DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

ABBOTT POINT OF CARE INC.
MELISSA ROBINSON
ASSOCIATE DIRECTOR REGULATORY AFFAIRS
400 COLLEGE ROAD EAST
PRINCETON NJ 08540

July 8, 2016

Re: k153357
Trade/Device Name: i-STAT Alinity System with i-STAT Sodium test
Regulation Number: 21 CFR 862.1665
Regulation Name: Sodium test system
Regulatory Class: II
Product Code: JGS
Dated: June 27, 2016
Received: June 28, 2016

Dear Melissa Robinson:

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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k153357

Device Name
i-STAT Alinity System with i-STAT Sodium test

Indications for Use *(Describe)*
The i-STAT Alinity System with i-STAT Sodium test is intended for use in point of care or clinical laboratory settings. The i-STAT Alinity System with Sodium test is intended for the quantitative measurement of sodium in arterial and venous whole blood.
Sodium measurements are used for monitoring electrolyte imbalances.

For in vitro diagnostic use.

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 21CFR 807.92.

1. Submitter Information

Owner	Abbott Point of Care Inc. 400 College Road East Princeton, NJ 08540
Contact	Primary: Melissa Robinson Associate Director Regulatory Affairs melissa.robinson@abbott.com Phone: 609-454-9371 Secondary: Susan Tibedo Director Regulatory Affairs susan.tibedo@abbott.com Phone: 609-454-9360
Date Prepared	July 06, 2016

2. Device Information

Proprietary Name	i-STAT® Alinity System with i-STAT Sodium test
Common Name	i-STAT Alinity Instrument, i-STAT Alinity and handheld
Regulation Number	862.1665 (Class II)
Classification Code	JGS
Device Classification Name	Electrode, Ion Specific, Sodium

3. Predicate Device

Proprietary Name	i-STAT® 1 Wireless Analyzer
Common Name	i-STAT 1 Analyzer, i-STAT Analyzer and handheld
510(k) Number	k103195
Regulation Number	862.1665 (Class II)
Classification Code	JGS
Device Classification Name	Electrode, Ion Specific, Sodium

4. Device Description

The i-STAT Alinity System is a handheld, *in vitro* diagnostic analytical device designed to run i-STAT test cartridges. The system is designed for use at or near point of patient care, by trained medical professionals and is for prescription use only and is for use in point of care and laboratory settings.

The i-STAT Alinity System is comprised of the instrument, rechargeable battery, base station, electronic simulator, control material, printer and i-STAT test cartridges. The i-STAT Alinity Instrument features a barcode scanner, user interface with touch screen display and wireless capability. The instrument reports quantitative results within approximately 2 minutes.

The i-STAT cartridge contains test reagents which are located on the biosensors chips. The instrument interacts with the cartridge to move fluid across the biosensors and generate a quantitative result. Cartridges require two to three drops of whole blood which are typically applied to the cartridge using a syringe.

5. Intended Use Statement

The i-STAT Alinity System with i-STAT Sodium test is intended for use in point of care or clinical laboratory settings. The i-STAT Alinity System with Sodium test is intended for the quantitative measurement of sodium in arterial and venous whole blood.
Sodium measurements are used for monitoring electrolyte imbalances.
For *in vitro* diagnostic use.

6. Summary Comparision of Technological Characteristics

Characteristics	**Predicate Device (k103195)**	**Candidate Device i-STAT Alinity system**
Intended Use	The i-STAT 1 Wireless Analyzer is used by trained medical professionals for running a variety of clinical chemistry tests and test panels contained in i-STAT test cartridges. The test for sodium, as part of the i-STAT System, is	The i-STAT Alinity Instrument is intended to be used by trained medical professionals for a variety of in vitro diagnostic tests and test panels using i-STAT test cartridges. The test for sodium, as part of the i-STAT System, is

Characteristics	Predicate Device (k103195)	Candidate Device i-STAT Alinity system
	intended for use in the in vitro quantification of sodium in arterial, venous or capillary whole blood. Sodium measurements are used for monitoring electrolyte imbalances	intended for use in the in vitro quantification of sodium in arterial or venous whole blood. Sodium measurements are used for monitoring electrolyte imbalances
Sample Type	Fresh arterial, venous or capillary whole blood.	Fresh arterial or venous whole blood.
Power	Two 9-volt lithium batteries, or rechargeable battery.	Lithium-Ion rechargeable battery
Principle of Measurement	Sodium: Ion selective electrode	Same
Reagent Format	Cartridge	Same
Reagent Storage and Stability	Storage: 2°C to 8°C (35-46°F)	Same
Quality Checks	A series of quality checks are automatically run each test cycle prior to the system generating a result. Quality checks verify the analyzer motor, electrical, pressure and temperature systems and cartridge elements.	Same
Data Storage	1,000 patient records	500 patient records
Connectivity	TCP/IP 802.11 (WiFi) b/g	TCP/IP 802.11 a/b/g/n
Barcode Technology	Class II laser bar code scanner	Imager that reads 1-D and 2-D barcodes
User Interface	19 keys for data entry	LCD touch screen
User Interface Screen	A grey scale LCD (3.5 in.)	A color LCD screen (5 in.)

7. Performance Characteristics

Analytical Performance

a. Precision

Precision 20 days (aqueous materials)

The precision of the i-STAT Sodium Test on the i-STAT Alinity Instrument was evaluated using 5 levels of aqueous materials. This 20-day multi-day precision testing was was based on CLSI document EP05-A3: *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition.* The study was conducted using 10 instruments and one cartridge lot over 20 days at one site. The results of the 20-day precision study using the initial runs (including any outlying runs) are shown in Table 1.

Table 1: 20-day Precision Study Results (including outlying runs)

Calibration Verification Material Level	N	Mean (mmol/L)	S_T (mmol/L)	CV_T (%)	Sr (mmol/L)	CVr (%)	Srr (mmol/L)	CVrr (%)	Sdd (mmol/L)	CVdd (%)
CV L1	80	99.6	0.43	0.43	0.36	0.36	0.22	0.22	0.00	0.00
CV L2	80	121.2	0.32	0.27	0.31	0.26	0.02	0.017	0.09	0.074
CV L3	80	133.7	0.34	0.26	0.29	0.22	0.17	0.13	0.00	0.00
CV L4	80	160.9	0.96	0.60	0.96	0.60	0.00	0.00	0.00	0.00
CV L5	80	180.2	0.56	0.31	0.38	0.21	0.42	0.23	0.00	0.00

Precision (whole blood)

The whole blood precision of the i-STAT Sodium Test on the i-STAT Alinity Instrument was evaluated using venous whole blood (native or altered) samples targeted to be within a low abnormal, normal and high abnormal sodium levels.

One cartridge lot was used across 3 point of care sites. At each site, each sample was tested 3 times on each of 7 i-STAT Alinity Instruments (total of 21 test results per sample). The largest estimate of precision was 0.50 mmol/L as shown in Table 2.

Table 2: Whole Blood Precision Results

Concentration Level	Site	N	Mean (mmol/L)	Within-Instrument		Total	
				SD	%CV	SD	%CV
<138 mmol/L (abnormal low)	1	21	114.6	0.50	0.43	0.50	0.43
	2	21	115.0	0.38	0.33	0.38	0.33
	3	21	114.2	0.44	0.38	0.44	0.38
138 to 146 mmol/L (normal)	1	21	140.0	0.00	0.00	0.00	0.00
	2	21	139.8	0.31	0.22	0.45	0.32
	3	21	141.6	0.49	0.34	0.51	0.36
>146 mmol/L (abnormal high)	1	21	156.0	0.38	0.24	0.38	0.25
	2	21	155.1	0.36	0.23	0.36	0.23
	3	21	165.9	0.30	0.18	0.30	0.18

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 Sodium Test was evaluated on the i-STAT Alinity Instruments by preparing a series of sodium concentration levels in whole blood that spanned the reportable range of the test. The best fitting regression model was a second order model, and the non-linearity ranged from -0.40 to 0.66 mmol/L. The linearity of the i-STAT Sodium Testused with the i-STAT Alinity Instruments was demonstrated over the reportable range (100 – 180 mmol/L).

c. Recovery

The recovery of the i-STAT Sodium test was evaluated on the i-STAT Alinity Instrument by creating a series of sodium concentration levels in whole blood, measuring their expected value on the predicate and determining the recovery bias and % recovery. The % recovery ranged from 99.9% to 100.6%.

d. Limit of Quantitation (LoQ)

The study was based on the CLSI EP17-A2: *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures.* The LoQ of the i-STAT Sodium Test was evaluated on the i-STAT Alinity Instruments using whole blood that was altered to low sodium concentrations (< 100 mmol/L) and two cartridge lots. The LoQ for the i-STAT Sodium Test on the i-STAT Alinity Instrument was determined to be 80 mmol/L.

e. Interference

The interference performance of the i-STAT Sodium Test on the i-STAT Alinity Instrument was evaluated using whole blood and plasma test samples based on CLSI EP07-A2: *Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition*. The effect of each potentially interfering compound was evaluated by comparing the performance of a test sample spiked to a high concentration of the compound and a control test sample spiked with an equal volume of solvent. A compound was identified as an interferent if the difference between the spiked test sample and the control was > 4 mmol/L. Compounds that do not interfere with the i-STAT Sodium Test are shown in Table 3; those compounds that do interfere are shown in Table 4.

Table 3: Non-Interfering Compounds and Test Concentrations

Substance	Test Concentration	
	mmol/L (unless specified	(mg/dL)*
Acetaminophen	1.33	20.10
Acetyl Cysteine	10.2	166.45
Ascorbic Acid	0.342	6.02
Bromide (therapeutic)	2.5	19.98
β-Hydroxybutyric Acid	6.0	62.47
Calcium (Total)	5.0	20.04
Lactate	6.6	58.79
Magnesium	15	36.46
Salicylic Acid	4.34	59.94
Ibuprofen	2.425	50.03
Heparin	3 U/mL	n/a
Ammonium	2.0	10.70
Lithium	3.2	2.22
Acetyl Salicyclic Acid	3.62	65.22
Bilirubin	0.342	20.01
Hemoglobin	2 g/L	200.00
Triglyceride	37	3233.80
Uric Acid	1.4	23.54

*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.

Table 4: Interfering Compounds and Interfering Concentrations

Compound	Test Concentration (mmol/L)	(mg/dL)
Bromide	37.5	299.64
Nithiodote (sodium thiosulfate)	16.7	264.04

A bromide concentration above 16.65 mmol/L may give a falsely decreased i-STAT Sodium Test result of more than 4 mmol/L.

A sodium thiosulfate concentration above 3.57 mmol/L may give a falsely increased i-STAT Sodium Test result of more than 4 mmol/L.

f. Anticoagulant Study

The sample type comparison study was performed using the i-STAT Sodium Test on the i-STAT Alinity Instrument and 40 blood samples ranging from 100 to 180 mmol/L. The comparator condition for this study was heparinized whole blood and the test condition was non-anticoagulated whole blood. The Deming regression result was a slope of 1.00 and a correlation coefficient of 1.00.

g. Method Comparison with Predicate Device

The method comparison study compared the clinical results of the i-STAT Sodium Test on the i-STAT Alinity Instrument to the i-STAT Sodium Test performance on the i-STAT 1 Wireless Analyzer (predicate). This study was conducted across 4 point of care sites. The study included 174 subjects using whole blood (venous or arterial) samples covering the measuring range 100 to 180 mmol/L. The Weighted Deming regression for all 4 sites combined had a regression slope of 1.0 and correlation coefficient of 0.999.

8. Conclusion

Analytical and clinical studies have shown the i-STAT Alinity System to be safe and effective for its intended use. The results of these studies demonstrate that performance of the i-STAT Alinity System is substantially equivalent to the predicate device.