510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

k200986

B Applicant

OPTI Medical Systems, Inc.

C Proprietary and Established Names

OPTI® B-Lac Cassette

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
CHL	Class II	21 CFR 862.1120 - Blood Gases (pCO_2, pO_2) And Blood pH Test System	CH - Clinical Chemistry
GKR	Class II	21 CFR 864.5620 - Automated hemoglobin system	HE - Hematology
GLY	Class II	21 CFR 864.7500 - Whole blood hemoglobin assays	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

Modification of the pCO_2 sensor in an existing device (k093280) following a field corrective action for pCO_2.

B Measurand:

pH, pO_2, pCO_2, total hemoglobin (tHb) and oxygen saturation (SO_2).

C Type of Test:

Quantitative - using optical fluorescence and reflectance technology.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The OPTI® B-Lac cassette is intended to be used for the in vitro measurement of pH, pO_2, pCO_2, total hemoglobin (tHb), and % Saturated O_2 in sodium heparinized venous blood samples on the OPTI CCA-TS and OPTI CCA-TS2 platform in a clinical laboratory location.

- Measurements of blood gases (pCO_2, pO_2) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances.
- Total hemoglobin (tHb) measurement is used to determine the hemoglobin content of human blood.
- Oxygen saturation (SO_2) measurement is used to determine the oxygen capacity of the hemoglobin.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

OPTI CCA-TS/TS2 Analyzers

IV Device/System Characteristics:

A Device Description:

The OPTI® B-Lac cassette is a disposable, single use cassette that contains four sensors for *in vitro* quantitative measurements of pO_2, pCO_2, pH and Lactate. The cassette includes additional laser-based measurements of total hemoglobin (tHb) and SO_2. The pO_2, pH, tHb, and SO_2 sensors were not modified from the previous clearance (k093280). The B-Lac cassette is sealed in a foil pouch along with a desiccant and is marked with a barcode label that includes a lot identification number, calibration information, and expiration date.

B Principle of Operation:

The OPTI® B-Lac cassette uses fluorescence optodes to measure the intensity of light emitted from fluorescent dyes exposed to specific analytes. The concentration of the analyte is determined by the calculation of the difference in fluorescence measured at a defined calibration point and that measured with the unknown concentration of analyte. The principles of

measurement of pO_2, pCO_2 and pH for the B-Lac cassette are similar to those used with existing cassette styles that are used on the OPTI CCA-TS/TS2 (k984299).

V Substantial Equivalence Information:

A Predicate Device Name(s):

ABL90 FLEX Series, OPTI CCA-TS2

B Predicate 510(k) Number(s):

k092686, k131126

C Comparison with Predicate(s):

Device Comparison Table: pH, pO_2, pCO_2 and tHb

Device & Predicate Device(s):	k200986	k092686
Device Trade Name	OPTI® B-Lac Cassette	ABL90 FLEX
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended to be used for in vitro measurements of pH, pO_2, pCO_2 and tHb (total hemoglobin) in heparinized venous whole blood samples.	Same
Measured Parameter	pH, pO_2, pCO_2 and tHb (total hemoglobin)	Same
Measurement Temperature	37 °C	Same
General Device Characteristic Differences		
Sample Type	Sodium heparin venous blood	Arterial and venous whole blood with heparin anticoagulant
Test Environment	Clinical laboratory setting	Laboratory environment, near patient or point-of-care (POC) setting
Measurement Principle	pH: fluorescence pO_2: fluorescence pCO_2: fluorescence tHb: Optical reflectance	pH: electrochemistry pO_2: optical pCO_2: electrochemistry ctHb: spectrophotometry

Device & Predicate Device(s):	k200986	k092686
	measurement.	
Reportable Ranges	pH: 6.818 - 7.8 pO_2: 10 - 700 mmHg pCO_2: 10 - 200 mmHg mmol/L tHb: 5.0 – 24 g/L	pH: 6.818 – 7.797 pO_2: 30.1 - 488 mmHg pCO_2: 15.4 – 98.3 mmHg tHb: 0.1 – 24 g/dL
Sample Volume	125 µL	65 – 150 µL
Measurement Time	180 s from sample introduction	35 s
Test Consumable Storage	Refrigerated storage (2 – 8°C) until expiry date including max 28 days at room temperature	Sensor Pack: 2 – 8°C storage until expiry date Fluid Pack: 2 – 25°C storage until expiry date

Device Comparison Table: SO_2

Device & Predicate Device(s):	k200986	k131126
Device Trade Name	OPTI® B-Lac cassette	OPTI CCA TS2 E-Series Cassettes
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended to be used for in vitro measurements of oxygen saturation (SO_2), in heparinized venous whole blood samples.	Same.
Reportable Ranges	SO_2: 60% - 100%	Same
Sample Volume	125 µL	Same
Measurement Time	180 s from sample introduction	Same
General Device Characteristic Differences		
Sample type	Whole blood (sodium heparinized, venous)	Whole blood, serum, and plasma (heparinized, venous or arterial)
Test Environment	Clinical laboratory setting	Clinical laboratory setting or POC locations
Test Consumable Storage	Refrigerated storage (2 – 8°C) until expiry date	Room temperature storage (4 – 30°C) until

Device & Predicate Device(s):	k200986	k131126
	including max 28 days at room temperature.	expiration date

VI Standards/Guidance Documents Referenced:

CLSI EP5-A3 - Evaluations of Precision Performance of Quantitative Measurement in Methods; Approved Guideline – Third Edition

CLSI EP6-A – Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

CLSI EP7-A2 – Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition

CLSI EP17-A2 – Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

In-House Within Run Precision Evaluation:
Within run precision testing was performed using venous whole blood manipulated to three different levels (tonometered for gases, spiked or diluted for tHb) and three levels of aqueous quality control solutions (OPTI Check Level 1, 2 and 3) following the experimental protocol recommended in the CLSI guideline EP05-A3. The samples were run in multiple replicates on three separate lots of B-Lac cassettes. Each lot was run on one OPTI CCA-TS and one OPTI CCA-TS2 analyzer for pH, pCO_2, pO_2, tHb, and SO_2.

The data supported that the performance in venous whole blood in clinical laboratory settings as demonstrated in k093280 for pO_2, pH, tHb, and SO_2 has not changed. A summary of the within-run precision results for one representative lot for pCO_2 is presented in the tables below:

Venous whole blood:
pCO_2

Sample Description	OPTI CCA TS				OPTI CCA TS2			
	Mean (mm Hg)	N	SD	%CV	Mean (mm Hg)	N	SD	%CV
Level 1	14.9	9	0.5	3.69	16.0	9	0.9	5.74
Level 2	38.3	10	0.7	1.77	39.5	10	1.0	2.42
Level 3	75.6	10	2.3	3.11	78.4	10	2.4	3.11

Aqueous controls:

pCO_2

Sample Description	OPTI CCA TS				OPTI CCA TS2			
	Mean (mm Hg)	N	SD	%CV	Mean (mm Hg)	N	SD	%CV
Level 1	22.1	10	1.4	6.30	22.9	10	0.9	3.93
Level 2	40.1	8	1.0	2.40	41.4	8	1.2	2.91
Level 3	65.7	9	1.3	1.95	67.1	9	1.3	1.86

In-House Multi-Day Precision Testing:

A 20-Day precision study was performed using three levels of aqueous quality control solutions, following the experimental protocol recommended in the CLSI guideline EP05-A3. Typical within-run, between-day and total precision were determined from four runs per day over 20 days on three lots of B-Lac cassettes. Each lot of cassette was run on one OPTI CCA-TS and one OPTI-CCA-TS2 analyzer. The data supported that the performance in venous whole blood in clinical laboratory settings as demonstrated in k093280 for pO_2, pH, tHb, and SO_2 has not changed. A summary of the multi-day precision results for one representative lot for pCO_2 is presented in the tables below:

pCO_2

Sample Description	Mean (mm Hg)	N	Within-Run		Between Day		Between-Instrument		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Level 1	25.9	160	1.55	6.0	0.00	0.0	0.19	0.7	1.56	6.0
Level 2	41.3	160	0.54	1.3	0.00	0.0	0.28	0.7	0.63	1.5
Level 3	68.5	160	2.04	3.0	0.00	0.0	0.50	0.7	2.14	3.1

2. Linearity:

To evaluate the linearity of the B-Lac pCO_2, pO_2, pH, tHb and SO_2, venous whole blood samples from different donors collected in sodium heparin tubes were tonometered with a range of $\%CO_2$ and $\%O_2$ gas mixtures to generate samples with pCO_2, pO_2, pH, and SO_2 values spanning the claimed measuring ranges. Venous whole blood was manipulated (centrifuged and spiked with red blood cells or diluted with plasma, then tonometered with 6% CO_2/ 12% O_2 gas) to obtain tHb values spanning the claimed measuring range. Testing was performed using three different lots of B-Lac cassettes with three replicate measurements being taken for each lot for each sample, on one CCA-TS analyzer and one CCA-TS2 analyzer. The concentrations for pH and tHb were assigned using the ABL90 FLEX analyzer. For pO_2 and pCO_2 the concentrations were assigned by tonometry as well as using the ABL90 FLEX analyzer. The SO_2 concentration was assigned using the OPTI CCA TS/TS2 E Series Cassette.

The data supported that the performance in venous whole blood in clinical laboratory settings as demonstrated in k093280 for pO_2, pH, tHb, and SO_2 has not changed. For the pCO_2 sensor, the results of the linear regression analysis per instrument type are presented in the table below:

pCO2

Instrument	Value Assignment	Slope	Intercept	R^2
OPTI CCA-TS	Tonometry	0.980	-0.73	0.999
	ABL90 FLEX	1.035	-3.75	0.996
OPTI CCA-TS2	Tonometry	0.999	-2.09	0.999
	ABL90 FLEX	1.030	-2.70	0.999

The linearity study results support that the assays are linear across the following claimed reportable ranges:

Parameter	Reportable Range
pCO_2	10-200 mm Hg
pO_2	10-700 mm Hg
pH	6.818-7.8
tHb	5-24 g/dL
SO_2	60-100%

3. Analytical Specificity/Interference:

The B-Lac cassette was evaluated to determine the potential interference of endogenous and exogenous substances. The study used human venous whole blood samples and was conducted for all the analytes at two concentration levels (see table below). For pH, pCO_2, pO2, tHb and SO_2, two different analyte levels were generated by tonometering with different gas mixtures. For tHb, the low level sample was generated by dilution with plasma. All the samples were spiked with the potential interferents (test samples) and were measured against the samples that were not spiked (control samples). The sponsor states that interferences were considered to be non-significant if the bias between the test and control samples were as follows:

Parameter	Maximum allowed difference (analyte level)
pCO_2	2.5 mmHg (83 mm Hg) or 4% (17 mm Hg)
pO_2	2.5 mmHg (48 mm Hg) or 4% (416 mmHg)
pH	0.02 (7.17 or 7.52)
tHb	0.6 g/dL (<10 g/dL or 12-18 g/dL)
SO_2	3% (70.9% or 99.9%)

The table below summarizes the results of the interference testing performed:

Substance	Highest concentration tested	Interference				
		pH	pCO_2 (mmHg)	pO_2 (mmHg)	tHb (g/dL)	SO_2 (%)
Acetaminophen	1.66 mmol/L	No	No	No	No	No
Acetylsalicylic acid	3.33 mmol/L	N/A	No	No	No	No

Substance	Highest concentration tested	Interference				
		pH	pCO_2 (mmHg)	pO_2 (mmHg)	tHb (g/dL)	SO_2 (%)
Ascorbic acid	0.23 mmol/L	No	No	No	No	No
β-hydroxybutyric acid	16.03 mmol/L	No	No	No	**Yes**	No
Bilirubin	0.26 mmol/L	No	No	No	No	No
Cardiogreen	0.0065 mmol/L	No	No	No	**Yes**	**Yes**
Cysteine (hydrochloride hydrate)	6.41 mmol/L	N/A	No	No	No	No
Ethanol	86.8 mmol/L	No	No	No	No	No
Evans Blue	0.0104 mmol/L	No	No	**Yes**	**Yes**	**Yes**
Glycolic acid	10 mmol/L	N/A	No	No	No	**Yes**
Halothane	0.759 mmol/L	No	No	No	No	No
Ibuprofen	2.43 mmol/L	N/A	No	No	No	No
Intralipid	1%	No	No	No	**Yes**	No
Methylene Blue	0.125 mmol/L	No	No	**Yes**	**Yes**	**Yes**
Sodium Chloride	20 mmol/L	No	No	No	**Yes**	No
Glucose	22.22 mM	N/A	N/A	N/A	N/A	N/A
Hydroxyurea	0.5 mM	N/A	N/A	N/A	N/A	N/A
Pyruvic acid	0.24 mM	N/A	N/A	N/A	N/A	N/A

The substances that were found to have significant interference are listed in the Operator's manuals. In addition, for pH, the labeling includes the following limitation for fluorescein, which was tested in a separate study not reviewed in this submission:
"At the interferent concentration tested (1.064 mM), the pH will be suppressed. However, for lower concentrations, the pH may show a bias."

4. Assay Reportable Range:

   Please see the linearity study above.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Traceability for all analytes was previously described and reviewed in k093280.
   Total hemoglobin (tHb) shelf-life stability studies were reviewed and considered acceptable to support the claims previously cleared in k093280.

6. Detection Limit:

   Linearity studies were used to support the lower end of the measuring range for pH, pCO_2, pO_2, tHb and SO_2 (see section VII.A.2 above).

7. Assay Cut-Off:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   A method comparison study was conducted using native venous whole blood samples collected in sodium heparin blood collection tubes. A small percentage (<10%) manipulated blood samples (tonometered, spiked or diluted) were added to cover the measurement ranges. This method comparison study was carried out using three different lots of B-Lac cassettes on both OPTI CCA-TS and OPTI CCA-TS2 instruments. Each blood sample was tested in singlicate across three CCA-TS and three CCA-TS2 analyzers with one cassette lot per analyzer. Each sample was also tested on predicate instruments with the ABL90 FLEX used for pH, pCO_2, pO_2 and tHb and OPTI CCA E-series cassettes for SO_2.

   The results on the OPTI CCA-TS and OPTI CCA-TS2 instrument types were analyzed separately. The data supported that the performance in venous whole blood in clinical laboratory settings as demonstrated in k093280 for pO_2, pH, tHb and SO_2 has not changed. The linear regression analysis for the first sample measurement for pCO_2 is presented in the tables below:

   B-Lac/OPTI CCA-TS Test System

Parameter	Comparator method	Slope	Intercept	R^2
pCO_2	ABL90 Flex	0.950	1.316	0.978

   B-Lac/OPTI CCA-TS2 Test System

Parameter	Comparator method	Slope	Intercept	R^2
pCO_2	ABL90 Flex	1.003	-0.122	0.999

2. Matrix Comparison:

   Not applicable. For use with sodium heparinized venous whole blood samples only.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The following reference ranges were included in the labeling. The sponsor also noted that each facility should establish its own reference ranges.

Parameter	Units	Range	Reference Source
pCO_2	mmHg	30.0-50.0	Tietz[1]
pO_2	mmHg	70.0-700.0	Tietz[1]
pH	pH units	7.35-7.45	Tietz[1]
tHb	g/dL	12.0-17.0	Tietz[1]
SO_2	%	95.0-98.0	Henry[2]

[1]Tietz; Burtis C, et al (Eds.), Textbook of Clinical Chemistry and Molecular Diagnostics, 4th Ed., (Elsevier Saunders, 2006).
[2]J. B. Henry, Clinical Diagnosis and Management by Laboratory Methods, 19th Ed., 1996.

F Other Supportive Instrument Performance Characteristics Data:

1. Method Comparison at Altitude:

   A method comparison at altitude study was conducted to evaluate the performance of the B-Lac cassette pCO_2, pO_2 and pH sensors and measured tHb and SO_2 parameters against the ABL90 FLEX Analyzer at a range of altitudes. Both contrived venous whole blood samples and aqueous control materials were used in the study and testing was conducted at two clinical sites (1080 feet and 10151 feet altitude) for venous whole blood samples and at four clinical sites (ranging from 75 feet – 10551 altitude) for aqueous control samples. The results of the study supported the performance of the B-Lac cassette for all parameters up to 10151 feet altitude.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.