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

A. 510(k) Number:
k080370

B. Purpose for Submission:
Clearance of a modified device (adding CO-OX to an already cleared instrument).

C. Measurand:
Blood gases, blood pH, sodium, potassium, calcium, chloride, glucose, carboxyhemoglobin, hemoglobin

D. Type of Test:
Potentiometric for pH, pCO2, Na+, K+, Cl-, Ca++
Amperometric for pO2, Glucose
Spectrophotometry for CO-Oximeter parameters

E. Applicant:
SenDx Medical, Inc.

F. Proprietary and Established Names:
ABL80 FLEX CO-OX

Regulatory Information:

1. Regulation section:

Description	CFR Section
Blood gases and blood pH	862.1120
Sodium test system	862.1665
Potassium test system	862.1600
Calcium test system	862.1145
Chloride test system	862.1170
Glucose test system	862.1345
Carboxyhemoglobin assay	864.7425
Automated hemoglobin system	864.5620
Oximeter to measure hemoglobin	864.7500
Quality Control Material	862.1660

2. Classification:

Description	Class
Blood gases and blood pH	Class II
Sodium test system	Class II
Potassium test system	Class II
Calcium test system	Class II
Chloride test system	Class II
Glucose test system	Class II
Carboxyhemoglobin assay	Class II
Automated hemoglobin system	Class II
Oximeter to measure hemoglobin	Class II
Quality Control Material	Class I

3. Product code:

Description	Product Code
Blood gases and blood pH	CHL
Sodium test system	JGS
Potassium test system	CEM
Calcium test system	JFP
Chloride test system	CGZ
Glucose test system	CGA
Carboxyhemoglobin assay	GHS
Automated hemoglobin system	GKR
Oximeter to measure hemoglobin	GLY
Quality Control Material	JJY

4. Panel:
   75 (Clinical Chemistry)

H. Intended Use:

1. Intended use(s):
   See indications for use below.
2. Indication(s) for use:
   The ABL80 FLEX CO-OX is a portable, automated system that measures pH, blood gases, electrolytes, glucose, and oximetry in whole blood. The ABL80 FLEX CO-OX system is intended for use by trained technologists, nurses, physicians and therapists. It

is intended for use in a laboratory environment, near patient or point-of-care setting.

These tests are only performed under a physicians order:

pH, pO2,and pCO2, : pH, pCO2 and pO2 measurements are used in the diagnosis and treatment of life-threatening acid-base disturbances.

Potassium (cK+): potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.

Sodium (cNa+): sodium measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic secretion, or other diseases involving electrolyte imbalance.

Calcium (cCa2+): calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

Chloride (cCl-): chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such a cystic fibrosis and diabetic acidosis.

Glucose (cGlu): glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Total Hemoglobin (ctHb): total hemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia.

sO2: oxygen saturation, more specifically the ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus reduced hemoglobin.

FO2Hb: oxyhemoglobin as a fraction of total hemoglobin.

FCOHb: carboxyhemoglobin measurements are used to determine the carboxyhemoglobin content of human blood as an aid in the diagnosis of carbon monoxide poisoning.

FMetHb: methemoglobin as a fraction of total hemoglobin.

FHHb: reduced hemoglobin as a fraction of total hemoglobin.

3. Special conditions for use statement(s):
   For prescription use.

4. Special instrument requirements:
   ABL80 FLEX CO-OX

I. Device Description:

The submitted device is the same device as the ABL80 FLEX (k051804) with the exception of the addition of oximetry and the changes to the pump tube, sample inlet, sample volume, and solution pack. As pH, pO2, pCO2, potassium, sodium, calcium, chloride, and glucose were already cleared for use in the k051804 submission, the focus of this clearance is on only the changes to the device (changes to the pump tube, sample inlet, sample volume, solution pack, and addition of the analytes total hemoglobin, *s*O2, *F*O2Hb, *F*COHb, *F*MetHb, and *F*HHb) .

J. Substantial Equivalence Information:

1. Predicate device name(s):
   SenDx Medical, Inc. ABL80 FLEX
   Radiometer Medical ApS ABL700 Series
2. Predicate 510(k) number(s):
   k051804
   k980130
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
		ABL80 FLEX
Blood Gas Measurement	pH, pCO_2, pO_2	Same
Electrolyte Measurement	cK^+, cNa^+, cCa^{2+}, cCl^-	Same
Metabolite Measurement	*c*Glucose	Same
Calibration Method	Two-point liquid calibration	Same
Sensors	Potentiometric, amperometric	Same
Storage conditions of sensor cassette	Same	Same
Storage conditions for the Solution Pack	Same	Same
		ABL700
Blood Gas Measurement	pH, pCO_2, pO_2	Same
Electrolyte Measurement	cK^+, cNa^+, cCa^{2+}, cCl^-	Same
Metabolite Measurement	*c*Glucose	Same
Hemoglobin Measurement	Photo spectroscopy	Same
Sensors	Potentiometric, amperometric	Same

Differences		
Item	Device	Predicate
		ABL80 FLEX
Oximetry System	Contains oximetry system	No oximetry system
Pump tube	Incorporated into analyzer	Incorporated into sensor cassette

Differences		
Item	Device	Predicate
Sample inlet	Self-cleaning inlet	Inlet requires manual wiping
Sample volume	100 micro liters	70 microliters
Solution Pack	Contains sulforhodamine for QC of co-oximetry	No sulforhodamine
		ABL700
Oximetry System	Based on a 138-wavelength spectrophotometer with a measuring range of 467-672 nm	Based on a 128-wavelength spectrophotometer with a measuring range of 478-672 nm
Calibration and QC solutions	Calibration and QC solutions, plus a waste reservoir are contained in one solution pack	Discrete bottles or ampoules

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

None referenced.

L. Test Principle:

There are three different measuring principles employed.

Potentiometry: A potential is recorded using a voltmeter, which relates to the concentration of the sample. A reference electrode is used to provide a stable, fixed potential against which other potential differences can be measured. This measurement technique is used for pH, pCO2 and electrolytes.

Amperometry: The magnitude of an electrical flow of current is proportional to the concentration of the substance being oxidized or reduced at an electrode. This measurement technique is used for pO2 and Glucose.

CO-Oximetry: Measurements involve ultrasonically lysing the whole blood sample and then utilizing a broad spectrum spectrometer to evaluate the sample at a variety of wavelengths.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:

   Samples were heparinized whole blood from healthy, voluntary donors. The blood was prepared to obtain multiple concentration levels of each measured parameter. For sO2 and *F*COHb, the blood was mixed with appropriate gas mixture to attain test levels. For *F*MetHb and *F*HHb the blood was chemically treated to attain test levels.

   Five replicates per level and analyte were measured on each ABL80 FLEX CO-OX. The test was repeated for 3 days. A single operator performed each test within each

day. Multiple operators performed test between days. The standard deviation (SD) and coefficient of variation (%CV) were calculated on pooled results using analysis of variance.

Results/Acceptance criteria:

The table below lists SD and %CV for the parameters of the ABL80 FLEX CO-OX analyzer.

Parameter	Mean Level	Unit	ABL80 FLEX CO-OX	
			SD	%CV
*c*tHb (sO2 100%)	7.2	g/dL	0.07	1.0%
*c*tHb (sO2 100%)	14.5	g/dL	0.13	0.9%
*c*tHb (sO2 100%)	23.8	g/dL	0.21	0.9%
*c*tHb (sO2 0%)	14.8	g/dL	0.12	0.8%
*s*O2 (tHb 7 g/dL)	100.5	%	0.14	0.1%
*s*O2 (tHb 15 g/dL)	100.1	%	0.06	0.1%
*s*O2 (tHb 25 g/dL)	99.8	%	0.08	0.1%
*s*O2 (tHb 15 g/dL)	0.4	%	0.08	N/A
FO_2Hb (tHb 7 g/dL)	98.4	%	0.14	0.1%
FO_2Hb (tHb 15 g/dL)	98.7	%	0.07	0.1%
FO_2Hb (tHb 25 g/dL)	99.2	%	0.23	0.2%
FO_2Hb (tHb 15 g/dL)	0.2	%	0.08	N/A
*F*COHb (tHb 15 g/dL)	21.1	%	0.09	0.4%
*F*COHb (tHb 15 g/dL)	0.1	%	0.05	N/A
*F*MetHb (tHb 15 g/dL)	22.3	%	0.11	0.5%
*F*MetHb (tHb 15 g/dL)	1.6	%	0.06	N/A
*F*HHb (tHb 15 g/dL)	97.4	%	0.20	0.2%
*F*HHb (tHb 15 g/dL)	-0.1	%	0.06	N/A

A precision study was performed to assess the reproducibility of sample measurement in the ABL80 FLEX CO-OX when samples are performed by end-users at the point-of-care. The method used for this study was repeat measurements on several levels of aqueous samples in analysis mode. Aqueous samples consisted of ampoules containing 3 different levels of all parameters. Ampoules were chosen at random and analyzed once. This study was performed by five different point of care personnel at two different hospital locations. The site users had no previous experience with the ABL80 FLEX CO-OX.

Results from each site were tabulated separately. The mean, standard deviation (SD), and coefficient of variance (%CV) were calculated for each test level and parameter. The data were not pooled due to small biases between sites. The biases are largely due to the nature of the test samples. The test samples were aqueous quality control materials packaged in glass ampoules with an included gas phase. The gas phase produces a temperature dependency of the gas tensions and pH which, if not equilibrated to the same temperature at each site, will produce small biases of the gas and pH measurements between sites due to the temperature differences at the test sites.

Hospital Site 1					
			LEVEL		
Parameter	Unit	Statistic	Level 1	Level 2	Level 3
*c*tHb	g/dL	Mean	8.2	13.1	19.6
		SD	0.04	0.08	0.11
		%CV	0.5	0.6	0.6
*s*O2	%	Mean	49.9	96.6	69.8
		SD	0.01	0.06	0.02
		%CV	0	0.1	0
FO_2Hb	%	Mean	44.6	92.1	49.1
		SD	0.01	0.01	0.01
		%CV	0	0	0
*F*COHb	%	Mean	5.7	2.5	19.6
		SD	0.04	0.07	0.04
		%CV	0.7	2.6	0.2
*F*MetHb	%	Mean	5	2.1	10
		SD	0	0.02	0
		%CV	0.1	1	0
*F*HHb	%	Mean	44.8	3.2	21.3
		SD	0.03	0.06	0.03
		%CV	0.1	1.8	0.1

Hospital Site 2					
			LEVEL		
Parameter	Unit	Statistic	Level 1	Level 2	Level 3
*c*tHb	g/dL	Mean	8.3	13.1	19.6
		SD	0.04	0.05	0.13
		%CV	0.5	0.4	0.6
sO2	%	Mean	49.9	96.6	69.8
		SD	0	0.08	0.04
		%CV	0	0.1	0.1
FO_2Hb	%	Mean	44.6	92.1	49.1
		SD	0	0	0
		%CV	0	0	0
*F*COHb	%	Mean	5.6	2.5	19.6
		SD	0.04	0.08	0.04
		%CV	0.7	3	0.2
*F*MetHb	%	Mean	5	2.1	10
		SD	0	0.05	0
		%CV	0	2.5	0
*F*HHb	%	Mean	44.8	3.2	21.3
		SD	0.04	0.05	0.03
		%CV	0.1	1.6	0.1

b. Linearity/assay reportable range:
Reference method comparison for oximetry (tHb, *s*O2, O_2Hb, HHb, COHb and

MetHb) were against ABL735 analyzers. Samples were heparinized whole blood from healthy, voluntary donors. The blood was prepared to obtain high, mid, and low concentration levels of each measured parameter covering the reportable range. For tHb, the plasma volume of the sample was adjusted to attain test levels. For sO2 and *F*COHb, the blood was mixed with an appropriate gas mixture to attain test levels. For *F*MetHb and *F*HHb the blood was chemically treated to attain test levels using sodium dithionite in TRIS-buffer for HHb and potassium nitrite in isotonic saline solution for MetHb. Four replicates per level and parameter were measured on each ABL80 FLEX CO-OX. Each sample was split with the reference method analyzer.

Results:

The results of the linearity testing and the reportable range for each parameter are shown in the table below.

ctHb g/dL		
ABL80 Mean	ABL735 Mean	Mean Bias
5	5	0
11.6	11.6	0
14	14.2	-0.2
15.1	15.5	-0.4
17.7	18.1	-0.4
24.6	25.6	-1

sO2 %		
ABL80 Mean	ABL735 Mean	Mean Bias
0.1	0.2	-0.1
20	19.5	0.5
53.2	52.1	1.1
70.1	69.4	0.7
94	92.8	1.2
100	100	0

FO2Hb %		
ABL80 Mean	ABL735 Mean	Mean Bias
0.1	0.2	-0.1
18.1	17.8	0.3
50.6	50.2	0.4
68.7	68.5	0.2
90.5	90.8	-0.3
98.5	98.3	0.2

FCOHb %		
ABL80 Mean	ABL735 Mean	Mean Bias
0.4	0.2	0.2
1.5	1.1	0.4
3.4	2.5	0.9
8.6	8.8	-0.2
13.9	13.8	0.1
26.1	25.8	0.3

FMetHb %		
ABL80 Mean	ABL735 Mean	Mean Bias
0.7	0.7	0
1.7	1	0.7
5.3	5.3	0
7.8	7.4	0.4
11.2	10.8	0.4
26.4	26.4	0

FHHb %		
ABL80 Mean	ABL735 Mean	Mean Bias
0	0	0
1.6	2.2	-0.6
4.9	5.8	-0.9
29.4	30.3	-0.9
72.6	73.7	-1.1
98.5	98.9	-0.4

	ctHb (g/dL)	sO2 (%)	FO2Hb (%)	FCOHb (%)	FMetHb (%)	FHHb (%)
N	24	24	24	24	24	24
Slope	0.95	1.005	0.999	0.988	0.989	0.999
Intercept	0.468	0.304	0.138	0.393	0.309	-0.621
R	1	1	1	0.999	1	1
Min	5	0.1	0.1	0.2	0.7	0
Max	25.6	100	98.5	26.1	26.4	98.9

The claimed testing ranges are noted below with the lower range from the limit of quantitation study in section M.1.d below:

Parameter	Unit	Test Range	N
*c*tHb	g/dL	7 – 25	180
*s*O2	%	0 – 100	180
FO_2Hb	%	0 – 100	180
*F*COHb	%	0 – 20	90
*F*MetHb	%	0 – 20	90
*F*HHb	%	0 – 100	45

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
The SP80 CO-OX solution pack consists of four solution pouches. These solutions are used for calibration and quality control of the ABL80 FLEX CO-OX system. Each solution contains varying analyte concentrations. The true value for each solution is assigned from testing during manufacture. During testing, Reference Ampoules are tested at the same time as the solution lot.

The true values of the reference ampoules are determined using reference methods specified at Radiometer Medical. The true values for pH are traceable to the Chemical Reference Laboratory, Danish Accreditation no. 119 and to SRM from NIST. All other parameters are traceable to SRM from NIST. The following SRM types are used: SRM 1701, SRM 1702, SRM 1703, SRM 186 IF, SMR 186 IIf, SRM 919a, SRM 999, SRM 915, and SRM 917a.

Stability testing was performed to verify solution values over shelf life at minimum and maximum storage temperatures. The stability is calculated from the difference between the initial values of each parameter at the time of production and the final values after storage at the maximum storage temperature until the product expires.

True values, QC assigned values, QC acceptance ranges, and decay coefficients are programmed onto the solution pack iButton at time of manufacture. This information is read into the analyzer at time of installation.

Listed below are representative nominal true values of each solution:

Parameter	Solution 1 PN 41924	Solution 2 PN 42470	Solution 3 PN 41926	Solution 4 PN 42471
tHb, g/dL	--	19.8	0.0	13.2
*s*O2, %	--	70.9	0.0	97.8
*F*O2Hb, %	--	48.4	0.0	92.3
*F*COHb, %	--	21.7	0.0	4.0
*F*MetHb, %	--	10.0	0.0	1.7
*F*HHb, %	--	19.8	0.0	2.1

d. *Detection limit:*

The optical system in the oximetry module is a spectrophotometer with a linear output as a function of specific analyte concentrations. Because the raw instrument output at low levels for some measured quantities can result in negative concentrations, the user is able to truncate these as noted below.

The lower limit of detection (LLD) study was performed on 5 ABL80 FLEX CO-OX. Samples were whole human blood prepared at test levels. A total of 75 samples per level were tested. Each sample was split with 2 ABL735 reference analyzers. The mean bias from reference and pooled precision estimates (reproducibility, S_x) was calculated for each level. They were then combined to obtain an estimate of total error (TE) at each level, using TE = |Bias| + 2 x Sx. The 95% confidence interval indicates the range in which a sample with a true value equal to the LLD will be measured. A summary of results is shown in the below tables and is present in the device labeling.

Not truncated

Parameter	Unit	Level	Bias	Reproducibility (S_x)	95% Confidence Interval		
					TE	Lower	Upper
*ct*Hb	g/dL	7	0.09	0.17	0.43	6.75	7.43
*s*O2	%	0	0.07	0.18	0.43	-0.29	0.43
*F*O2Hb	%	0	0.07	0.21	0.49	-0.35	0.49
*F*COHb	%	0	0.45	0.33	1.11	-0.21	1.11
*F*MetHb	%	0	-0.23	0.48	0.73	-1.19	0.73
*F*HHb	%	0	-0.24	0.57	0.90	-1.38	0.90

Truncated

Parameter	Unit	Level	Bias	Reproducibility (S_x)	95% Confidence Interval		
					TE	Lower	Upper
*ct*Hb	g/dL	7	0.09	0.17	0.43	6.75	7.43
*s*O2	%	0	0.07	0.18	0.43	0	0.43
*F*O2Hb	%	0	0.07	0.21	0.49	0	0.49
*F*COHb	%	0	0.45	0.33	1.11	0	1.11
*F*MetHb	%	0	-0.23	0.48	0.73	0	0.73
*F*HHb	%	0	-0.24	0.57	0.90	0	0.90

e. Analytical specificity:

A test of analytical specificity was performed using multiple potential interfering substances. Either aqueous or whole blood samples were prepared with known parameter concentrations at normal levels. The samples were split and spiked with either the interferent (test), or an equal amount of diluent without interferent (control.) Three replicates each of control (C) and test (T) samples were run for each substance as follows: C, C1, T1, C, C2, T2, C, C3, T3.

Results:

The difference between the mean of C1, C2, C3 and T1, T2, T3 was calculated as the amount of interference. The 95% Confidence Interval for the difference between two means was used to determine if the mean difference between test and control samples was statistically significant. If (3.5 * SD) < Mean Δ < (3.5 * SD), the sponsor defined that the difference in parameter between test and control samples is zero and difference is not significant. The tables below summarize substances, test concentrations, parameter concentrations, and test results. Values that are bold were determined by the sponsor to be significant interference based on the above definition and are noted in the reference manual.

Parameter		ctHb	sO2	FO2Hb	FCOHb	FMetHb	FHHb
		g/dL	%	%	%	%	%
Substance	Level						
pH	6.85	-0.052	**-1.11**	**-2.494**	0.046	**1.371**	**1.073**
	7.15	-0.023	-0.426	-1.002	-0.019	0.603	0.42
	8	-0.152	0.607	**-1.068**	0.337	**1.316**	-0.585
Fluorescein	250 mg/L	**1.312**	**-3.205**	**-9.501**	**-4.142**	**10.717**	**2.92**
Beta-carotene*	3.7 µmol/L	0	0	0.0011	0.0001	-0.0012	0.01
Patent Blue V	10 mg/L	-0.207	0.455	**1.531**	-0.604	-0.479	-0.45
Methylene Blue	10 mg/L	-0.473	0.689	**3.71**	0.171	**-3.219**	-0.664
	30 mg/L	**-1.629**	**2.692**	**13.7**	0.297	**-11.192**	**-2.803**
	60 mg/L	**-3.005**	**4.245**	**27.839**	**-1.248**	**-21.501**	**-5.087**
Cardio Green	7 mg/L	0.049	0.01	0.198	0.012	-0.267	-0.01
	30 mg/L	-0.329	0.398	**1.552**	0.015	**-1.171**	-0.393
Evans Blue	5 mg/L	-0.117	-0.242	0.103	-0.267	-0.075	0.237
Intralipid	2%	-0.031	0.017	-0.319	0.15	0.189	-0.017
	5%	-0.057	-0.01	**-1.426**	0.446	0.975	0.005
HiCN	30%	-0.302	-0.327	-33.704	0.131	**33.404**	0.172
	100%	0.452	**100.01**	-98.151	**1.11**	**95.92**	**1.122**
SHb	20%	**-2.12**	-0.034	-0.008	-0.007	-0.041	0.036
	50%	**-4.492**	**1.744**	**-5.67**	-0.01	**7.285**	**-1.607**
Bilirubin (unconjugated)	20 mg/dL	-0.029	-0.017	-0.265	0.022	0.227	0.015
Bilirubin (conjugated)	20 mg/dL	0.043	0.055	0.078	0.045	-0.068	-0.054

* Interference calculated from spectrum

f. Assay cut-off:
Not Applicable

2. Comparison studies:
   a. Method comparison with predicate device:

Reference method comparison for oximetry (tHb, sO2, O_2Hb, HHb, COHb and MetHb) was against ABL735 analyzers. Samples were heparinized whole blood from healthy, voluntary donors. The blood was prepared to obtain high, mid, and low concentration levels of each measured parameter covering the reportable range. For ctHb, the plasma volume of the sample was adjusted to attain test levels. For sO_2 and FCOHb, the blood was mixed with an appropriate gas mixture to attain test levels. For FMetHb and FHHb the blood was chemically treated to attain test levels using sodium dithionite in TRIS-buffer for HHb and potassium nitrite in isotonic saline solution for MetHb. Five replicates per level and parameter were measured on each ABL80 FLEX CO-OX. Results are summarized below.

Parameter	Range	Units	Slope	Offset	R^2	$S_{y.x}$
*c*tHb	7 - 25	g/dL	1.016	-0.003	0.999	0.23
	4 - 16	mmol/L	1.016	0.002	0.999	0.14
*s*O2	0 - 100	%	1.007	0.402	1.000	0.32
FO_2Hb	0 - 100	%	0.999	0.377	1.000	0.35
*F*COHb	0 - 20	%	0.993	0.072	1.000	0.18
*F*MetHb	0 - 20	%	1.011	-0.414	0.998	0.44
*F*HHb	0 - 100	%	0.998	-0.565	1.000	0.47

An additional study using 44 blood samples that spanned the test range for the ABL80 Flex CO-OX was performed testing each sample once. Samples were heparinzed whole human blood as well as altered human blood. The altered samples (40 samples altered 4 samples unaltered) were prepared as follows: ctHb - blood was spun to separate plasma and RBC. Plasma and RBC were remixed in varying ratios to obtain ctHb levels. sO2, FO2Hb, FHHb > 0% - blood was treated with sodium dithionite to remove O2 or mixed with O2 gas at varying levels. FCOHb - blood was mixed with CO gas at varying levels. FMetHb - blood was treated with KNO2. Results are summarized below.

	ctHb	sO2	FO2Hb	FCOHb	FMetHb	FHHb
	g/dL	%	%	%	%	%
N	44	44	44	44	44	44
Slope	0.955	1.006	1.004	1.004	0.982	1
Intercept	0.388	0.402	0.367	0.171	0.172	-0.872
R	0.999	1	1	0.999	0.999	1
Min	4.5	0	0	0.2	0.2	0
Max	24.9	100	99	26.1	30.1	98.7

An accuracy study was performed at a point of care site to demonstrate accuracy by the intended users of the device. Over 3 days, 21 collected patient blood samples were compared to the ABL835. Summary regression and bias statistics are shown below:

	ctHb	sO2	FO2Hb	FCOHb	FMetHb	FHHb
	g/dL	%	%	%	%	%
N	44	47	47	47	47	47
Slope	0.967	1	0.99	0.999	0.979	0.993
Intercept	-0.124	0.433	0.548	0.7	0.127	-0.398
R	0.991	1	0.999	0.998	0.997	1
Sample range	8.1 - 23.5	0.0 - 99.5	0.0 - 97.9	0.0 - 20.2	0.1 - 21.0	0.5 - 98.9

b. Matrix comparison:
Not Applicable.

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):
   Not Applicable.

4. Clinical cut-off:
   Not Applicable.

5. Expected values/Reference range:
   The reference range for each parameter has been established in the literature. Typical reference ranges for parameters measured by the ABL80 FLEX CO-OX are summarized below:

Parameter	Units	For adults' arterial blood at 37° C	
		Reference Range	Sex
*c*tHb	g/dL	13.5 - 17.5 12.0 - 16.0	m[1] f[1]
	mmol/L	8.4 – 10.9 7.4 - 9.9	m[1] f[1]
sO2	%	95 – 99	m, f[2]
FO_2Hb	%	94 – 98	m, f[1]
*F*COHb	%	0.5 - 1.5	m, f[1]
*F*MetHb	%	0.0 - 1.5	m, f[1]

1. Tietz NW., Logan NM. Reference ranges. In: Tietz NW, ed. Fundamentals of clinical chemistry. 3rd ed. Philadelphia: WB Saunders Company, 1987:944-75.

2. Siggaard-Andersen O, Wimberley PD, Fogh-Andersen N, Gothgen IH. Arterial oxygen status determined with routine pH/blood gas equipment and multi-wavelength

hemoximetry: reference values, precision and accuracy. Scand J Clin Lab Invest 1990; 50, Suppl 203:57-66.

N. Instrument Name:

ABL80 FLEX CO-OX

O. System Descriptions:

1. Modes of Operation:
   Discrete, Single line random access, multi-tests analysis.
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:
   Automatic sample aspiration.
4. Specimen Sampling and Handling:
   This device is intended to be used with whole blood samples. The sponsor recommends sample handling procedures in the package inserts of the assays.
5. Calibration:
   The ABL80 FLEX CO-OX is equipped with the QC^3 automatic quality control system. This provides a calibration process that measures three solutions with different analyte concentrations. These three measured values are used in different combinations of two points each to establish three two point calibration lines for each analyte. One calibration line is consistently used to report sample results, with the other two calibration lines used to evaluate system linearity.
6. Quality Control:
   The SP80 CO-OX solution pack consists of four solution pouches. These solutions are used for calibration and quality control of the ABL80 FLEX CO-OX system. Each solution contains varying analyte concentrations. The true value for each solution is assigned from testing during manufacture. During this test, Reference Ampoules are tested at the same time as the solution lot.

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

None

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.