February 14, 2020

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

Re: K191360
Trade/Device Name: i-STAT CHEM8+ cartridge with the i-STAT 1 System
Regulation Number: 21 CFR 862.1145
Regulation Name: Calcium Test System
Regulatory Class: Class II
Product Code: JFP
Dated: January 15, 2020
Received: January 16, 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,

Marianela Perez-Torres, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191360

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 ionized calcium in arterial or venous whole blood in point of care or clinical laboratory settings.

Ionized calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

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

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Date Prepared: February 14, 2020

510(k) Number: K191360

2. Device Information

Proprietary Name: i-STAT CHEM8+ cartridge with i-STAT 1 System

Common Name: Chemistry test, analyzer, handheld

Product code	Device Classification name	Regulation Number	Class	Panel
JFP	Electrode, Ion Specific, Calcium	862.1145	II	Clinical Chemistry

3. Predicate Device

Proprietary Name: Ionized Calcium test with the Epocal EPOC Blood Analysis System

510(k) Number: K061597

Product code	Device Classification name	Regulation Number	Class	Panel
JFP	Electrode, Ion Specific, Calcium	862.1145	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 ionized calcium (iCa). 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 ionized calcium in arterial or venous whole blood in point of care or clinical laboratory settings.

Ionized calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

6. Summary Comparison of Technological Characteristics

Feature or Characteristic	Predicate Ionized Calcium Test with EPOC Blood Analysis System (K061597)	Candidate Ionized Calcium Test with i-STAT 1 System
Intended Use	Measurement of Ionized Calcium is used in diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.	The i-STAT CHEM8+ cartridge with the i-STAT 1 System is intended for use in the *in vitro* quantification of ionized calcium in arterial or venous whole blood in point of care or clinical laboratory settings. Ionized calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease

Feature or Characteristic	Predicate Ionized Calcium Test with EPOC Blood Analysis System (K061597)	Candidate Ionized Calcium Test with i-STAT 1 System
		and tetany.
Reportable Range	0.25 – 4.00 mmol/L	0.25 – 2.50 mmol/L (mEq/L)
Sample Type	Arterial or venous whole blood	Arterial or venous whole blood
Sample Volume	At least 92 µL	95 µL
Sample Preparation	Ready to Use	Ready to Use
Traceability	NIST SRM 956	NIST SRM 956
Calibration	On board the instrument initiated once test card is inserted	1-point on-board contained within the cartridge
Time to Test (Sample Stability)	Immediately after drawing sample	Heparinized samples: within 10 minutes of collection
Principle of Measurement	Ion selective electrode	Ion selective electrode
Reagent Format	Test Card	Cartridge
Reagent Storage and Stability	15 to 30°C (59 to 86°F)	2°C to 8°C (35-46°F)
Analyzer Type	Handheld	Handheld

7. Performance Characteristics

Analytical Performance

a. Precision

Precision 20 days (Aqueous Materials)

The precision of the i-STAT iCa 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 iCa test on the i-STAT 1 Analyzer

i-STAT Test	Calibration Verification Level	N	Mean / Median	Total		Within-run		Between-run		Between-day	
				S_T	CV_T (%)	S_r	CV_r (%)	S_{rr}	CV_{rr} (%)	S_{dd}	CV_{dd} (%)
iCa (mmol/L)	CV L1	81	2.328	0.0132	0.6	0.0121	0.5	0.0037	0.2	0.0038	0.2
	CV L2 / Control L1*,[a]	81	1.484	0.0103	0.7	0.0096	0.6	0.0025	0.2	0.0026	0.2

Table 1: 20-day Precision of i-STAT iCa test on the i-STAT 1 Analyzer											
i-STAT Test	Calibration Verification Level	N	Mean / Median	Total		Within-run		Between-run		Between-day	
				S_T	CV_T (%)	S_r	CV_r (%)	S_{rr}	CV_{rr} (%)	S_{dd}	CV_{dd} (%)
	CV L3 / Control L2*	81	1.299	0.0067	0.5	0.0062	0.5	0.0020	0.2	0.0018	0.1
	CV L4 / Control L3*,[a]	80	0.724	0.0038	0.5	0.0036	0.5	0.0009	0.1	0.0008	0.1
	CV L5	80	0.262	0.0040	1.5	0.0035	1.3	0.0015	0.6	0.0010	0.4

* 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.
[a] Non-normal distribution (p-value <0.010), the median value was used to calculate %CV.

Precision (Whole Blood)

A whole blood repeatability analysis was conducted using the data collected across three point of care sites. Two hundred and forty-one samples (132 venous and 109 arterial) were measured in duplicate. The mean values for each sample were divided into four subintervals for each sample type taking into consideration the lower and upper limits of the reference interval, 1.12 mmol/L and 1.32 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 (%)
0.25 - 0.75	10	0.438	0.0097	2.2
0.75 – 1.2	93	1.094	0.0173	1.6
1.2 – 1.5	22	1.278	0.0134	1.0
1.5 – 2.5	7	2.109	0.0183	0.9

Table 3: Arterial whole blood				
Sample Range (mmol/L)	N	Mean (mmol/L)	SD	CV (%)
0.25 - 0.75	3	0.445	0.0041	0.9
0.75 – 1.2	73	1.110	0.0329	3.0
1.2 – 1.5	27	1.244	0.0105	0.8
1.5 – 2.5	6	1.725	0.0091	0.5

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 iCa 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 best fitting regression model was a second order model. The absolute degree of nonlinearity results met the acceptance criteria for each of the levels tested. Therefore, the i-STAT iCa demonstrated linearity over the reportable range

0.25 – 2.50 mmol/L. Regression summary of the iCa response 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 iCa test on the i-STAT 1 Analyzer

i-STAT Test (mmol/L)	Reportable Range (mmol/L)	Range Tested (mmol/L)	Slope	Intercept	R^2
iCa	0.25 – 2.50	0.22 – 2.81	0.9738	0.360	0.999

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 iCa test was evaluated on the i-STAT 1 Analyzer using whole blood that was altered to low iCa (< 0.25 mmol/L). The study was conducted over four (4) days using two (2) cartridge lots. The LoQ for the i-STAT iCa test was determined to be 0.21 mmol/L, which is below the lower limit of the i-STAT iCa test reportable range (0.25 – 2.50 mmol/L).

d. Limit of Blank and Detection (LoB/LoD)

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

The LoB/LoD of the i-STAT iCa test was evaluated on the i-STAT 1 Analyzer using whole blood that was altered to a "blank" ionized calcium concentration for LoB testing and two "low" ionized calcium concentrations for LoD testing. The LoB and LoD were determined based on the maximal LoB or LoD value obtained for each cartridge lot tested. The LoB for i-STAT iCa test was determined to be 0.14 mmol/L and the LoD was determined to be 0.15 mmol/L.

e. Interference

The interference performance of the i-STAT iCa test on the i-STAT 1 Analyzer was evaluated using whole blood samples based on CLSI EP07 ED3: *Interference Testing in Clinical Chemistry, Third Edition*. The effect of each substance was evaluated by comparing the performance of a control sample, spiked with blank solvent solution, with the test results from a sample spiked with the potentially interfering substance at the toxic/pathological concentration based on CLSI EP37 ED1: *Supplemental Tables for Interference Testing in Clinical Chemistry, First Edition*, as applicable. A substance was identified as an interferent if the difference between the control and test samples was outside of the allowed error (Ea) for the i-STAT test.

Table 5 contains the list of potentially interfering substances tested for the i-STAT Ionized Calcium test and the interference results.

Table 5: Summary of Substances Tested and Interference Results for the i-STAT iCa test				
Substance	**Test Concentration**		**Interference (Yes/No)**	**Interference Results**
	mmol/L	**mg/dL**		
Acetaminophen	1.03	15.6	No	
Bilirubin	0.684	40	No	
Cholesterol	10.3	400	No	
Hemoglobin	10 g/L	1000	No	
β-Hydroxybutyric Acid	6.0*	62.46	No	
L-Ascorbic Acid	0.298	5.25	No	
Leflunomide	0.722*	19.5	Yes	Decreased results ≥ 0.4 mmol/L
Lithium Bromide	37.5*	325.69	No	
Lithium Lactate	10	90	Yes	Decreased results ≥ 6.3 mmol/L
Lithium Salicylate	0.207	2.86	No	
Lithium Thiocyanate	0.898	5.22	Yes	Decreased results ≥ 0.874 mmol/L
Magnesium Chloride	4.1	10	No	
N-Acetyl-L-Cysteine	0.92	15.0	No	
Potassium Chloride	8	59.6	No	
Sodium Chloride	170	993.48	No	
Sodium Iodide	2.99*	44.82	No	
Sodium Thiosulfate	16.7*	264.04	Yes	Decreased results ≥ 5.5 mmol/L
Teriflunomide	0.722*	19.5	Yes	Decreased results ≥ 0.1 mmol/L
Triglyceride	16.94	1500	No	

* No CLSI EP37-ED1 test concentration available. 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

f. Method Comparison with Predicate Device

Method comparison was demonstrated in a study comparing the i-STAT iCa test performance on the i-STAT 1 to the EPOC Blood Analysis System. The study was based on CLSI guideline EP09c-ED3. Venous and arterial blood specimens were evaluated and analyzed on the i-STAT 1 against venous and arterial blood specimens on the EPOC Blood Analysis System. A Passing-Bablok linear regression analysis was performed using the first replicate result from the i-STAT 1 versus the singlicate result of the comparative method.

The i-STAT System automatically runs a comprehensive set of quality checks of both the analyzer and cartridge performance each time a sample is tested. This internal quality system will suppress results by generating a Quality Check Code (QCC) if the analyzer, cartridge or sample does not meet certain internal specifications. When a QCC occurs, a single code number, the type of problem and

the next step to be taken will be displayed on the i-STAT Analyzer. The failure rate for a single cartridge due to QCCs may be as high as 4%. The rate of failure for two consecutive cartridges due to QCCs may be as high as 1.7%.

Table 6: Method Comparison Results				
i-STAT Test	**N**	**Slope**	**Intercept**	**r**
iCa	250	1.00	-0.02	0.99

8. Conclusion

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