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

A. 510(k) Number:

K063407

B. Purpose for Submission:

This is an original-traditional 510(k) for a 16 parameter automated hematology analyzer and leukocyte differential cell counter with reagents, calibrator, and controls.

C. Manufacturer and Instrument Name:

Shenzhen Mindray Bio-Medical Electronics Co. LTD, BC-3200 Auto Hematology Analyzer

D. Type of Test or Tests Performed:

WBC, Lymph #, Mid#, Gran#, Lymph%, Mid%, Gran%, RBC, HGB, MCV, MCH, MCHC, RDW, HCT, MPV, and WBC Histogram, RBC Histogram, and PLT Histogram

E. System Descriptions:

1. Device Description:

   The BC-3200 Auto Hematology Analyzer is a quantitative, automated hematology analyzer and leukocyte differential cell counter for In Vitro Diagnostic use in clinical laboratories. It is only to be used by trained medical professionals to identify the normal patient, with all normal system-generated parameters, and toflag or identify patient results that require additional studies. The analyzer provides analysis results of 16 parameter of human blood and three histograms.

2. Principles of Operation:

   WBCs are counted and sized by the impedence method. This method is based on the measurement of changes in electrical resistance produced by a particle, which in this case is a blood cell suspended in a conductive diluent as it passes through an aperture of known dimensions. HGB is determined by the colorimetric method. RBCs and PLTs are counted by the impedence method also. In addition, for RBCs and Plts, volumetric metering is used. An accurate cell count cannot be obtained unless the precise volume of diluted sample that passes through the aperture during the count cycle is known. The analyzer uses a volumetric metering unit to control the count cycle and to ensure that a precise volume of sample is analyzed for the measurement.

3. Modes of Operation:

   Closed Vial Whole Blood Mode, Whole Blood Mode for veinous blood, and Predilute Mode for capillary blood.

4. Specimen Identification:

   Barcode or manual keyboard entry.

5. Specimen Sampling and Handling:

   Samples are manually loaded into a sample compartment one at a time. The BC-3200 utilizes an automatic sampling and mixing device for sample processing. The Mindray calibrator is called SC-CAL PLUS.

6. Calibration:

   The device has two calibration programs: manual calibration and auto calibration using commercial calibrators. The Mindray calibrator is called SC-CAL PLUS.

7. Quality Control:

   The device has two QC programs: L-J Analysis and X-B Analysis. The Mindray three level control is called BC-3D.

8. Software:

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

   Yes____X____ or No________ Mindray has provided software documentation at a moderate level of concern that conforms to the FDA software guidance document.

F. Regulatory Information:

1. Regulation section:

   21 CFR 864.5220, Automated differential cell counter

2. Classification:

   Class II

3 Product code:

   GKZ

4. Panel:

   Hematology (81)

G. Intended Use:

1. Indication(s) for Use:

   The BC-3200 Auto Hematology Analyzer is a quantitative, automated hematology analyzer and leukocyte differential cell counter to be used in clinical laboratories for In Vitro Diagnostic Use. The intended use of the BC-3200 Auto Hematology analyzer is to identify the normal patient, with all normal system-generated parameters, and to flag or identify patient results that require additional studies.

2. Special Conditions for Use Statement(s):

   N/A

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

   COULTER® A^{C}T diff 2™ Analyzer, K0990352

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Intended Use	The BC-3200 auto hematology analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter for In Vitro Diagnostic Use in clinical laboratories.	Same

Similarities		
Item	**Device**	**Predicate**
Sample Types	Whole Blood Mode and Prediluted Mode	Same
Sample Processing	Utilizes an automatic sampling, diluting, and mixing device for sample processing.	Same
Calibration	Provides 2 calibration programs: manual calibration and auto calibration using commercial calibrators.	Same
Aperture Alert	Minimize the possibility of reporting erroneous results caused by a partial or transient aperture clog or by other aperture disturbance.	Same

Differences		
Item	**Device**	**Predicate**
Operating Modes	Closed Vial Whole Blood Mode	Closed Vial Whole Blood Mode and Open Vial Whole Blood Mode
Throughput	1 minute/analysis	60 seconds or les
Quality Control	Provides 2 QC programs: L-J Analysis and X-B Analysis	Provides 1 QC program: L-J Analysis
Recommended Controls	BC-3D: Low, Normal, & High	4C PLUS: Abnormal Low, Normal, Abnormal High
Sample Volume Aspirated	13µL whole blood 20µL prediluted blood	18µL whole blood 20µl prediluted blood
Parameters	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, Lymph%, Lymph#, Mid%, Mid#, Gran%, Gran#, RDW, MPV	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, Ly%, Ly#, MO%, MO#, GR%, GR#, RDW, MPV

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

Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA. December 4, 2001

J. Performance Characteristics*:*

1. Analytical Performance:

   a. Accuracy:

   Correlation is determined by comparing the results (both CBC and DIFF) obtained by the BC-3200 to those by the Coulter AC·T diff 2™ and by comparing the DIFF results obtained by the BC-3200 to those by manual differential.

   Table 1: Correlation to Coulter A^C·T diff 2™

Parameter	Samples (n)	Mean		Difference ratio (D%)	Slope (a)	Intercept (b)	Correlation coefficient (r)
		BC-3200	Ac T diff 2				
WBC	103	10.4	10.3	2.4	1.0097	-0.0282	0.9994
Lymph#	98	1.9	2.1	11.8	0.9918	-0.1864	0.9890
Mid#	98	0.7	0.5	40.5	2.1022	-0.3798	0.9187
Gran#	98	6.1	6.0	3.7	0.9886	0.146	0.9978
Lymph%	98	25.8	29.3	11.5	0.7935	2.5772	0.9751
Mid%	98	9.0	6.7	43.0	0.7569	3.8798	0.4644
Gran%	98	65.2	64.0	3.4	0.9046	7.347	0.9707
RBC	103	4.31	4.27	1.7	0.9916	0.0702	0.9971
HGB	103	12.6	12.5	1.2	0.9951	0.0853	0.9982
HCT	103	37.6	37.2	2.2	1.0041	0.2953	0.9950
MCV	103	87.8	87.5	1.2	0.9549	4.3174	0.9824
MCH	103	29.2	29.5	1.6	0.9426	1.4345	0.9791
MCHC	103	33.3	33.7	1.8	0.7759	7.1720	0.6784
RDW	103	13.1	13.5	4.7	0.4393	7.1667	0.9569
PLT	103	226	230	8.0	0.8882	21.837	0.9961
MPV	102	8.5	8.9	4.7	0.7037	2.2287	0.9334

Table 2: Correlation to Manual Differential

Parameter	Samples	Mean		Slope	Intercept	Correlation Coefficient r
		BC-3200	Manual differential			
Lymph%	196	26.8	30.4	0.7575	3.7958	0.95
Mid%	196	9.2	9.0	0.3739	5.822	0.57
Gran%	196	64.0	60.6	0.8456	12.721	0.94

b. *Precision/Reproducibility*:

Reproducibility is stated in terms of both Standard Deviation (SD) and Coefficient of Variation (CV%). Reproducibility was determined by replicate testing (n = 11) with samples of low, normal and high concentrations, three samples for each concentration. For each sample, results of the 2nd to 11th runs were adopted to calculate the SD and CV%.

Table 3: Imprecision, Low Concentration Samples

1	WBC $\times 10^3$ / µL	RBC $\times 10^6$ /µL	HGB (g/dL)	MCV (fl)	PLT $\times 10^3$ /µL
mean	4.1	2.88	9.2	64.6	162
SD	0.07	0.04	0.1	0.40	5.06
CV(%)	1.63	1.45	0.8	0.62	3.12
2	WBC $\times 10^3$ / µL	RBC $\times 10^6$ /µL	HGB (g/dL)	MCV (fl)	PLT $\times 10^3$ /µL
mean	3.2	3.02	9.3	72.9	155
SD	0.03	0.03	0.1	0.21	7.02
CV(%)	0.99	1.06	1.0	0.28	4.53
3	WBC $\times 10^3$ / µL	RBC $\times 10^6$ /µL	HGB (g/dL)	MCV (fl)	PLT $\times 10^3$ /µL
mean	3.1	1.91	5.6	61.0	61
SD	0.06	0.03	0.1	0.24	5.11
CV(%)	1.84	1.76	1.1	0.39	8.39

Table 4: Imprecision, Normal Concentration Samples

1	WBC $\times10^3$ / µL	RBC $\times10^6$ /µL	HGB (g/dL)	MCV (fl)	PLT $\times10^3$ /µL
mean	10.1	4.60	13.1	83.3	244
SD	0.12	0.03	0.09	0.38	8.05
CV(%)	1.18	0.73	0.7	0.45	3.30
2	WBC $\times10^3$ / µL	RBC $\times10^6$ /µL	HGB (g/dL)	MCV (fl)	PLT $\times10^3$ /µL
mean	9.8	5.34	15.2	83.1	249
SD	0.10	0.04	0.12	0.27	4.86
CV(%)	0.99	0.78	0.8	0.33	1.95
3	WBC $\times10^3$ / µL	RBC $\times10^6$ /µL	HGB (g/dL)	MCV (fl)	PLT $\times10^3$ /µL
mean	11.3	5.27	15.0	85.9	231
SD	0.13	0.04	0.06	0.21	8.53
CV(%)	1.11	0.73	0.4	0.25	3.70

Table 5: Imprecision, Normal Concentration Samples

1	WBC $\times10^3$ / µL	RBC $\times10^6$ /µL	HGB (g/dL)	MCV (fl)	PLT $\times10^3$ /µL
mean	10.1	4.60	13.1	83.3	244
SD	0.12	0.03	0.09	0.38	8.05
CV(%)	1.18	0.73	0.7	0.45	3.30
2	WBC $\times10^3$ / µL	RBC $\times10^6$ /µL	HGB (g/dL)	MCV (fl)	PLT $\times10^3$ /µL
mean	9.8	5.34	15.2	83.1	249
SD	0.10	0.04	0.12	0.27	4.86
CV(%)	0.99	0.78	0.8	0.33	1.95
3	WBC $\times10^3$ / µL	RBC $\times10^6$ /µL	HGB (g/dL)	MCV (fl)	PLT $\times10^3$ /µL
mean	11.3	5.27	15.0	85.9	231
SD	0.13	0.04	0.06	0.21	8.53
CV(%)	1.11	0.73	0.4	0.25	3.70

Inter-laboratory Precision:

Two laboratories, each having one BC-3200 installed, were selected for the test. Three samples of various concentrations (respectively low, normal and high) were prepared, each with sufficient volume to run twice on both of the BC-3200s. Each BC-3200 was operated by one operator, who conducted the test from beginning to the end. Each sample was divided into two aliquots, and the two aliquots were analyzed respectively by the two selected laboratories within the same day of preparation. Each aliquot was run twice on the BC-3200 and both runs were conducted within a short interval. No outlier was found during the test. Based on the data acquired, repeatability variance (S^{r2}), between laboratory variance (S^{j2}), and reproducibility variance (S_R^2) of the following parameters, WBC, RBC, PLT, HGB, Lymph%, Mid% and Gran%,, were calculated for ea concentration.

Table 6: Within-run Precision and Total Precision

		Low	Normal	High
WBC×10^3 / µL				
Mean		2.13	8.10	20.68
Repeatability variance	S_r^2	0.0025	0.0098	0.0613
Between Laboratory variance	S_L^2	0.0000	0.0151	0.0000
Reproducibility variance	S_R^2	0.0025	0.0249	0.0613
	S_R	0.0500	0.1578	0.2476
	CV%	2.35%	1.95%	1.20%
Gran(%)				
Mean		32.53	60.98	81.30
Repeatability variance	S_r^2	1.1050	0.0221	0.0637
Between Laboratory variance	S_L^2	1.7588	0.7703	0.0932
Reproducibility variance	S_R^2	2.8638	0.7924	0.1569
	S_R	1.6923	0.8902	0.3961
	CV%	5.20%	1.46%	0.49%
Lymph (%)				
Mean		12.65	28.83	51.30
Repeatability variance	S_r^2	0.2073	0.0613	3.0439
Between Laboratory variance	S_L^2	0.0000	1.3307	6.4781

Reproducibility variance	S_R^2	0.2073	1.3920	9.5220
	S_R	0.4553	1.1798	3.0858
	CV%	3.60%	4.09%	6.02%
Mid (%)				
Mean		6.05	10.20	16.18
Repeatability variance	S_r^2	0.0490	0.0098	0.6655
Between Laboratory variance	S_L^2	0.0205	0.0751	1.3786
Reproducibility variance	S_R^2	0.0695	0.0849	2.0441
	S_R	0.2636	0.2914	1.4297
	CV%	4.36%	2.86%	8.84%
RBC ($\times 10^6$ /μL)				
Mean		2.48	4.89	5.80
Repeatability variance	S_r^2	0.0004	0.0065	0.0085
Between Laboratory variance	S_L^2	0.0007	0.0013	0.0000
Reproducibility variance	S_R^2	0.0011	0.0078	0.0085
	S_R	0.0332	0.0883	0.0922
	CV%	1.34%	1.81%	1.59%
HGB (g/L)				
Mean		6.35	14.08	19.13
Repeatability variance	S_r^2	0.0000	0.0025	0.0123
Between Laboratory variance	S_L^2	0.0050	0.0601	0.0952
Reproducibility variance	S_R^2	0.0050	0.0626	0.1075
	S_R	0.0707	0.2502	0.3279
	CV%	1.11%	1.78%	1.71%
MCV (fl)				
Mean		77.28	86.73	96.33
Repeatability variance	S_r^2	0.1103	0.0123	0.0907
Between Laboratory variance	S_L^2	2.2562	1.5252	2.7160
Reproducibility variance	S_R^2	2.3665	1.5375	2.8067
	S_R	1.5383	1.2400	1.6753
	CV%	1.99%	1.43%	1.74%

PLT ($\times 10^3$ /µL)				
Mean		94.75	258.25	468.50
Repeatability variance	S_r^2	13.2453	16.2699	12.5033
Between Laboratory variance	S_L^2	14.5024	69.9901	65.7484
Reproducibility variance	S_R^2	27.7477	86.2600	78.2517
	S_R	5.2676	9.2876	8.8460
	CV%	5.56%	3.60%	1.89%

Table 6 Appendix

WBC	Form A			Form B			Form C		
Laboratory	Low	Normal	High	Low	Normal	High	Low	Normal	High
1	2.2	8.1	20.5	2.15	8.2	20.75	0.07	0.14	0.35
	2.1	8.3	21						
2	2.1	8	20.6	2.1	8	20.6	0	0	0
	2.1	8	20.6						

Gran(%)	Form A			Form B			Form C		
Laboratory	Low	Normal	High	Low	Normal	High	Low	Normal	High
1	32.5	60.2	81.1	31.45	60.35	81.05	1.48	0.21	0.07
	30.4	60.5	81						
2	33.5	61.6	81.8	33.6	61.6	81.55	0.14	0	0.35
	33.7	61.6	81.3						

Lymph (%)	Form A			Form B			Form C		
Laboratory	Low	Normal	High	Low	Normal	High	Low	Normal	High
1	12.8	29.9	51.7	12.75	29.65	53.3	0.07	0.35	2.26
	12.7	29.4	54.9						
2	12.1	28	50	12.55	28	49.3	0.64	0	0.99
	13	28	48.6						

Mid (%)	Form A			Form B			Form C		
Laboratory	Low	Normal	High	Low	Normal	High	Low	Normal	High
1	6.1	9.9	15.8	6.2	10	15.25	0.14	0.14	0.78
	6.3	10.1	14.7						
2	6.1	10.4	16.5	5.9	10.4	17.1	0.28	0	0.85
	5.7	10.4	17.7						

RBC	Form A			Form B			Form C		
Laboratory	Low	Normal	High	Low	Normal	High	Low	Normal	High
1	2.44	4.78	5.84	2.455	4.845	5.765	0.02	0.09	0.11
	2.47	4.91	5.69						
2	2.51	4.99	5.89	2.495	4.94	5.84	0.02	0.07	0.07
	2.48	4.89	5.79						

HGB	Form A			Form B			Form C		
Laboratory	Low	Normal	High	Low	Normal	High	Low	Normal	High
1	6.3	13.9	18.8	6.3	13.9	18.9	0	0	0.14
	6.3	13.9	19						
2	6.4	14.3	19.4	6.4	14.25	19.35	0	0.07	0.07
	6.4	14.2	19.3						

MCV	Form A	Form B	Form C						
Laboratory	Low	Normal	High	Low	Normal	High	Low	Normal	High
1	76.5	85.9	95.2	76.2	85.85	95.15	0.42	0.07	0.07
	75.9	85.8	95.1						
2	78.5	87.5	97.8	78.35	87.6	97.5	0.21	0.14	0.42
	78.2	87.7	97.2						

PLT	Form A			Form B			Form C		
Laboratory	Low	Normal	High	Low	Normal	High	Low	Normal	High
1	88	265	466	91.5	264.5	462.5	4.95	0.71	4.95
	95	264	459						
2	97	248	474	98	252	474.5	1.41	5.66	0.71
	99	256	475						

c. *Linearity*:

Linearity was determined by running diluted samples. RBC,HGB are diluted by blood plasma of the sample, while WBC and PLT are diluted by specified diluent. Concentrations from 0 to 100% were tested, each concentration twice. The average of the two runs is taken as the result, together with the concentration, to calculate per the linear regression equation.

Table 7: WBC Linearity

Dilution%	Test 1	Test 2	Mean	Ideal	Error	Proportional Error
100	117.1	115.9	116.50	120.01	3.51	2.9
80	99.8	100.1	99.95	96.01	-3.94	-4.1
60	73.4	72.1	72.75	72.00	-0.75	-1.0
40	47.8	48.6	48.20	48.00	-0.20	-0.4
20	23.1	23.1	23.10	23.99	0.89	3.7
10	12.1	12.0	12.05	11.99	-0.06	-0.5
5	6.0	6.2	6.10	6.00	-0.10	-1.7
2.5	3.0	2.9	2.95	2.99	0.04	1.3
1.25	1.3	1.3	1.30	1.49	0.19	12.8
0.625	0.5	0.5	0.50	0.74	0.24	32.4
0.3125	0.2	0.1	0.15	0.36	0.21	58.3
0	0	0	0.00	-0.01	-0.01	/
Slope	1.2002					
Intercept	-0.0129					

Table 8: RBC Linearity

Dilution%	Test 1	Test 2	Mean	Ideal	Error	Proportional Error
100	8.46	8.43	8.445	8.519	0.074	0.9
80	6.91	6.86	6.885	6.819	-0.066	-1.0
60	5.12	5.17	5.145	5.119	-0.026	-0.5
40	3.42	3.46	3.440	3.419	-0.021	-0.6
20	1.71	1.69	1.700	1.719	0.019	1.1
10	0.89	0.87	0.880	0.869	-0.011	-1.3
5	0.46	0.46	0.460	0.444	-0.016	-3.6
2.5	0.21	0.22	0.215	0.232	0.017	7.3
1.25	0.10	0.13	0.115	0.125	0.010	8.0
0	0.00	0.00	0.000	0.019	0.019	/
Slope	0.0850					
Intercept	0.0191					

Table 9: HGB Linearity

Dilution%	Test 1	Test 2	Mean	Ideal	Error	Proportional Error
100	25.6	25.6	25.60	25.40	-0.20	-0.8
80	20.5	20.1	20.30	20.33	0.03	0.1
60	15.1	14.9	15.00	15.26	0.26	1.7
40	10.1	10.1	10.10	10.19	0.09	0.9
20	5.2	5.0	5.10	5.11	0.01	0.2
10	2.7	2.6	2.65	2.58	-0.07	-2.7
5	1.4	1.4	1.40	1.31	-0.09	-6.9
2.5	0.7	0.7	0.70	0.68	-0.02	-2.9
1.25	0.4	0.4	0.40	0.36	-0.04	-11.1
0	0.0	0.0	0.00	0.04	0.04	/
Slope	0.2536					
Intercept	0.0425					

Table 10: PLT Linearity

Dilution%	Test 1	Test 2	Mean	Ideal	Error	Proportional Error
100	1014	1008	1011.0	1040.3	29.3	2.8
80	850	858	854.0	832.5	-21.5	-2.6
60	631	650	640.5	624.8	-15.7	-2.5
40	425	419	422.0	417.0	-5.0	-1.2
20	221	208	214.5	209.3	-5.2	-2.5
10	109	101	105.0	105.4	0.4	0.4
5	53	53	53.0	53.5	0.5	0.9
2.5	23	17	20.0	27.5	7.5	27.3
1.25	8	5	6.5	14.5	8.0	55.2
0	0	0	0.0	1.6	1.6	/
Slope	10.3871					
Intercept	1.5618					

d. *Carryover*:

Carryover was determined by first running the high concentration sample for three consecutive times (i1, i2, i3) and then the low concentration sample three consecutive times (j1, j2, j3), and finally calculating per the following equation: Carryover (%) = $[(j1 - j3)/ (i3-j3)] \times 100\%$. The test was then repeated using the high level control.

Table 11: Carryover, High Concentration Sample

Parameter	High Concentration Sample (Whole Blood)			Low Concentration Sample (Whole Blood)			Carryover %
	i1	i2	i3	j1	j2	j3	
WBC($\times 10^3$ / μL)	19.7	20.4	20.0	1.9	1.9	1.9	0%
RBC($\times 10^6$ /μL)	6.34	6.24	6.2	1.87	1.96	1.85	0.46%
HGB(g/dL)	25.4	25.0	24.8	3.3	3.2	3.2	0.46%
PLT($\times 10^3$ /μL)	404	390	396	31	34	33	0%

Table 12: Carryover, High Level Control

Parameter	High Concentration Sample (High Level Control)			Low Concentration Sample (Specified Diluent)			Carryover %
	i1	i2	i3	j1	j2	j3	
WBC($\times 10^3$ / μL)	21.7	21.3	21.7	0.0	0.0	0.0	0%
RBC($\times 10^6$ /μL)	5.88	5.79	5.79	0.00	0.00	0.00	0%
HGB(g/dL)	18.8	18.7	18.9	0.0	0.0	0.0	0%
PLT($\times 10^3$ /μL)	453	438	429	0	0	0	0%

e. *Interferring Substances*:

N/A

2. <u>Other Supportive Instrument Performance Data Not Covered Above:</u>

Ability to Flag Abnormal Histograms:

BC-3200's ability to flag abnormal WBC histograms was determined by comparing 200 sample results obtained by the BC-3200 to those obtained by manual differential.

Table 13: Ability to Flag Abnormal WBC Histograms

Manual differential	BC-3200	
	Positive (39)	Negative (161)
Positive (40) Negative (160)	TP □22□ FP □17□	FN □18□ TN □143□
Agreement%	False Positive Ratio (%)	False Negative Ratio (%)
82.5	10.6	45

Reference Ranges

A Normal Ranges Study was conducted to assess the Reference Ranges for the BC-3200 analyzer. Whole-blood samples were collected from 121 donors.

Table 14: Reference Ranges

Parameter	Units	Sex	Mean	90%Confidence Low Limit	90%Confidence High Limit
WBC	$\times 10^3$cells /µL	M/F	6.86	3.47	10.25
RBC	$\times 10^6$cells /µL	M/F	4.56	3.54	5.58
Hgb	g/ dL	M/F	13.40	10.27	16.52
Hct	ratio	M/F	40.12	30.98	49.26
MCV	fL	M/F	88.18	80.82	95.55
MCH	pg	M/F	29.36	26.57	32.15
MCHC	g/ dL	M/F	33.33	32.09	34.56
Plt	$\times 10^3$cells/µL	M/F	209.92	119.62	300.22
RDW	%	M/F	12.81	11.53	14.10
MPV	fL	M/F	8.47	7.07	9.87
LY	%	M/F	27.33	18.11	36.55
MO	%	M/F	9.45	5.23	13.67
GR	%	M/F	63.26	51.62	74.89

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.