DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 10, 2017

ABBOTT POINT OF CARE INC.
MARIA L. FIGUEROA
SR. SPECIALIST REGULATORY AFFAIRS
400 COLLEGE ROAD EAST
PRINCETON NJ 08540

Re: k163271
Trade/Device Name: i-STAT Alinity System with i-STAT Glucose test
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: CGA
Dated: March 13, 2017
Received: March 14, 2017

Dear Ms. 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. 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,

Kellie B. Kelm -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)*
K163271

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

Indications for Use *(Describe)*

The i-STAT Alinity System with i-STAT Glucose test is intended for use in point of care or clinical laboratory settings. The i-STAT Alinity System with Glucose test is intended for the quantitative measurement of glucose in arterial and venous whole blood.

Glucose measurements are used in the diagnosis, monitoring, and treatment of carbohydrate metabolism disorders including, but not limited to, diabetes mellitus, idiopathic hypoglycemia, and pancreatic islet cell carcinoma. The i-STAT Glucose test with the i-STAT Alinity System has not been evaluated in neonates.

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.
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Contact

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Date Prepared: April 6, 2017

2. Device Information

Proprietary Name: i-STAT Alinity System with the i-STAT Glucose test

510(k) Number: K163271

Product code	Device Classification name	Regulation Number	Class	Panel
CGA	Glucose Test System	862.1345	II	Clinical Chemistry

3. Predicate Device

Proprietary Name: i-STAT 1 Wireless Analyzer

510(k) Number: K103195

Product code	Device Classification name	Regulation Number	Class	Panel
CGA	Glucose Test System	862.1345	II	Clinical Chemistry

4. Device Description

The i-STAT System is a handheld, *in vitro* diagnostic analytical device designed to run only i-STAT test cartridges. 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.

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 test cartridge contains test reagents which are located on the sensors. The instrument interacts with the cartridge to move fluid across the sensors 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 Glucose test is intended for use in point of care or clinical laboratory settings. The i-STAT Alinity System with Glucose test is intended for the quantitative measurement of glucose in arterial and venous whole blood.

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

The i-STAT Glucose test with the i-STAT Alinity System has not been evaluated in neonates.

For *in vitro* diagnostic use.

6. Summary Comparison of Technological Characteristics

Similarities and Differences: System (Test and Instrument)		
Feature or Characteristic	**Predicate Device (K103195) i-STAT Glucose test with the i-STAT 1 Wireless Analyzer**	**Candidate Device i-STAT Glucose test with the i-STAT Alinity instrument**
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 glucose, as part of the i-STAT System, is intended for use in the *in vitro* quantification of glucose in arterial, venous, or capillary whole blood. 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.	The i-STAT Alinity System with i-STAT Glucose test is intended for use in point of care or clinical laboratory settings. The i-STAT Alinity System with Glucose test is intended for the quantitative measurement of glucose in arterial and venous whole blood. Glucose measurements are used in the diagnosis, monitoring, and treatment of carbohydrate metabolism disorders including, but not limited to, diabetes mellitus, idiopathic hypoglycemia, and pancreatic islet cell carcinoma. The i-STAT Glucose test with the i-STAT Alinity System has not been evaluated in neonates. For in vitro diagnostic use.
Principle of Measurement	Glucose is measured amperometrically. Oxidation of glucose, catalyzed by the enzyme glucose oxidase, produces hydrogen peroxide (H_2O_2).	Same
Calibration	1-point on-board (contained within the cartridge)	Same
Test Traceability	NIST SRM965	Same
Test Reportable Range	20 – 700 mg/dL	Same
Sample Type	Fresh capillary, arterial or venous whole blood.	Fresh arterial or venous whole blood.
Sample Volume	65 - 95 µL	Same

Similarities and Differences: System (Test and Instrument)		
Feature or Characteristic	**Predicate Device (K103195) i-STAT Glucose test with the i-STAT 1 Wireless Analyzer**	**Candidate Device i-STAT Glucose test with the i-STAT Alinity instrument**
Time to test	~2 minutes	Same
Test Format	Cartridge	Same
Test preparation	Ready to use	Same
Test 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
Wireless connectivity capability	Yes	Same
Power	Two 9-volt lithium batteries, or rechargeable battery.	Lithium-Ion rechargeable battery
Barcode scanning capability	Yes	Same
Data storage capability	Yes	Same
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 Glucose Test on the i-STAT Alinity Instrument 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 10 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 Study Results

Calibration Verification Level	N	Mean (mg/dL)	S_T (mg/dL)	CV_T (%)	S_r (mg/dL)	CV_r (%)	S_{rr} (mg/dL)	CV_{rr} (%)	S_{dd} (mg/dL)	CV_{dd} (%)
CV L1	80	26.9	0.42	1.56	0.22	0.82	0.34	1.26	0.12	0.45
CV L2	80	41.0	0.34	0.83	0.20	0.49	0.18	0.44	0.21	0.51
CV L3	80	125.0	0.32	0.26	0.21	0.17	0.23	0.18	0.09	0.07
CV L4	80	286.7	0.77	0.27	0.53	0.18	0.52	0.18	0.22	0.08
CV L5	80	600.6	3.47	0.58	2.42	0.40	2.26	0.38	1.06	0.18

Precision (whole blood)

The whole blood precision of the i-STAT Glucose Test on the i-STAT Alinity Instrument was evaluated using venous whole blood (native or altered) samples targeted to six different glucose levels within the i-STAT Glucose test reportable range.

One test 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 results of the whole blood precision are shown in Table 2.

Table 2: Whole Blood Precision Results

Concentration Level (mg/dL)	Site	N	Mean (mg/dL)	Within-Instrument		Total			
				SD	%CV	SD	SD 95% CI	%CV	%CV 95% CI
30-50	1	21	37.1	0.36	0.97	0.36	(0.27, 0.52)	0.97	(0.74, 1.40)
	2	21	35.3	0.56	1.59	0.56	(0.43, 0.81)	1.59	(1.21, 2.30)
	4	21	43.6	0.51	1.16	0.51	(0.39, 0.73)	1.16	(0.89, 1.68)
51-110	1	21	104.0	0.22	0.21	0.22	(0.17, 0.32)	0.21	(0.16, 0.30)
	2	21	84.5	0.51	0.61	0.51	(0.39, 0.74)	0.61	(0.46, 0.88)
	4	21	92.7	0.46	0.50	0.46	(0.35, 0.67)	0.50	(0.38, 0.72)
111-150	1	21	134.6	0.49	0.36	0.51	(0.39, 0.74)	0.38	(0.29, 0.55)
	2	21	120.3	0.64	0.54	0.64	(0.49, 0.93)	0.54	(0.41, 0.77)
	4	21	115.3	0.48	0.42	0.48	(0.37, 0.70)	0.42	(0.32, 0.61)
151-250	1	21	182.9	0.70	0.38	0.70	(0.54, 1.01)	0.38	(0.29, 0.55)
	2	21	194.0	0.63	0.33	0.63	(0.48, 0.91)	0.33	(0.25, 0.47)
	4	21	217.2	0.49	0.22	0.54	(0.41, 0.81)	0.25	(0.19, 0.37)
251-400	1	21	347.3	1.71	0.49	1.71	(1.31, 2.47)	0.49	(0.38, 0.71)
	2	21	352.0	1.43	0.41	1.43	(1.09, 2.07)	0.41	(0.31, 0.59)
	4	21	348.7	2.53	0.73	2.53	(1.94, 3.66)	0.73	(0.56, 1.05)
401-700	1	21	548.9	7.46	1.36	7.46	(5.70, 10.78)	1.36	(1.04, 1.96)
	2	21	575.8	2.60	0.45	2.81	(2.13, 4.13)	0.49	(0.37, 0.72)
	4	21	526.5	3.56	0.68	3.56	(2.72, 5.14)	0.68	(0.52, 0.98)

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 Glucose test was evaluated on the i-STAT Alinity Instruments by preparing a series of glucose 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 absolute value of non-linearity ranged from 0.00 to 23.8 mg/dL. The i-STAT Glucose test used with the i-STAT Alinity Instruments demonstrated linearity over the reportable range (20-700 mg/dL).

c. Recovery

The recovery of the i-STAT Glucose test was evaluated on the i-STAT Alinity Instrument by creating a series of glucose concentration levels in whole blood, measuring their assigned value on the predicate and determining the recovery bias and % recovery. The % recovery ranged from 94.6% to 100.3% across the glucose reportable range (20-700 mg/dL).

d. 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 Glucose test was evaluated on the i-STAT Alinity Instruments using whole blood that was altered to low glucose concentrations (< 20 mg/dL) and two test cartridge lots. The LoQ for the i-STAT Glucose test on the i-STAT Alinity Instrument was determined to be 5.558 mg/dL.

e. Interference

The interference performance of the i-STAT Glucose test on the i-STAT Alinity Instrument 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 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 > 10% of the mean of glucose test results for the control sample. Compounds that do not interfere with the glucose test are shown in

Table 3; those compounds that do interfere are shown in **Error! Reference source not found.**.

Table 3: Non-Interfering Compounds and Test Concentrations

Substance	Test Concentration	
	(mmol, unless specified)	mg/dL
Acetaminophen	1.33	20.10
Acetaldehyde	0.045	0.20

Substance	Test Concentration	
	(mmol, unless specified)	mg/dL
Acetoacetate	2.0	21.60
L-Ascorbic Acid	0.342	6.02
Acetyl Cysteine	10.2	166.45
Ammonium Chloride	2.0	10.70
Bromide	37.5	325.69
β-Hydroxybutyric Acid	6.00	62.47
Dopamine	0.006	0.09
Ethanol	86.8	399.89
Fluoride	0.105	0.27
Formaldehyde	0.133	0.40
Glycolic Acid	10.0	76.05
Gentamicin	0.021	3.13
Glucosamine	0.030	0.54
Glutathione, reduced	3	92.20
Guaifenesin	15	297.33
Hemoglobin	2g/L	200
Heparin	3U/mL	n/a
Ibuprofen	2.425	50.03
Isoniazid	0.292	4.00
Lactate	6.6	63.37
Mannose	1.00	18.02
Maltose	13.3	455.26
pH	8.0	n/a
Pyruvate	0.309	2.90
Salicylate	4.34	62.52
Thiocyanate	6.9	44.86
Triglyceride	37	3233.80
Uric Acid	1.4	23.54
Sodium Thiosulfate	16.7	264.04
Bilirubin	0.342	19
Cholesterol	13	503
Creatinine	0.442	5
Fructose	1	18
Galactose	0.84	15
Xylose	3	45

A hydroxyurea concentration above 0.43 mmol/L may give a falsely elevated i-STAT glucose test result of more than 10%.

f. Anticoagulant Study

The sample type comparison study was performed using the i-STAT Glucose Test on the i-STAT Alinity Instrument and 40 blood samples across the glucose concentration range. 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. Altitude study

The effects of altitude were evaluated for the i-STAT Glucose test on the i-STAT Alinity Instrument at altitude of up to 10,000 feet above sea level. The altitude performance was evaluated using two lots of cartridges, commercially available i-STAT Glucose control materials that represented 3 Glucose levels.

The performance of the i-STAT Glucose test used with the i-STAT Alinity Instrument at altitude up to 10,000 feet was found to be equivalent to the performance of the i-STAT Glucose test at sea level.

h. Oxygen study

The effects of Oxygen were evaluated for the i-STAT Glucose test on the i-STAT Alinity Instrument using whole blood samples. The performance of the i-STAT Glucose test was evaluated at low and high levels of oxygen at four glucose levels

This study demonstrated equivalent glucose results when evaluated at low and high oxygen levels for all glucose concentrations tested.

Comparison Study

i. Method Comparison with Predicate Device

The method comparison study compared the clinical results of the i-STAT Glucose Test on the i-STAT Alinity Instrument to the i-STAT Glucose Test performance on the i-STAT 1 Wireless Analyzer (predicate). This study was conducted across 3 point of care sites. The study included 237 subjects using whole blood (venous or arterial) samples covering the measuring range 24 to 673 mg/dL. The Weighted Deming regression for all 3 sites combined had a regression slope of 0.999, intercept of 1.164 and correlation coefficient of 1.000.

8. Conclusion

Analytical and clinical studies have shown the i-STAT Glucose test with 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 Glucose test with the i-STAT Alinity System is substantially equivalent to the predicate device.