August 2, 2021

OPTI Medical Systems, Inc.
Theron Gober
Director, Quality and Regulatory
235 Hembree Park Drive
Roswell, Georgia 30114

Re: K200986
Trade/Device Name: OPTI® B-Lac Cassette
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood Gases (pCO_2, pO_2) And Blood pH Test System
Regulatory Class: Class II
Product Code: CHL, GKR, GLY
Dated: March 3, 2021
Received: March 4, 2021

Dear Theron Gober:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k200986

Device Name
OPTI® B-Lac Cassette

Indications for Use *(Describe)*
The OPTI® B-Lac cassette is intended to be used for the in vitro measurement of pH, PO2, PCO2, total hemoglobin (tHb), and % Saturated O2 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 (pCO2, pO2) 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 (SO2) measurement is used to determine the oxygen capacity of the hemoglobin.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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OPTI® Medical Systems B-Lac Cassette

510(k) Summary

Submitted by:	OPTI Medical Systems, Inc. Phone Number: (770) 510-4444 Fax Number: (770) 510-4447
Contact:	Theron Gober
Date of Preparation:	April 6, 2020
Current 510(k):	K200986
Device Trade Name:	OPTI® B-Lac Cassette
Common Name:	Blood gas Analyzer
Type of Test:	Measurement of pH, PO_2, PCO_2, total hemoglobin (tHb) and SO_2
Classification Names:	Blood gas and pH test system Automated hemoglobin test system Whole blood hemoglobin test system
Regulations:	862.1120 864.5620 864.7500 862.1450
Product codes:	CHL GKR GLY
Panel:	Cliinical Chemistry, Hematology
Predicate Devices:	Instrumentation Laboratory GEM Premier 4000

1. REASON FOR SUBMISSION

The purpose of this submission is to provide data to demonstrate that the new B-Lac cassette design meets the performance claims included in the previous submission referenced above and that it is substantially equivalent to the referenced predicate device. This submission includes changes to the PCO_2 sensor as well as the new algorithms utilized to calculate concentrations for these sensors. No changes have been made to the pH or PO_2 sensors or the measurement of tHb or SO_2 (Saturated Oxygen). In addition, changes to the software that were made to the OPTI CCA-TS (K984299) and CCA-TS2 (K131126), referred to as OPTI CCA-TS/TS2, to implement the algorithms for the PCO_2, sensors are documented.

2. DEVICE DESCRIPTION

2.1. OPTI CCA-TS and OPTI CCA-TS2 Instruments

The OPTI CCA-TS/TS2 are portable devices, microprocessor-based instrument using optical fluorescence for the measurement blood gases, electrolytes and enzymes. The OPTI CCA-TS/TS2utilize a color, graphical touch screen user interface.

A disposable, single-use cassette contains all of the elements needed for calibration, sample measurement, and waste containment. Specific calibration information from the cassette is scanned into the analyzer by holding the cassette package in front of the bar code scanner. The cassette is then placed into the measurement chamber.

The analyzer warms the cassette to 37.0±0.1°C and performs a calibration verification. When calibration is verified, the analyzer aspirates the blood sample into the cassette and across the optode sensors. Fluorescence emission is then measured after equilibrating with the blood sample. After a single measurement, the cassette containing the blood sample is removed from the analyzer and discarded. The analyzer contains no reagents, blood, or waste.

No changes to the OPTI CCA-TS/TS2analyzer's hardware have been made to accommodate the addition of the parameters associated with the B-Lac cassette, thus the electromagnetic compatibility remains unchanged from prior claims of the OPTI CCA-TS. The software driving the analyzer has been updated according to internal design control and verification procedures

of the Quality System at OPTI Medical Systems, Inc. to accommodate the addition of the B-Lac cassette.

2.2. OPTI B-LAC Cassette

The B-Lac cassette is a disposable, single use cassette that contains four (4) sensors for *in vitro* quantitative measurements of PO_2, PCO_2, pH. There is an additional laser based measurement of total hemoglobin (tHb) and SO_2. 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.

2.2.1. Principle of Measurement

The 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.

2.2.2. Calibration

Each lot of B-Lac cassettes is calibrated during the manufacturing process. The process utilizes multi-levels of high precision standard solutions spanning the operating range for pH. For O_2 and CO_2 the calibration parameters are determined using specially targeted calibration standards focusing on the clinically critical ranges. Every cassette package has a bar code label containing this calibration information as well as its lot number and expiration date. A one-point calibration is performed each time a cassette is used. The B-Lac cassette uses a proprietary dry-calibration for the pH sensor. For the Blood Gas sensors PO_2 and PCO_2, a precision gas mixture similar to that used by conventional blood analyzers is used. The calibration for the tHb and SO_2 measurements is factory set for each analyzer.

During the calibration and measurement processes, diagnostic tests are automatically performed to assure correct operation of the instrument and measurement of the cassette. These tests include automatic checks of the cassette for packaging integrity, proper cassette

temperature control, and proper equilibration behavior of the sensors during calibration and measurement, automatic detection of bubbles and short sample during aspiration, and automatic detection of dirty optics.

Three levels of standard control solutions (OPTI Check Level 1, 2 and 3) are supplied by Bionostics Inc., of Acton Massachusetts. Each level of control solution contains a different concentration of PO_2, PCO_2, pH, K, Na, Ca, Cl.

3. INDICATIONS FOR USE

The OPTI® B-Lac cassette is intended to be used for the in vitro measurement of pH, PO2, PCO2, , total hemoglobin (tHb), and % Saturated O2 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 (pCO2, pO2) 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 (SO2) measurement is used to determine the oxygen capacity of the hemoglobin.

4. TECHNOLOGICAL CHARACTERISTICS

The primary technological characteristics and intended use of the OPTI® B-Lac Cassette used with the OPTI CCA-TS/TS2 Analyzers are substantially equivalent to other legally marketed devices used for the quantitative measurement of blood gases, pH, and metabolites (lactate).

As indicated in Table 1~~Table 1~~, the OPTI® B-Lac Cassette is substantially equivalent to significant characteristics of the identified predicate device, the Radiometer ABL90 Flex (K092686) and the OPTI CCA TS2 E-Series Cassettes (K131126).

Table 1: Comparison of the OPTI® B-Lac Cassette with the predicate device

	B-Lac on OPTI CCA TS & TS2	ABL90 FLEX	Comparison
510(k) #	k200986	K092686	
Item	Subject of this submission	Predicate	
Intended use	The OPTI Medical B-Lac cassette is intended to be used for the in vitro measurement of pH, PO2, PCO2, total hemoglobin (tHb), and % Saturated O2 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 (pCO2, pO2) 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 (SO2) measurement is used to determine the oxygen capacity of the hemoglobin.	The ABL90 FLEX analyzer is a portable, automated analyzer that measures pH, blood gases, electrolytes, glucose, lactate, bilirubin and oximetry in whole blood. It is intended for use in a laboratory environment, near patient or point-of-care setting.	ABL90 FLEX: Similar
Where used	Hospital (Laboratory Environment)	Laboratory environment	ABL90 FLEX: Similar
Measured Parameter	pH, PCO_2, PO_2, tHb (total hemoglobin) and SO_2 (oxygen saturation).	pH, PCO_2, PO_2, tHb (total hemoglobin) and SO_2 (oxygen saturation).	ABL90 FLEX: Similar
Sample Type	Whole blood (sodium heparinized, venous)	Whole blood samples	ABL90 FLEX: Same
Reportable ranges	pH: 6.818 to 7.8 *P*O2: 10 to 700 mmHg *P*CO2: 10 to 200 mmHg tHb: 5.0 to 24 g/dL	pH: 6.818 to 7.797 *P*O2: 30.1 to 488 mmHg *P*CO2: 15.4 to 98.3 mmHg tHb: 0.1 to 24 g/dL	ABL90 FLEX: Similar

	B-Lac on OPTI CCA TS & TS2	ABL90 FLEX	Comparison
510(k) #	k200986	K092686	
Item	Subject of this submission	Predicate	
Sample Volume	125 µL	65 -150 µL	ABL90 FLEX: Similar
Test consumable	Single use cassette with optical fluorescence multi-sensor array Port for sample introduction Fluid waste chamber	Sensor cassette and solution pack	ABL90 FLEX: Similar
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	ABL90 FLEX: Similar
Measurement sequence	Calibrate cassette Introduce sample – Measure Display Results	Introduce sample Measure Display results	ABL90 FLEX: similar
Measurement time	180 sec from sample introduction	35 sec	ABL90 FLEX: Similar
Measurement Temperature	37^0C	37^0C	ABL90 FLEX: Same
Error detection	QC system to detect user errors QC system for reader self-check QC system to detect cassette non-conformance	QC system to detect user errors QC system for reader self-check QC system to detect test cartridge non-conformance	ABL90 FLEX: similar
Measurement Principle	pH: fluorescence *P*O2: fluorescence *P*CO2: fluorescence tHb– Optical reflectance measurement.	pH, pCO2, K+, Na+, Ca2+, Cl-, Glu: electrochemistry *P*O2: optical *ctHb, sO2, FO2Hb, FCOHb, FHHb, FMetHb, FHbF and ctBil*: Spectrophotometry	ABL90 FLEX: Similar

	B-Lac on OPTI CCA TS & TS2	OPTI CCA TS2 E-Series Cassettes	Comparison
510(k) #	k200986	K131126 (TS2)	
Item	Subject of this submission	Predicate	
Intended use	The OPTI Medical B-Lac cassette is intended to be used for the in vitro measurement of pH, PO2, PCO2, -total hemoglobin (tHb), and % Saturated O2 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 (pCO2, pO2) 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 (SO2) measurement is used to determine the oxygen capacity of the hemoglobin.	The OPTI CCA-TS & TS2 cassette is intended to be used for in vitro measurements of pH, PO_2, PCO_2, total hemoglobin (tHb), Na+, K+ Ca++ and oxygen saturation (SO_2), in heparinized whole blood, plasma, and serum samples (either arterial or venous) on the OPTI CCA-TS & TS2 system, in either a clinical laboratory setting or point-of-care locations.	OPTI-CCA: Similar
Where used	Hospital (Laboratory Environment)	Hospital (Laboratory or near patient)	OPTI-CCA: Similar
Measured Parameter	SO_2 (oxygen saturation).	SO_2.	OPTI-CCA: Similar
Sample Type	Whole blood (sodium heparinized, venous)	Whole blood, serum, and plasma (heparinized, venous or arterial)	OPTI-CCA: Similar
Reportable ranges	SO2: 60% to 100%	SO2: 60% to 100%	OPTI-CCA: Similar
Sample Volume	125 µL	125 µL	OPTI-CCA: Same
Test consumable	Single use cassette with optical fluorescence multi-sensor array Port for sample introduction Fluid waste chamber	Single use cassette with optical fluorescence multi-sensor array Port for sample introduction Fluid waste chamber	OPTI-CCA: Same
Test consumable storage	Refrigerated storage (2 – 8°C) until expiry date including max 28 days at room temperature.	Room temperature storage (4 – 30°C) until expiry date	OPTI-CCAE-Ca: Similar

	B-Lac on OPTI CCA TS & TS2	OPTI CCA TS2 E-Series Cassettes	Comparison
510(k) #	k200986	K131126 (TS2)	
Item	Subject of this submission	Predicate	
Measurement sequence	Calibrate cassette Introduce sample – Measure Display Results	Calibrate cassette Introduce sample – Measure Display Results	OPTI-CCA-E-Ca: Same
Measurement time	180 sec from sample introduction	180 sec from sample introduction	OPTI-CCA-E-Ca: Similar
Measurement Temperature	37^0C	37^0C	OPTI-CCA-E-Ca: Same
Error detection	QC system to detect user errors QC system for reader self-check QC system to detect cassette non-conformance	QC system to detect user errors QC system for reader self-check QC system to detect cassette non-conformance	OPTI-CCA-E-Ca: Same
Measurement Principle	SO2 – Optical reflectance measurement.	SO2: Optical reflectance measurement.	OPTI-CCA-E-Ca: Similar

4.1. Summary of Performance Testing

The design verification tests that were performed are listed in Table 2~~Table 2~~.

Table 2: Summary of Performance Testing

Verification	Standard Used	Testing Guidance Used
20-Day Precision (in-house)	Claims submitted in K093280 (based on CLIA 1988 specifications)	CLSI EP5-A3, volume 34, Number 13
Within Run Precision (in-house)	Claims submitted in K093280 (based on CLIA 1988 specifications)	CLSI EP5-A3, volume 34, Number 13
Method Comparison - (in-house)	Whole blood – Tonometry/ABL90 Flex	CLSI EP9-A2, Volume 22, Number 19
Method Comparison - Altitude	Whole blood – Tonometry/ABL90 Flex OPTI Check Control Material	None, regression analysis and bias analysis at critical levels
Interference (in-house)	Whole blood samples	CLSI EP7-A2, Volume 25, Number 27
Stability (in-house)	OPTI Check Control Material	BS EN ISO 13640-2002

4.1.1. OPTI Medical B-Lac – In-House 20-Day Precision Testing

The 20-Day precision study was carried out following the experimental protocol recommended in the CLSI guideline EP05-A3, volume 34, Number 13. Typical Within-Run (Swr) and Total (ST) precision were determined from paired samples run twice daily over 20 days on three lots of B-Lac cassettes run on OPTI CCA-TS/TS2 analyzers using three levels of aqueous quality control solution. The precision performance for the redesigned B-Lac cassette was determined to meet the performance claims made in the original B-Lac cassette submission (K093280) for all analytes.

4.1.2. OPTI Medical B-Lac – In-House Within Run Precision Testing

Within run precision testing was performed using whole blood and aqueous solutions following the experimental protocol recommended in the CLSI guideline EP05-A3, volume 34, Number 13. Typical within run (Swr) precision was determined from multiple repeats on three lots of B-Lac cassettes run on OPTI CCA-TS/TS2 analyzers using three levels of aqueous quality controls and whole blood manipulated to 3 different levels. The precision performance for the redesigned B-Lac cassette was determined to meet the performance claims made in original B-Lac cassette submission (K093280) for all analytes.

4.1.3. OPTI Medical B-Lac Cassette – In-House Method Comparison

In-house method comparison studies following the CLSI guideline EP9-A2, Volume 22, Number 19 (2002) for the B-Lac pH, PCO_2 , PO_2 sensors and measured tHb and SO_2 were performed on whole blood samples tonometered to different levels using different O_2/CO_2 gas mixtures to generate test levels for pH, PCO_2 , PO_2, and SO_2 and samples were manipulated to obtain test levels for tHb. The results were compared to the gravimetric target for PCO_2 and PO_2 based on the gas concentration and to the predicate device ABL90 Flex for pH, PCO_2 , PO_2, and tHb and the E series cassettes on the OPTI CCA-TS/TS2 for SO_2. The performance of the redesigned B-Lac cassette was determined to meet the performance claims included in the previous 510(K) submission K093280 for all analytes.

4.1.4. OPTI Medical B-Lac – In-House Linearity Testing

4.1.5. OPTI Medical B-Lac – In-House Interference Testing

Interference testing was performed for the PCO_2, PCO_2, ph, sensors and measured tHb and SO_2 for the B-Lac cassette following the CLSI guideline EP07-A, volume 22, Number 27 (2002). In all 16 interferents were tested for PCO_2, PCO_2, ph, tHb, and SO_2. There were several interferents found for tHb, and SO_2, no interferents for $PCO2$ and only one interferent for PO_2 and pH.

4.1.6. Altitude testing

To evaluate the performance of the B-Lac cassette PCO_2, PO_2, pH, sensors at a range of altitudes, method comparison studies were performed on whole blood and ampuled aqueous control materials at the following sites:

- Westbrook, Maine, USA, 75 feet (Aqueous)
- Roswell, Georgia, USA, 1080 feet (Aqueous and Whole Blood)
- Beech Mountain, North Caroling, USA, 5560 feet (Aqueous)
- Leadville, Colorado, USA, 10151 feet (Aqueous and Whole Blood)

Testing for the B-Lac cassette was performed on the OPTI CCA TS and OPTI CCA-TS platforms against the predicate device (ABL90 Flex - K092686) for whole blood. Whole blood samples were tonometered to obtain samples that span the range for PCO_2, PO_2, and pH, and spiked or diluted for tHb at both 1180 ft. and 10,151 ft. Aqueous solutions were measured for PCO_2, pH, tHb and Saturate O_2 at all sites and the results compared to the reference site in Roswell, Georgia. Analysis of the data for linearity and bias at the critical limits was calculated. The performance of the B-Lac cassette with redesigned PCO2 sensors was demonstrated to meet the performance claims included in the previous 510(K) submission K093280 when tested with whole blood samples at 1180 feet and 10151 feet (PCO_2, PO_2, pH, tHb) and aqueous samples at all altitudes tested (PCO_2, PO_2, pH, tHb, and SO_2).

4.1.7. OPTI Medical B-Lac –Stability Testing

Stability testing was performed to establish the shelf life for the redesigned B-Lac cassette. The purpose of this test was to collect aqueous control data to evaluate the stability of pH, PO_2, PCO_2, tHb, and SO_2 on the redesigned B-Lac cassette. The redesigned B-Lac cassette includes

improvements to the PCO_2 sensors while keeping the pH, PO_2, tHb, and SO_2 the same. The study includes an evaluation of cassettes that have been subjected to 2 cycles of simulated shipping temperature extremes prior to refrigeration. Three Lots of B-Lac cassettes were tested with one Lot being subjected to two cycles of elevated and frozen temperatures cycles. Performance of the B-Lac cassette has been demonstrated to meet the performance claims for up to 6 months shelf life. Real time testing will continue for 13 months to demonstrate that the shelf life for the new cassette is equivalent to the shelf life (12 mos.) for the B-Lac cassette included in the previous 510(K) submission K093280.

5. CONCLUSION

Analysis of the data collected during performance testing studies for the OPTI B-Lac Cassette using the OPTI CCA-TS/TS2 analyzers demonstrates that the redesigned B-Lac Cassette performance in venous whole blood in clinical laboratory setting is substantially equivalent for all analytes.