February 7, 2020

Abbott Point of Care Inc.
Susan Tibedo
Director, Regulatory Affairs
400 College Road East
Princeton, NJ 08540

Re: K191298
Trade/Device Name: i-STAT CHEM8+ cartridge with the i-STAT 1 System
Regulation Number: 21 CFR 862.1160
Regulation Name: Bicarbonate/carbon dioxide test system
Regulatory Class: Class II
Product Code: JFL
Dated: January 6, 2020
Received: January 7, 2020

Dear Susan Tibedo:

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,

Kellie B. Kelm, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191298

Device Name
i-STAT CHEM8+ cartridge with the i-STAT 1 System

Indications for Use *(Describe)*
The i-STAT CHEM8+ cartridge with the i-STAT 1 System is intended for use in the in vitro quantification of total carbon dioxide in arterial or venous whole blood in point of care or clinical laboratory settings.

Carbon dioxide measurements are used in the diagnosis, monitoring, and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

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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510(k) Summary

The information in this 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter Information

Owner	Abbott Point of Care Inc. 400 College Road East Princeton, NJ 08540
Contact	Primary: Susan Tibedo Director Regulatory Affairs susan.tibedo@abbott.com Phone: 609-454-9360 Secondary: Maria Figueroa Manager Regulatory Affairs maria.l.figueroa@abbott.com Phone: 609-454-9271
Date Prepared	February 5, 2020
510k Number	K191298

2. Device Information

Proprietary Name	i-STAT CHEM8+ Cartridge with i-STAT 1 Analyzer
Common Name	Chemistry test, analyzer, handheld

Product code	Device Classification name	Regulation Number	Class	Panel
JFL	Bicarbonate, Carbon Dioxide Test System	862.1160	II	Clinical Chemistry

3. Predicate Device

Proprietary Name	SYNCHRON Systems TCO2 Reagent on UniCel DxC 600/800 SYNCHRON Clinical System
510(k) Number	K042291

Product code	Device Classification name	Regulation Number	Class	Panel
JFL	Bicarbonate, Carbon Dioxide Test System	862.1160	II	Clinical Chemistry

4. Device Description

The i-STAT CHEM8+ test cartridge contains test reagents to analyze whole blood at the point of care or in the clinical laboratory for total carbon dioxide (TCO_2). The test is contained in a single-use, disposable cartridge. Cartridges require two to three drops of whole blood which are typically applied to the cartridge using a transfer device.

The i-STAT 1 Analyzer is a handheld, *in vitro* diagnostic analytical device designed to run only i-STAT test cartridges. The instrument interacts with the cartridge to move fluid across the sensors and generate a quantitative result (within approximately 2 minutes).

The i-STAT 1 System is comprised of the i-STAT 1 analyzer, the i-STAT test cartridges and accessories (i-STAT 1 Downloader/Recharger, electronic simulator and portable printer). The system is designed for use by trained medical professionals at the patient point of care or in the clinical laboratory and is for prescription use only.

5. Intended Use Statement

The i-STAT CHEM8+ cartridge with the i-STAT 1 System is intended for use in the *in vitro* quantification of total carbon dioxide in arterial or venous whole blood in point of care or clinical laboratory settings.

Carbon dioxide measurements are used in the diagnosis, monitoring, and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

6. Summary Comparison of Technological Characteristics

Feature or Characteristic	Predicate SYNCHRON Systems TCO_2 Reagent on UniCel DxC 600/800 SYNCHRON Clinical System (K042291)	Candidate i-STAT TCO_2 Test with i-STAT 1 System
Intended Use	The CO_2 test is intended for the quantitative determination of carbon dioxide in human serum or plasma. Carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.	The i-STAT CHEM8+ cartridge with the i-STAT 1 System is intended for use in the *in vitro* quantification of total carbon dioxide in arterial or venous whole blood in point of care or clinical laboratory settings. Carbon dioxide measurements are used in the diagnosis, monitoring, and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.
Reportable Range	5-50 mmol/L (Serum or Plasma)	5-50 mmol/L (mEq/L)
Sample Type	Serum or plasma	Arterial or venous whole blood
Sample Volume	0.5 mL (500 µL)	95 µL
Preparation	Sample tubes prepared and then processed within analyzer	Ready to Use
Traceability	Unknown traceability reference	IFCC Reference Measurement Procedure
Calibration	Must be conducted every 24 hours and with each new reagent	1-point on-board contained within the cartridge
Time to Test (Sample Stability)	Serum or plasma: Within 8 hours at room temperature, or up to 48 hours if stored at +2°C to +8°C	Heparinized samples: within 10 minutes of collection
Principle of Measurement	Ion selective electrode	Ion selective electrode
Reagent Format	Reagent handling system, stored within analyzer	Cartridge
Reagent Storage and Stability	Room temperature	2°C to 8°C (35-46°F)
Analyzer Type	Floor Model	Handheld

7. Performance Characteristics

Analytical Performance

a. Precision

Precision 20 days (Aqueous Materials)

The precision of the i-STAT TCO_2 test on the i-STAT 1 Wireless Analyzer was evaluated using 5 levels of aqueous materials. This 20-day multi-day precision testing was based on CLSI document EP05-A3: *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition.* The study was conducted using multiple instruments and one test cartridge lot over 20 days at one site. Total precision ('within-laboratory', S_T), within-run, (S_r), between-run, (S_{rr}) and between-day, (S_{dd}) were estimated for each level. The results of the 20-day precision study are shown in **Table 1.**

Table 1: 20-Day Precision of i-STAT TCO_2 test on the i-STAT 1 Analyzer

Analyte	Fluid Level	N	Mean/ Median	Total		Repeatability		Between-Run		Between-Day	
				S_T	$\%CV_T$	S_r	$\%CV_r$	S_{rr}	$\%CV_{rr}$	S_{dd}	$\%CV_{dd}$
TCO_2 mmol/L	CV L1	81	12.2	0.29	2.4	0.26	2.1	0.08	0.7	0.08	0.7
	CV L2 / Control L1*	80	18.2	0.31	1.7	0.30	1.6	0.07	0.4	0.07	0.4
	CV L3 / Control L2*	80	23.6	0.64	2.7	0.58	2.5	0.21	0.9	0.15	0.6
	CV L4 / Control L3*,	80	31.8	1.36	4.3	1.26	4.0	0.20	0.6	0.49	1.5
	CV L4B	81	44.3	0.93	2.1	0.69	1.6	0.32	0.7	0.53	1.2

*The aqueous control materials (Control L1, L2, L3) are also used as the middle levels of the calibration verification set (CV L2, CV L3, CV L4). The aqueous fluids are the same.

Precision (Whole Blood)

A whole blood repeatability analysis was conducted using the data collected across three point of care sites. Two hundred and seventy-nine samples (178 venous and 101 arterial) were measured in duplicate. The mean values for each sample were divided into four subintervals for each sample type taking into consideration the medical decision levels of 6, 20, and 33 mmol/L.

The results are provided in **Table 2** and **Table 3** below:

Table 2: Venous whole blood				
Sample Range (mmol/L)	**N**	**Mean (mmol/L)**	**SD**	**CV (%)**
7 - 15	15	9.43	0.483	5.1
15 - 25	61	21.25	0.665	3.1
25 - 35	82	27.72	0.625	2.3
35 - 47	20	39.33	1.037	2.6

Table 3: Arterial whole blood				
Sample Range (mmol/L)	**N**	**Mean (mmol/L)**	**SD**	**CV (%)**
14 - 15	3	14.33	0.577	4.0
15 - 25	46	22.29	0.521	2.3
25 - 35	48	28.10	0.520	1.9
35 - 50	4	39.50	0.866	2.2

b. Linearity

The study was designed based on CLSI EP06-A: *Evaluation of the Linearity of Quantitative Measurement Procedures.*

The linearity of the i-STAT TCO_2 test on the i-STAT 1 Analyzer was evaluated by preparing whole blood samples of varying analyte levels that spanned the reportable range of the test. The i-STAT TCO_2 test demonstrated linearity over the reportable range 5 – 50 mmol/L. Regression summary of the TCO_2 response (in mmol/L) versus the concentration of the whole blood samples of varying analyte levels is provided in **Table 4**.

Table 4: Regression Summary for the i-STAT TCO_2 test on the i-STAT 1 Analyzer					
i-STAT Test (mmol/L)	**Reportable Range (mmol/L)**	**Range Tested (mmol/L)**	**Slope**	**Intercept**	**R^2**
TCO_2	5 – 50	4 - 52	1.0281	-0.1259	0.99379

c. Limit of Quantitation (LoQ)

The study was based on the CLSI EP17-A2: *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline–Second Edition.*

The LoQ of the i-STAT TCO_2 test was evaluated on the i-STAT 1 Analyzer using whole blood that was altered to low TCO_2 ($\leq$ 5.0 mmol/L). The study was conducted over four (4) days using two (2) cartridge lots. The LoQ for the i-STAT TCO_2 test was determined to be 4 mmol/L, which is below the lower limit of the i-STAT TCO_2 test reportable range (5 - 50 mmol/L).

d. Interference

The interference performance of the i-STAT TCO_2 test on the i-STAT 1 Analyzer was evaluated using whole blood test samples based on CLSI EP07-A2: *Interference*

Testing in Clinical Chemistry; Approved Guideline – Second Edition. The effect of each substance at each TCO_2 level was evaluated by comparing the performance of a test sample spiked to a high concentration of the substance and a control sample spiked with an equal volume of solvent. A substance was identified as an interferent if the difference between the spiked test sample and the control was greater than the allowable error defined as the greater of 4 mmol/L or 10% of the mean TCO_2 result for the control sample. None of the substances evaluated (See **Table 5**) were found to interfere with the i-STAT TCO_2 test.

Table 5: List of Substances and Test Concentrations		
Substance	**Test Concentration***	
	as specified	**mg/dL**
Bilirubin	342 µmol/L	20
Hemoglobin	2 g/L	200
Thiopental	248 µmol/L	6.01
Triglyceride	37 mmol/L	3233.8
Intralipid	N/A	7092

*The molecular weight of the substance tested was used to convert the test concentration from mmol/L to mg/dL. The molecular weight of each substance could vary depending on the form chosen.

Comparison Study

e. Method Comparison with Predicate Device

The accuracy of the TCO_2 assay on the i-STAT CHEM8+ (blue) cartridge on the i-STAT 1 Analyzer was evaluated by a method comparison study for agreement with the predicate device. The study was conducted across three point of care sites. A total of 294 specimens, 183 lithium heparin venous whole blood specimens and 111 lithium heparin arterial whole blood specimens were tested. Twenty-one of 294 samples (7.14%) were contrived.

Table 6: Passing-Bablok Regression Summary of Venous and Arterial Data Combined				
i-STAT Test	**N**	**Slope**	**Intercept**	**r**
TCO_2	294	1.04	0.17	0.97

The data was analyzed separately for venous whole blood and arterial whole blood samples by Passing-Bablok regression analysis comparing the first replicate of the candidate device results to the singlicate result of lithium heparin plasma samples on the predicate device. Results are presented in **Table 7** and **Table 8** below.

Table 7: Passing-Bablok Regression Summary of Venous Data				
Site	**N**	**Sample Range Tested (mmol/L)**	**Regression Equation**	**r**
1	23	19 – 33	y = 1.83 + 0.98x	0.87
2	50	9 – 41	y = 0.00 + 1.00x	0.98
3	93	15 – 46	y = 0.00 + 1.08x	0.98
combined	183*	6 – 46	y = -0.01 + 1.05x	0.98

* Includes 17 contrived specimens.

Table 8: Passing-Bablok Regression Summary of Arterial Data				
Site	**N**	**Sample Range Tested (mmol/L)**	**Regression Equation**	**r**
1	53	14 – 39	y = 3.58 + 0.97x	0.96
2	48	15 – 50	y = 1.00 + 1.00x	0.96
3	6	23 – 29	N/A	
combined	111*	7 – 50	y = 1.07 + 1.03x	0.94

* Includes 4 contrived specimens.

8. Conclusion

The results of these studies demonstrate that performance of the i-STAT CHEM8+ TCO_2 test with the i-STAT 1 System are substantially equivalent to the comparative method.