	12.9	3.7
8	55.5	1.8	3.2	135.6	3.5	2.6	362.3	6.8	1.9
9	56.7	2.4	4.2	135.8	4.4	3.3	359.5	11.1	3.1
10	55.4	1.6	3.0	133.2	3.2	2.4	344.5	7.6	2.2
11	55.0	0.7	1.2	136.3	1.8	1.3	349.7	9.8	2.8
12	58.0	3.0	5.2	138.8	1.9	1.4	346.0	8.8	2.5

b. Linearity/assay reportable range:

A venous blood sample was drawn by venipuncture from a single subject. The sample was adjusted to have a Hematocrit of 42 ± 2% and adjusted to a low glucose level by metabolic depletion of glucose upon aging at room temperature, the "Low" pool. A sample was spiked to a high level of glucose near the upper limit of the tested range of system performance, the "High" pool, by addition of glucose. Glucose levels were determined by the YSI 2300 glucose analyzer.

Known volumes of each of the Low and High pools were mixed to prepare nine samples with a range of glucose concentrations 20 to 600 mg/dL. This study was conducted over a period of one day, using one lot of strips and twelve iBGStar meters.

Data were evaluated for linearity according to the guidelines given CLSI EP6-A, *Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guidelines*.

A plot of iBGStar data versus YSI reference data was constructed. First-order, Second-order and Third-order polynomial regression analysis was performed on the data.

The first-order (linear) model was fitted to the data using weighted least-squares regression. First-order, second-order and third-order polynomial regression coefficients and their standard errors were computed, together with degrees of freedom and standard errors of regression

The statistical significance of any non-linearity was assessed by determining whether the non-linear coefficients of the second-order and third-order polynomial models were significantly non-zero using Student's *t* test. For these coefficients, the t statistic and the significance of the *t*-statistic (*p* value) were computed. The better fitting (second-order or third-order) polynomial was selected for comparative analysis against the first-order model. Deviation from linearity was computed at each concentration.

The bias for sample concentrations < 75 mg/dL was less than 1.5 mg/dL and bias for glucose sample concentrations > 75 mg/dL did not exceed 6.3%.

Order	**Coeff. Symbol**	**Coeff. Value**	**Coeff. SE**	***t*-stat**	**p Value**
First	b0	-2.70	1.32	-	-
First	b1	1.04	0.01	-	-
Second	b0	-1.32	3.25	-	-
Second	b1	0.95	0.02	-	-
Second	b2	1.88×10^{-4}	3.74×10^{-5}	5.02	2.40×10^{-3}
Third	b0	1.20	4.09	-	-
Third	b1	0.90	0.06	-	-
Third	b2	4.12×10^{-4}	2.24×10^{-4}	1.84	0.13
Third	b3	-2.38×10^{-7}	2.35×10^{-7}	-1.01	0.36

The *t*-statistics shown in Table 4 indicate that the second-order polynomial model has significant non-linearity ($p < 0.05$)

Differences between linear and non-linear models were evaluated at each sample glucose concentrations and differences show deviations to be no more than 5% for sample glucose concentrations > 75 mg/dL, and were zero for sample glucose concentrations < 75 mg/dL.

Weighted linear regression analysis results in an equation of y = 1.04x - 2.7

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

Controls and test strips are identical to those cleared in k071393.

The control level 2 is offered in kit. The level 4 control solution can be requested by calling Customer service at 1-800-633-1610.

d. Detection limit:

The reportable range is 20 to 600 mg/dL based on the linearity/assay reportable range study above (section M.1.b).

e. Analytical specificity:

Interference study was designed according to CLSI EP7-A2 guideline. 23 common endogenous and exogenous interference substances were evaluated by spiking venous blood with three levels of glucose concentrations (70, 120 and 300 mg/dL). The glucose samples were spiked with five levels of the potentially interfering compounds and tested on 3 lots of test strips. Bias was calculated as the mean percent difference in glucose reading between the test and control concentration groups. All samples tested showed % bias within ± 10% between the test and the control groups. The sponsor claims no significant interference (≤ 10% difference) for the substances and concentrations shown in the table below:

The following substances up to concentrations listed shall have no significant effect on test results (≤ ± 10%)	
Acetaminophen	20 mg/dL
Ascorbic acid	2 mg/dL
Bilirubin	15 mg/dL
Caffeine	6 mg/dL
Cholesterol	600 mg/dL
Fructose	18 mg/dL
Galactose	120 mg/dL
Ibuprofen	50 mg/dL
Lactose	10 mg/dL
a-Lipoic Acid	2 mg/dL
Maltose	120 mg/dL
Methyl-DOPA	1.5 mg/dL
Salicylate	60 mg/dL
Sucrose	20 mg/dL
Tolazamid	5 mg/dL
Uric acid	23.5 mg/dL
Xylose	120 mg/dL

The sponsor has the following limitations in their labeling:

"Results may be overestimated with abnormally high concentrations of ascorbic acid (vitamin C) > 2 mg/dL (0.11 mmol/L)."

f. Assay cut-off:

Not applicable.

2. Comparison studies:

   a. Method comparison with predicate device:

   The system accuracy of the iBGStar BGMS was assessed by analysis of fresh capillary whole blood samples obtained by finger stick from 100 individuals on 13 days (over a 30 day period) at a single clinical site. Glucose concentrations measured with the iBGStar BGMS were compared to measurements on the YSI 2300. Eight venous samples were spiked or depleted to achieve specific glucose ranges.

   Samples were collected and analyzed over 30 days. A single lot of test strips were used and at least ten vials of test strips were used.

   93 capillary whole blood samples obtained by fingerstick and 7 donor samples were used in the system accuracy analysis. The range of reference glucose concentrations obtained during this study was from 34.8 to 508.7 mg/dL. In order to supplement the five samples below 60 mg/dL, three additional samples were glycolyzed. Four samples were spiked to achieve specimens with glucose above 450 mg/dL. The range of hematocrit obtained during this study was from 31.9% to 51.9%.

   The singlicate iBGStar glucose concentrations were plotted vs. the YSI 2300 glucose analyzer reference and linear regression was performed:

Comparison	n	Slope (95% CI)	y-Int (95% CI)	Sy.x	r
iBGStar glucose vs. YSI plasma glucose	100	1.028 (± 0.023)	-6.190 (± 4.804)	12.77	0.994

Summary of system accuracy results for glucose concentrations < 75 mg/dL of iBGStar vs. YSI:

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
11/17 (65%)	17/17 (100%)	17/17 (100%)

Summary of system accuracy results for glucose concentrations ≥ 75 mg/dL of iBGStar vs. YSI:

Within ±5%	Within ±10%	Within ±15%	Within ±20%
56/83 (67%)	76/83 (92%)	82/83 (99%)	83/83 (100%)

   b. Matrix comparison:

   Not applicable. Only capillary whole blood samples are an acceptable matrix.

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 and alternative site testing study:

The iBGStar User Study including Alternative Site Testing was conducted to assess the performance of the iBGStar BGMS in the hands of the intended uses for blood sampling from the finger and alternative sites (the palm and forearm) and for the user to evaluate the ease of using the system to obtain a blood glucose reading. Results were analyzed by comparing the alternative site (palm and forearm) and fingerstick blood glucose readings obtained by the lay user against the YSI 2300 STAT Plus reference value.

System accuracy user palm results of iBGStar vs. YSI:

for glucose concentrations < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
6/7 (85.7%)	7/7 (100%)	7/7 (100%)

for glucose concentrations ≥ 75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
45/100 (45%)	77/100 (77%)	87/100 (87%)	96/100 (96%)

System accuracy user forearm results of iBGStar vs. YSI:

for glucose concentrations < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
4/7 (57.1%)	7/7 (100%)	7/7 (100%)

for glucose concentrations ≥ 75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
41/98 (41.8%)	68/98 (69%)	84/98 (85.7%)	94/98 (95.9%)

System accuracy user finger results of iBGStar vs. YSI:

for glucose concentrations < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
4/7 (57.1%)	6/7 (85.7%)	7/7 (100%)

for glucose concentrations ≥ 75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
57/100 (57%)	88/100 (88%)	96/100 (96%)	98/100 (98%)

4. Clinical cut-off**:**

   Not applicable.

5. Expected values/Reference range:

   Expected blood glucose results for non-pregnant people without diabetes were cited from the literature[1] and presented in the labeling as follows:

   Fasting: 70-99 mg/dL

   [1]American Diabetes Association, Position Statement, Standards of Medical Care in Diabetes, Diabetes Care 34 (suppl1): S11-S61, 2011.

N. Instrument Names:

iBGStar Meter, iBGStar Diabetes Manager Application

O. System Descriptions:

1. Principles of Operation:

   The operating system requirements for the iBGStar Diabetes Manager Application are: iPhone Operating System version 3.0 or higher and at least 10 MB of available space. The app is for use on iPhone OS versions 3.0, 4.0 and 5.0.

2. Modes of Operation:

   Each test strip is single use and requires a sample volume of 0.5 uL.

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes ___X_____ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes _____ or No ___X____

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:

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

   iBGStar Diabetes Manager Application: Specimen identification is based on time and date of testing

4. Specimen Sampling and Handling:

   iBGStar meter: The glucose test is intended to be used with capillary whole blood from the finger, palm, and forearm only. The whole blood sample is applied directly to the test strip by capillary action.

   iBGStar Diabetes Manager Application: Data transmission from glucose meters using capillary whole blood samples

5. Calibration:

   There is no calibration required for the iBGStar meter by the user. The meter is plasma-calibrated and requires no coding.

6. Quality Control:

   Glucose control solutions at two different concentrations can be run with this device. One level of control solution is provided with the kit. Recommendations on when to test the control materials are provided in the labeling. An acceptable range for each control level is printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

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

1. A usability study was performed to assess the readability of the labeling for the US market by surveying the 107 lay users (aged 18-80 yrs old) that participated in the accuracy study. Participants varied in age, education, country of origin, and there were more men (61%) than women (39%). These lay users also completed a questionnaire to response to whether the device is easy to use and the Instructions for use were written in a way that makes it easy to use. The majority of the users responded that the device is very easy to use.

2. Flesch-Kincaid readability assessment was conducted and the results showed that the labeling (Owner's Guide, test strip package insert and control solution package insert) were written at the 8th grade level.

3. Customer service is available 24/7, 365 days a year. Toll free phone number is 1-800-633-1610 for customer support.

4. A sample volume study was performed to verify the test strip sample volume requirement and the test strip fill error requirement established for the iBGStar BGMS. One lot of test strips was tested using blood from ten donors. Blood at each concentration was applied to strips at five target sample volumes of 1.0, 0.6, 0.5, 0.4 and 0.25 µL. Protocols and acceptance criteria were provided and found to be acceptable. The sponsor concluded that sample volume of ≥0.4 µL produced accurate results and samples <0.4 µL give an error code.

5. Temperature and humidity operating conditions were evaluated for temperatures ranging from 10°C to 40°C and relative humidity from 25% to 90%. Protocol and acceptance criteria were provided and found to be acceptable. The results supported the Sponsor's claimed operating temperature from 10°C to 40°C (50°F to 104°F).

6. EMC testing was evaluated and certified by TUV Rheinland and a test report was submitted stating that the iBGStar passed all tests; dated November 3, 2010.

7. The device is intended for single-patient use only. Super-Sani Cloth Germicidal Disposable Wipes (Professional Disposables International, Inc., EPA Registration #9480-4) validated demonstrating complete inactivation of live virus for use with the meter lancing device, iPhone 4 and 4th generation iPod touch. The sponsor also demonstrated that there was no change in performance or in the external materials of the meter, lancing device , iPhone 4 and 4th generation iPod touch after 260 cleaning cycles and 260 disinfection cycles designed to simulate 5 years of device use.

8. A study was conducted to evaluate the effect of altitude on the iBGStar BGMS. 3 lots of test strips were tested on 12 meters using blood from 56 donors at that covered the range of 47 – 413 mg/dL glucose at 10,000 feet above sea level. Each venous blood sample was also tested by the YSI 2300 analyzer. The meter readings obtained were compared to the YSI method and the percent bias against the YSI results. Bias was within ± 10%. Based on the data, the sponsor claims that the iBGStar BGMS can be used at altitude up to 10,000 feet.

9. The sponsor performed a study to evaluate potential interference from hematocrit using nine different hematocrit (Hct) levels(20, 25, 30, 35, 40, 45, 50, 55, 60%) across the glucose measuring range (20-600 mg/dL). At each hematocrit level, 6 samples at glucose concentration of 30, 65, 150, 250, 350 and 450 mg/dL were tested against the YSI method. 3 lots of test strips were tested on 12 meters and the values were compared to the YSI method and the nominal hematocrit level (40%). All individual test results were within 15%, therefore the sponsor claims that hematocrit between 20% to 60% do not significantly affect the glucose results.

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.