February 28, 2020

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

Re: K183680
Trade/Device Name: i-STAT CHEM8+ cartridge with the i-STAT 1 System
Regulation Number: 21 CFR 864.6400
Regulation Name: Hematocrit measuring device
Regulatory Class: Class II
Product Code: JPI
Dated: January 23, 2020
Received: January 24, 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,

Takeesha Taylor-Bell
Chief
Division of Immunology and Hematology 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)*
K183680

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

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.

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	Primary: Susan Tibedo Director Regulatory Affairs susan.tibedo@abbott.com Phone: 609-454-9360 Secondary: Maria Figueroa Manager Regulatory Affairs maria.l.figueroa@abbott.com Phone: 609-454-9271
Date Prepared	February 19, 2020
510(k) Number	k183680

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
JPI	Device, Hematocrit Measuring	862.6400	II	Hematology

3. Predicate Device

Proprietary Name i-STAT Hematocrit test on the i-STAT EC4+ cartridge with the i-STAT Alinity System

510(k) Number k163342

Product code	Device Classification name	Regulation Number	Class	Panel
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 hematocrit (HCT). 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 hematocrit in arterial or venous whole blood in point of care or clinical laboratory settings. 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.

6. Summary Comparison of Technological Characteristics

Similarities and Differences		
Feature or Characteristic	**Predicate Device (K163342): i-STAT Hematocrit test on the i-STAT EC4+ cartridge with the i-STAT Alinity System**	**Candidate Device: i-STAT Hematocrit test with the i-STAT 1 System**
Intended Use	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 CHEM8+ cartridge with the i-STAT 1 System is intended for use in the *in vitro* quantification of hematocrit in arterial or venous whole blood in point of care or clinical laboratory settings. 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

Similarities and Differences		
Feature or Characteristic	**Predicate Device (K163342): i-STAT Hematocrit test on the i-STAT EC4+ cartridge with the i-STAT Alinity System**	**Candidate Device: i-STAT Hematocrit test with the i-STAT 1 System**
	The i-STAT Hematocrit test with the i-STAT Alinity System is not for use with capillary samples.	been evaluated in neonates.
Reportable Range	15 – 75 %PCV	Same
Sample Type	Arterial or venous whole blood	Arterial or venous whole blood
Sample Volume	65 µL	95 µL
Sample preparation	Ready to use	Same
Test Traceability	Microhematocrit Method	Same
Calibration	1-point on-board (contained within the cartridge)	Same
Analysis Time	~2 minutes	Same
Principle of Measurement	Hematocrit is measured using the conductivity method.	Same
Reagent Format	Cartridge	Same
Storage and Stability	Storage: 2°C to 8°C (35-46°F)	Same
Cartridge Case	White	Blue
Case thumb well	Small	Large, extends below the cartridge latch
Sample well	Visibly low contrast	Visibly high contrast

7. Performance Characteristics

Analytical Performance

a. Precision

Precision 20 days (Aqueous Materials)

The precision of the i-STAT Hematocrit test on the i-STAT 1 Analyzer was evaluated using 4 levels of aqueous materials. This 20-day precision study 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 Study Results HCT Test on the i-STAT 1 Wireless Analyzer

Fluid Level	N	Mean % PCV	Total		Within-run		Between-run		Between-day	
			S_T %PCV	CV_T (%)	S_r %PCV	CV_r (%)	S_{rr} %PCV	CV_{rr} (%)	S_{dd} %PCV	CV_{dd} (%)
CV L2 / Control L1	80	20.5	0.22	1.1	0.20	1.0	0.08	0.4	0.06	0.3
CV L3 / Control L2	80	32.4	0.31	1.0	0.29	0.9	0.08	0.2	0.07	0.2
CV L4 / Control L3	81	53.2	1.02	1.9	0.94	1.8	0.26	0.5	0.30	0.6
CV L5	80	63.9	0.87	1.4	0.79	1.2	0.31	0.5	0.18	0.3

Precision (Whole Blood)

A whole blood repeatability analysis was conducted using the data collected across three point of care sites. One hundred and ninety samples (123 venous and 67 arterial) were measured in duplicate. The mean values for each sample were divided into three subintervals for each sample type.

The results are provided in **Table 2** and **Table 3** below:

Table 2: Venous whole blood

Sample Range (%PCV)	N	Mean (%PCV)	SD	CV (%)
≤ 35	48	28.6	0.44	1.6
36 - 50	66	42.5	0.60	1.4
> 50	9	60.0	0.47	0.8

Table 3: Arterial whole blood				
Sample Range (%PCV)	**N**	**Mean (%PCV)**	**SD**	**CV (%)**
≤ 35	40*	27.2	1.93	7.1
36 - 50	21	39.9	0.82	2.0
> 50	6	62.9	0.65	1.0

*outliers included

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 Hematocrit 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 third order model. The absolute degree of nonlinearity results met the acceptance criteria for each of the levels tested. Therefore, the i-STAT Hematocrit test demonstrated linearity over the reportable range 15 – 75 %PCV. Regression summary of the Hematocrit response versus the concentration of the whole blood samples of varying analyte levels is also provided in **Table 4**.

Table 4: Regression Summary for the i-STAT Hematocrit test on the i-STAT 1 Analyzer					
i-STAT Test	**Reportable Range (%PCV)**	**Range Tested (%PCV)**	**Slope**	**Intercept**	**R^2**
Hematocrit	15 – 75 %PCV	14 - 79	1.0482	-2.0584	0.9973

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 Hematocrit test was evaluated on the i-STAT 1 Analyzer using four whole blood samples altered to low hematocrit levels (<15 %PCV). The study was conducted over three (3) days using two (2) cartridge lots. The LoQ for the i-STAT Hematocrit test was determined to be 12.4 %PCV, which is below the lower limit of the i-STAT Hematocrit test reportable range (15 – 75 %PCV).

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 Hematocrit test was evaluated on the i-STAT 1 Analyzer using whole blood that was altered to a “blank” hematocrit concentration for LoB testing and two “low” hematocrit 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 the i-STAT Hematocrit test was determined to be 0.66 %PCV and

the LoD was determined to be 1.38 %PCV.

e. Interference

The interference performance of the i-STAT Hematocrit test on the i-STAT 1 Analyzer 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 substance at each Hematocrit level was evaluated by comparing the performance of a test sample spiked to a high concentration of the substance and a control sample spiked with an equal volume of solvent. A substance was identified as an interferent if the 95% confidence interval of the difference between the test sample and the control sample was not within the allowable error (Ea) for the i-STAT test.

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

Table 5: Substances Tested and Interference Results for the i-STAT Hct test

Substance	Test Concentration[1]		Interference (Yes/No)	Interference Results
	mmol/L	mg/dL		
Bilirubin	0.342	20	No	
Intralipid	N/A	5296	No	
Lithium Bromide	37.5	325.69	Yes	Lithium Bromide ≥ 14.0 mmol/L decreases Hct results. Use an alternate method.
Nithiodote (Sodium Thiosulfate)	16.7	264.04	No	
Total Protein	12 g/dL	12000	Yes	• Protein levels above normal (>8.0 g/dL) showed interference at 10.2 g/dL for Hct (<40% PCV) • Protein level below normal (<6.5 g/dL) showed interference at 5.3 g/dL for Hct (<40% PCV)
Triglyceride	37	3233.8	No	
White Blood Cells	>50000 WBC/uL*	>50000 WBC/uL	Yes	WBC at >50000 WBC/uL showed increased results

*No CLSI EP37 1st edition test concentration available. Concentration from recently cleared device.

Comparison Study

f. Method Comparison with Predicate Device

Method comparison was demonstrated in a study comparing the performance of the i-STAT Hematocrit test with the i-STAT 1 System to the performance of the i-STAT

[1] The molecular weight of the compound tested was used to convert the test concentration from mmol/L to mg/dL. The molecular weight of each compound could vary depending on the form chosen.

Hematocrit test with the i-STAT Alinity Instrument. The study was based on CLSI guideline EP09c-ED3. Venous and arterial blood specimens were evaluated and analyzed on the i-STAT 1 analyzer against venous and arterial blood specimens on the i-STAT Alinity instrument. A Passing-Bablok linear regression analysis was performed using the first replicate result from the i-STAT 1 versus the mean 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
Hematocrit	194	1.030	-0.530	1.00

8. Conclusion

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