DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 22, 2017

Abbott Point of Care, Inc.
Laura Y. Joglekar
Associate Director, Regulatory Affairs
400 College Road East
Princeton, NJ 08540

Re: K163342
Trade/Device Name: i-STAT Hematocrit test with i-STAT Alinity System
Regulation Number: 21 CFR 864.6400
Regulation Name: Hematocrit measuring device
Regulatory Class: Class II
Product Code: JPI
Dated: July 24, 2017
Received: July 25, 2017

Dear Ms. Joglekar:

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 Part 801); 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 regulation (21 CFR Part 801), 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" (21CFR 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,

Leonthena R. Carrington -S

Lea Carrington
Director
Division of Immunology and Hematology 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)*
K163342

Device Name
i-STAT Hematocrit test with the i-STAT Alinity System

Indications for Use *(Describe)*
The i-STAT Alinity instrument with i-STAT tests is intended for use in point of care or clinical laboratory settings. The i-STAT Alinity system is intended for the quantitative measurement of various analytes in arterial and venous whole blood.

The i-STAT Hematocrit test is intended for use in the in vitro quantification of packed red blood cell volume fraction in arterial or venous heparinized whole blood, or in arterial or venous non-anticoagulated whole blood.

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

The i-STAT Hematocrit test with the i-STAT Alinity System is not for use with capillary samples.

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 21 CFR 807.92.

1. Submitter Information

Owner — Abbott Point of Care Inc.
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Princeton, NJ 08540

Contact — Primary: Laura Joglekar
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Date Prepared — July 24, 2017

2. Device Information

Proprietary Name — i-STAT Hematocrit test with the i-STAT Alinity System

Product code	Device Classification name	Regulation Number	Class	Panel
JPI	Device, Hematocrit Measuring	864.6400	II	Hematology
JGS	Electrode, Ion Specific, Sodium	862.1665	II	Clinical Chemistry

3. Predicate Device

Proprietary Name — i-STAT Hematocrit test with i-STAT 1 Wireless Analyzer
510(k) Number — K103195

Product code	Device Classification name	Regulation Number	Class	Panel
JPI	Device, Hematocrit Measuring	864.6400	II	Hematology

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.

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 sensors which are located on the biosensors chips. 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

Instrument

The i-STAT Alinity instrument with i-STAT tests is intended for use in point of care or clinical laboratory settings. The i-STAT Alinity system is intended for the quantitative measurement of various analytes in arterial and venous whole blood. For *in vitro* diagnostic use.

Test

The i-STAT Hematocrit test is intended for use in the in vitro quantification of packed red blood cell volume fraction in arterial or venous heparinized whole blood, or in arterial or venous non-anticoagulated whole blood.

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

The i-STAT Hematocrit test with the i-STAT Alinity System is not for use with capillary samples.

6. Summary Comparision of Technological Characteristics

Similarities and Differences: System (Test and Instrument)		
Feature or Characteristic	**Predicate Device (K103195):** **i-STAT Hematocrit test with the i-STAT1 Wireless Analyzer**	**Candidate Device:** **i-STAT Hematocrit test with the i-STAT Alinity instrument**
Intended Use: Instrument	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 i-STAT Alinity instrument with i-STAT tests is intended for use in point of care or clinical laboratory settings. The i-STAT Alinity system is intended for the quantitative measurement of various analytes in arterial and venous whole blood. For in vitro diagnostic use.
Intended Use: Test	The test for hematocrit, as part of the i-STAT System, is intended for use in the *in vitro* quantification of packed red blood cell volume fraction in arterial, venous, or capillary whole blood. Hematocrit measurements can aid in the determination and monitoring of normal or abnormal total red cell volume status including, but not limited to, conditions such as anemia, erythrobytosis, and blood loss related to trauma a surgery.	The i-STAT Hematocrit test is intended for use in the in vitro quantification of packed red blood cell volume fraction in arterial or venous heparinized whole blood, or in arterial or venous non-anticoagulated whole blood. 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 with the i-STAT Alinity System has not been evaluated in neonates. The i-STAT Hematocrit test with the i-STAT Alinity System is not for use with capillary samples.

Similarities and Differences: System (Test and Instrument)		
Feature or Characteristic	**Predicate Device (K103195): i-STAT Hematocrit test with the i-STAT1 Wireless Analyzer**	**Candidate Device: i-STAT Hematocrit test with the i-STAT Alinity instrument**
Principle of Measurement	Hematocrit is measured using the conductitivy method.	Same
Calibration	1-point on-board (contained within the cartridge)	Same
Test Traceability	Microhematocrit Method	Same
Test Reportable Range	15 – 75 %PCV	Same
Sample Type	Fresh capillary, arterial or venous whole blood.	Fresh arterial or venous whole blood.
Sample Volume	65 - 95 µL	Same
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

Similarities and Differences: System (Test and Instrument)		
Feature or Characteristic	**Predicate Device (K103195): i-STAT Hematocrit test with the i-STAT1 Wireless Analyzer**	**Candidate Device: i-STAT Hematocrit test with the i-STAT Alinity instrument**
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

a. Precision

Precision 20 days (aqueous materials)

The precision of the i-STAT Hematocrit test on the i-STAT Alinity Instrument was evaluated using 4 levels of aqueous materials. This 20-day precision testing was based on CLSI document EP5-A3: *Evaluation 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. The results of the 20-day precision study using all test results are shown in Table 1.

Table 1: 20-day Precision Study Results

Fluid	N	Mean (%PCV)	S_T (%PCV)	CV_T	S_r (%PCV)	CV_r	S_{rr} (%PCV)	CV_{rr}	S_{dd} (%PCV)	CV_{dd}
CV L2	80	16.9	0.46	2.72%	0.44	2.60%	0.09	0.53%	0.09	0.53%
CV L3	80	33.9	0.51	1.50%	0.48	1.42%	0.13	0.38%	0.11	0.32%
CV L4	80	55.2	0.49	0.89%	0.47	0.85%	0.12	0.22%	0.09	0.16%
CV L5	80	65.0	0.39	0.60%	0.37	0.57%	0.10	0.15%	0.09	0.14%

Precision (whole blood)

The whole blood precision of the i-STAT Hematocrit 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 hematocrit levels.

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 study are shown in Table 2.

Table 2: Whole Blood Precision Results

Level (%PCV)	Site	N	Mean (%PCV)	Within-Instrument		Total	
				SD	%CV	SD	%CV
< 38 (abnormal low)	1	21	34.6	0.44	1.26	0.51	1.49
	2	21	35.2	0.44	1.24	0.44	1.24
	4	21	34.4	0.49	1.42	0.50	1.45
38 – 51 (normal)	1	21	45.5	0.49	1.07	0.51	1.13
	2	21	42.5	0.44	1.03	0.52	1.22
	4	21	42.2	0.44	1.03	0.44	1.03
> 51 (abnormal high)	1	21	54.9	0.44	0.80	0.48	0.88
	2	21	53.1	0.30	0.57	0.30	0.57
	4	21	53.0	0.22	0.41	0.22	0.41

b. Linearity

The study was based on CLSI EP06-A: *Evaluation of the linearity of quantitative measurement procedures; Approved Guideline.* The linearity of the i-STAT Hematocrit test was evaluated on the i-STAT Alinity Instrument by preparing a series of whole blood samples with hematocrit levels that spanned the reportable range of the test. The best fitting regression model was a third order model, and the absolute value of the non-linearity ranged from 0.19 to 0.81 %PCV. The linearity of the i-STAT Hematocrit test used with the i-STAT Alinity Instruments was demonstrated over the reportable range (15 – 75 %PCV).

c. Recovery

The recovery of the i-STAT Hematocrit test was evaluated on the i-STAT Alinity Instrument by by preparing a series of whole blood samples with hematocrit levels that spanned the reportable range of the test, measuring their expected value on the predicate device and determining the % recovery. The % recovery ranged from 100.1% to 102.8%.

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 Hematocrit test was evaluated on the i-STAT Alinity Instrument using whole blood samples that were altered to low hematocrit levels (< 15 %PCV) and two test cartridge lots. The LoQ for the i-STAT Hematocrit test on the i-STAT Alinity Instrument was determined to be 14.0 %PCV, which is less than the low end of the reportable range of the test (15 %PCV).

e. Interference

The interference performance of the i-STAT Hematocrit 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 i-STAT Hematocrit results of a test sample spiked to a high concentration of the compound and the reference method result for the same sample. Testing was conducted at two hematocrit levels. A compound was identified as an interferent if the 95% confidence interval on the difference between the spiked test sample and the reference was > 10.8% of the mean reference value. Compounds that do not interfere with

the hematocrit test are shown in Table 3; those compounds that do interfere are shown in Table 4.

Table 3: Non-Interfering Compounds and Test Concentrations

Compound	Test Concentration (mmol/L)	Test Concentration (mg/dL)
Bromide**	< 37.5	< 325.69
Bilirubin	≤ 0.342	≤ 20.01
Sodium Thiosulfate	≤ 6.7	≤ 264.04
Triglyceride	≤ 37	≤ 3233.80
White Blood Cells	21 700 WBC/µL	

*Concentrations less than the test concentrations do not interfere
** Bromide (37.5 mmol/L) is an interferent with the sodium test and it may result in an increased rate of star outs (***) for the hematocrit test.

Table 4: Interfering Compounds and Interfering Concentrations

Compound	Test Concentration	Hematocrit Level (% PCV)	Result
Total Protein (human serum albumin)	>12 (g/dL)	26.5 – 31.5*	Interfering
Total Protein (human serum albumin)	>12 (g/dL)	57 – 63**	Non-interfering
White Blood Cells	(> 50,000 WBC/µL	26.5 – 31.5 *	Interfering

*Concentrations greater than the test concentrations do interfere
**Concentrations less than the test concentrations do not interfere

f. Anticoagulant Study

The sample type comparison study was performed using the i-STAT Hematocrit test on the i-STAT Alinity Instrument and 40 blood samples spanning the reportable range, 15 to 75 %PCV. The comparator condition for this study was heparinized whole blood and the test condition was non-anticoagulated whole blood. The Deming regression results were a slope of 1.00 and a correlation coefficient of 1.00.

g. Microhematocrit Reference Study

The microhematocrit reference study was performed using the i-STAT Hematocrit test on the i-STAT Alinity Instrument and 40 lithium heparinized whole blood samples spanning the reportable range, 15 to 75 %PCV. Two comparator conditions for this study were used: the K_2EDTA and K_3EDTA microhematocrit results for the 40 whole blood samples. The Deming regression of the i-STAT Hematocrit results (traceable to K_3EDTA reference) to the K_3EDTA microhematocrit results gave a slope of 1.02, an intercept of -0.53 and a coefficient of

determination (R^2) of 1.00.The Deming regression of the i-STAT Hematocrit results (traceable to K_2EDTA reference) to the K_2EDTA microhematocrit results gave a slope of 1.02, an intercept of -0.41 and a coefficient of determination (R^2) of 1.00.

h. Method Comparison with Predicate Device

The method comparison study compared the clinical results of the i-STAT Hematocrit test on the i-STAT Alinity Instrument to the results of the the i-STAT Hematocrit test on the i-STAT 1 Wireless Analyzer (predicate). The study was conducted across 3 point of care sites. The study included 240 whole blood (venous or arterial) samples covering the reportable range, 15 to 75 %PCV. The Weighted Deming regression for all 3 sites combined had a regression slope of 1.016 and correlation coefficient (r) of 0.995.

8. Conclusion

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