August 13, 2021

Abbott Point of Care Inc.
Maria Figueroa
Associate Director, Regulatory Affairs
400 College Road East
Princeton, New Jersey 08540

Re: K210958
Trade/Device Name: i-STAT CHEM8+ cartridge with the i-STAT 1 System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: CGA, CGL, JGS, CEM, CGZ, JFP, CDS, JFL, JPI
Dated: March 30, 2021
Received: March 31, 2021

Dear Maria Figueroa:

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)*
k210958

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 sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, hematocrit, and total carbon dioxide in arterial or venous whole blood in point of care or clinical laboratory settings.

Sodium measurements are used for monitoring electrolyte imbalances.
Potassium measurements are used in the diagnosis and monitoring of diseases and clinical conditions that manifest high and low potassium levels.
Chloride measurements are primarily used in the diagnosis, monitoring, and treatment of electrolyte and metabolic disorders including, but not limited to, cystic fibrosis, diabetic acidosis, and hydration disorders.
Ionized calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.
Glucose measurements are used in the diagnosis, monitoring, and treatment of carbohydrate metabolism disorders including, but not limited to, diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma.
Blood urea nitrogen measurements are used for the diagnosis, monitoring, and treatment of certain renal and metabolic diseases.
Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.
Hematocrit measurements can aid in the determination and monitoring of normal or abnormal total red cell volume status that can be associated with conditions including anemia and erythrocytosis. The i-STAT Hematocrit test has not been evaluated in neonates.
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

k210958

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: Maria Figueroa Associate Director Regulatory Affairs Phone: 609-454-9271 Secondary contact person for all communications: Secondary: Jaquelyn Gesumaria Senior Specialist Regulatory Affairs Phone: 609-454-9384
Date Prepared	August 12, 2021

2. Device Information

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

Common Name Chemistry test, analyzer, handheld

Product code	Device Classification name	Regulation Number	Class	Panel
CGA	Glucose Oxidase, Glucose	862.1345	II	Clinical Chemistry
CGL	Electrode, Ion Based Enzymatic, Creatinine	862.1225	II	Clinical Chemistry
JGS	Electrode, Ion Specific, Sodium	862.1665	II	Clinical Chemistry
CEM	Electrode, Ion Specific, Potassium	862.1600	II	Clinical Chemistry
CGZ	Electrode, Ion Specific Chloride	862.1170	II	Clinical Chemistry
CDS	Electrode, Ion Specific, Urea Nitrogen	862.1770	II	Clinical Chemistry

Product code	Device Classification name	Regulation Number	Class	Panel
JFL	Bicarbonate, Carbon Dioxide Test System	862.1160	II	Clinical Chemistry
JFP	Electrode, Ion Specific, Calcium	862.1145	II	Clinical Chemistry
JPI	Device, Hematocrit Measuring	862.6400	II	Hematology

3. Predicate Device

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

510(k) Numbers K183678
K183688
K191298
K191360
K183680

510(k) Number	Product code	Device Classification name	Regulation Number	Class	Panel
K183678	CGA	Glucose Oxidase, Glucose	862.1345	II	Clinical Chemistry
	CGL	Electrode, Ion Based Enzymatic, Creatinine	862.1225	II	Clinical Chemistry
K183688	JGS	Electrode, Ion Specific, Sodium	862.1665	II	Clinical Chemistry
	CEM	Electrode, Ion Specific, Potassium	862.1600	II	Clinical Chemistry
	CGZ	Electrode, Ion Specific Chloride	862.1170	II	Clinical Chemistry
	CDS	Electrode, Ion Specific, Urea Nitrogen	862.1770	II	Clinical Chemistry
K191298	JFL	Bicarbonate, Carbon Dioxide Test System	862.1160	II	Clinical Chemistry
K191360	JFP	Electrode, Ion Specific, Calcium	862.1145	II	Clinical Chemistry
K183680	JPI	Device, Hematocrit Measuring	862.6400	II	Hematology

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 sodium (Na), potassium (K), chloride (Cl), ionized calcium (iCa), glucose (Glu), blood urea nitrogen (BUN), creatinine (Crea), hematocrit (Hct), and 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 sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, hematocrit, and total carbon dioxide in arterial or venous whole blood in point of care or clinical laboratory settings.

Sodium measurements are used for monitoring electrolyte imbalances.

Potassium measurements are used in the diagnosis and monitoring of diseases and clinical conditions that manifest high and low potassium levels.

Chloride measurements are primarily used in the diagnosis, monitoring, and treatment of electrolyte and metabolic disorders including, but not limited to, cystic fibrosis, diabetic acidosis, and hydration disorders.

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

Glucose measurements are used in the diagnosis, monitoring, and treatment of carbohydrate metabolism disorders including, but not limited to, diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma.

Blood urea nitrogen measurements are used for the diagnosis, monitoring, and treatment of certain renal and metabolic diseases.

Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

Hematocrit measurements can aid in the determination and monitoring of normal or abnormal total red cell volume status that can be associated with conditions including anemia and erythrocytosis. The i-STAT Hematocrit test has not been evaluated in neonates.

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. Reason for Submission

Addition of anticoagulant free (non-anticoagulant) whole blood matrix to previously cleared i-STAT CHEM8+ cartridge with i-STAT 1 System under k183678, k183688, k191298, k191360 and k183680.

7. Summary Comparison of Technological Characteristics

Similarities and Differences		
Feature or Characteristic	**Candidate Device: i-STAT CHEM8+ cartridge with the i-STAT 1 System**	**Predicate Device: i-STAT CHEM8+ cartridge with the i-STAT 1 System (K183678, K183680, K183688, K191298, K191360)**
Intended Use	Same	The i-STAT CHEM8+ cartridge with the i-STAT 1 System is intended for use in the in vitro quantification of sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, hematocrit, and total carbon dioxide in arterial or venous whole blood in point of care or clinical laboratory settings. Sodium measurements are used for monitoring electrolyte imbalances. Potassium measurements are used in the diagnosis and monitoring of diseases and clinical conditions that manifest high and low potassium levels. Chloride measurements are primarily used in the diagnosis, monitoring, and treatment of electrolyte and metabolic disorders including, but not limited to, cystic fibrosis, diabetic acidosis, and hydration disorders. Ionized calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany. Glucose measurements are used in the diagnosis, monitoring, and treatment of carbohydrate metabolism disorders including, but not limited to, diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma. Blood urea nitrogen measurements are used for the diagnosis, monitoring, and treatment of certain renal and metabolic diseases. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a

<table>
<tr><th colspan="3">Similarities and Differences</th></tr>
<tr><th>Feature or Characteristic</th><th>Candidate Device: i-STAT CHEM8+ cartridge with the i-STAT 1 System</th><th>Predicate Device: i-STAT CHEM8+ cartridge with the i-STAT 1 System (K183678, K183680, K183688, K191298, K191360)</th></tr>
<tr><td></td><td></td><td>calculation basis for measuring other urine analytes.

Hematocrit measurements can aid in the determination and monitoring of normal or abnormal total red cell volume status that can be associated with conditions including anemia and erythrocytosis. The i-STAT Hematocrit test has not been evaluated in neonates.

Carbon dioxide measurements are used in the diagnosis, monitoring, and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.</td></tr>
<tr><td>Reportable Range</td><td>Same</td><td>Reportable Range:<table><tr><td>Sodium</td><td>100-180 mmol/L</td></tr><tr><td>Potassium</td><td>2.0-9.0 mmol/L</td></tr><tr><td>Chloride</td><td>65-140 mmol/L</td></tr><tr><td>Ionized Calcium</td><td>0.25-2.50 mmol/L</td></tr><tr><td>Glucose</td><td>20-700 mg/dL</td></tr><tr><td>BUN/Urea</td><td>3-140 mg/dL</td></tr><tr><td>Creatinine</td><td>0.2-20.0 mg/dL</td></tr><tr><td>Hematocrit</td><td>15-75 %PCV</td></tr><tr><td>TCO_2</td><td>5-50 mmol/L</td></tr></table></td></tr>
<tr><td>Sample Type</td><td>Same</td><td>Arterial or venous whole blood</td></tr>
<tr><td>Sample Volume</td><td>Same</td><td>95 µL</td></tr>
<tr><td>Sample Preparation</td><td>Same</td><td>Ready to Use</td></tr>
<tr><td>Sample Collection</td><td>• With balanced heparin anticoagulant
• With lithium heparin anticoagulant
• Without anticoagulant</td><td>• With balanced heparin anticoagulant
• With lithium heparin anticoagulant</td></tr>
<tr><td>Time Testing/Sample Stability (time from collection to sample fill)</td><td><table><tr><td colspan="2">With anticoagulant:</td></tr><tr><td>TCO_2, iCa</td><td>within 10 minutes</td></tr><tr><td>Na, K, Cl, Glu, BUN, Crea, Hct</td><td>within 30 minutes</td></tr><tr><td colspan="2">Without anticoagulant:</td></tr><tr><td>TCO_2, iCa, Na, K, Cl, Glu, BUN, Crea, Hct</td><td>within 3 minutes</td></tr></table></td><td><table><tr><td colspan="2">With anticoagulant:</td></tr><tr><td>TCO_2, iCa</td><td>within 10 minutes</td></tr><tr><td>Na, K, Cl, Glu, BUN, Crea, Hct</td><td>within 30 minutes</td></tr></table></td></tr>
</table>

8. Performance Characteristics

Analytical Performance

a. Precision

Precision 20 days (Aqueous Materials)

Precision of the i-STAT Sodium, Potassium, Chloride, Ionized Calcium, Glucose, Blood Urea Nitrogen, Creatinine, Hematocrit, and Total Carbon Dioxide tests in the i-STAT CHEM8+ cartridge with the i-STAT 1 System was previously reviewed under:

K183678 for Glucose and Creatinine
K183680 for Hematocrit
K186388 for Sodium, Potassium, Chloride and BUN
K191298 for TCO_2
K191360 for iCa

Precision (Whole Blood)

Whole blood precision of the i-STAT Sodium, Potassium, Chloride, Ionized Calcium, Glucose, Blood Urea Nitrogen, Creatinine, Hematocrit, and Total Carbon Dioxide tests in the i-STAT CHEM8+ cartridge with the i-STAT 1 System using whole blood venous and arterial specimens collected with lithium heparin was previously reviewed under:

K183678 for Glucose and Creatinine
K183680 for Hematocrit
K186388 for Sodium, Potassium, Chloride and BUN
K191298 for TCO_2
K191360 for iCa

b. Linearity

Linearity of the i-STAT Sodium, Potassium, Chloride, Ionized Calcium, Glucose, Blood Urea Nitrogen, Creatinine, Hematocrit, and Total Carbon Dioxide tests in the i-STAT CHEM8+ cartridge with the i-STAT 1 System was previously reviewed under:

K183678 for Glucose and Creatinine
K183680 for Hematocrit
K186388 for Sodium, Potassium, Chloride and BUN
K191298 for TCO_2
K191360 for iCa

c. Limit of Quantitation (LoQ)

LoQ of the i-STAT Sodium, Potassium, Chloride, Ionized Calcium, Glucose, Blood Urea Nitrogen, Creatinine, Hematocrit, and Total Carbon Dioxide tests in the i-STAT CHEM8+ cartridge with the i-STAT 1 System was previously reviewed under:

K183678 for Glucose and Creatinine
K183680 for Hematocrit
K186388 for Sodium, Potassium, Chloride and BUN
K191298 for TCO_2
K191360 for iCa

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

LoB and LoD of the i-STAT Ionized Calcium, Glucose, Creatinine, and Hematocrit tests in the i-STAT CHEM8+ cartridge with the i-STAT 1 System was previously reviewed under:

K183678 for Glucose and Creatinine
K183680 for Hematocrit
K191360 for iCa

e. Interference

The performance of the i-STAT Sodium, Potassium, Chloride, Ionized Calcium, Glucose, Blood Urea Nitrogen, Creatinine, Hematocrit, and Total Carbon Dioxide tests in the i-STAT CHEM8+ cartridge with the i-STAT 1 System in the presence of potentially interfering substances was previously reviewed under:

K183678 for Glucose and Creatinine
K183680 for Hematocrit
K186388 for Sodium, Potassium, Chloride and BUN
K191298 for TCO_2
K191360 for iCa

Comparison Study

f. Method Comparison of Candidate versus Predicate Device

Method comparison of the i-STAT Sodium, Potassium, Chloride, Ionized Calcium, Glucose, Blood Urea Nitrogen, Creatinine, Hematocrit, and Total Carbon Dioxide tests in the i-STAT CHEM8+ cartridge with the i-STAT 1 System using whole blood venous and arterial specimens collected with lithium heparin was previously reviewed under:

K183678 for Glucose and Creatinine
K183680 for Hematocrit
K186388 for Sodium, Potassium, Chloride and BUN
K191298 for TCO_2
K191360 for iCa

g. Matrix Equivalence

A matrix equivalence study was conducted at three (3) point of care sites to assess the performance of the i-STAT Sodium, Potassium, Chloride, Ionized Calcium, Glucose, Blood urea nitrogen, Creatinine, Hematocrit, and Total Carbon Dioxide tests in the i-STAT CHEM8+ cartridge on the i-STAT 1 System using non-anticoagulated venous and arterial whole blood samples. The matrix equivalence of each analyte in the i-STAT CHEM8+ cartridge was assessed by comparing samples collected without anticoagulant (candidate) to samples collected with balanced heparin or lithium heparin anticoagulant (primary sample). A Passing-Bablok linear regression analysis was performed using the first replicate result from the candidate (y-axis) versus the mean result from the primary sample (x-axis). The regression analysis results are summarized in the table below.

Analyte	N	Units	Candidate Range	Primary Sample Range	r	Slope	Intercept
Na	314	mmol/L	110 – 174	111 - 173	0.99	1.00	0.50
K	313	mmol/L	2.2 – 7.7	2.2 – 7.5	0.96	1.00	0.00
Cl	314	mmol/L	76 – 136	79 – 137	0.98	1.00	-0.50
iCa	314	mmol/L	0.41 – 2.48	0.71 – 2.28	0.85	1.04	-0.04
Glu	313	mg/dL	29 – 663	35 – 660	1.00	1.01	-0.63
BUN	310	mg/dL	4 – 120	4 – 118	1.00	1.00	0.00
Crea	312	mg/dL	0.2 – 19.4	0.2 – 19.4	1.00	1.00	0.00
Hct	311	%PCV	16 – 75	16 – 73	0.99	1.00	0.46
TCO_2	273	mmol/L	9 – 42	11 – 41	0.95	1.00	0.00

The results of the study support the addition of whole blood samples collected without anticoagulant for use with the i-STAT CHEM8+ cartridge on the i-STAT 1 System.

9. Conclusion

The results of the study demonstrate that performance of the i-STAT Sodium, Potassium, Chloride, Ionized Calcium, Glucose, Blood Urea Nitrogen, Creatinine, Hematocrit, and Total Carbon Dioxide tests in the i-STAT CHEM8+ cartridge with the i-STAT 1 System are substantially equivalent when tested using the anticoagulated and non-anticoagulated sample type.