510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K131930

B. Purpose of Submission:

The purpose of this submission is to add the IT *1-2-3* Platinum Path Sample Purification Kit for use with the previously cleared JBAIDS Anthrax Detection Kit.

C. Measurand:

The two assays in the JBAIDS Anthrax Detection Kit detect two different plasmids (pXO1 and pXO2) that are found in virulent strains of *B. anthracis.* The pXO1 plasmid is a 174-kb plasmid that carries the genes for the 3 proteins, (protective antigen [PA], edema factor [EF], and lethal factor [LF]) which comprise the anthrax toxin. The pXO2 plasmid is a 95-kb plasmid containing the genes (*cap A, cap B and cap C*) that encode the *B. anthracis* capsule. All known virulent forms of *B. anthracis* contain both of these plasmids and loss of one or both is associated with loss of virulence.

D. Type of Test:

The JBAIDS Anthrax Detection Kit uses real-time PCR with hydrolysis probes to detect *B. anthracis* DNA.

E. Applicant:

BioFire Diagnostics, Inc.

F. Proprietary and Established Names:

JBAIDS Anthrax Detection Kit

G. Regulatory Information:

1. Regulation section:

   21 CFR section 866.3045, In vitro diagnostic device for *Bacillus* spp. detection

2. Classification:

   Class II

3. Product code:

   NHT

4. Panel:

   Microbiology (83)

H. Intended Use:

1. Intended use(s):

   The Joint Biological Agent Identification and Diagnostic System (JBAIDS) Anthrax Detection System is a real-time polymerase chain reaction (PCR) test system intended for the qualitative *in vitro* diagnostic (IVD) detection of target DNA sequences on the pXO1 plasmid (Target 1) and the pXO2 plasmid (Target 2) from *Bacillus anthracis.* The system can be used to test the following:

   - Human whole blood collected in sodium citrate from individuals suspected of having anthrax
   - Positive blood cultures
   - Cultured organisms grown on blood agar plates.

   The JBAIDS Anthrax Target 2 assay is used as a supplementary test only after a positive result with the Target 1 Assay.

   The JBAIDS Anthrax Target 1 and Target 2 Assays are run on the JBAIDS instrument using the Diagnostic Wizard. Results are for the presumptive identification of *B. anthracis,* in conjunction with culture and other laboratory tests. The following considerations also apply:

   - The diagnosis of anthrax infection must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence, in addition to the identification of pXO1 and pXO2 targets either from cultures or from direct blood specimens.
   - The assays have not been evaluated with blood from individuals without clinical signs or symptoms who were presumed exposed and who subsequently developed anthrax (inhalation or other forms of the disease), or from individuals with any form of anthrax (inhalational, cutaneous, or gastrointestinal).
   - The level of plasmid targets that would be present in blood from individuals with early systemic infection is unknown.

- The definitive identification of *B. anthracis* from colony growth, liquid blood culture growth, or from blood specimens requires additional testing and confirmation procedures in consultation with public health or other authorities for whom reports are required.

The safety and effectiveness of other types of tests or sample types (not identified as "For in vitro diagnostic use") have not been established.

2. Indication(s) for use:

Not Applicable

3. Special conditions for use statement(s):

Results are for the presumptive identification of *B. anthracis,* in conjunction with culture and other laboratory tests. The following considerations also apply:

- The diagnosis of anthrax infection must be made based on history, signs, symptoms, exposure likelihood, other laboratory evidence, in addition to the identification of pXO1 and pXO2 targets either from cultures or from direct blood specimens.
- The assays have not been evaluated with blood from individuals without clinical signs or symptoms who were presumed exposed and who subsequently developed anthrax (inhalation or other forms of the disease), or from individuals with any form of anthrax (inhalational, cutaneous, or gastrointestinal).
- The level of plasmid targets that would be present in blood from individuals with early systemic infection is unknown.
- The definitive identification of *B. anthracis* from colony growth, liquid blood culture growth, or from blood specimens requires additional testing and confirmation procedures in consultation with public health or other authorities for whom reports are required.

The safety and effectiveness of other types of tests or sample types (not identified as "For in vitro diagnostic use") have not been established.

4. Special instrument requirements:

JBAIDS instrument

I. Device Description:

The Joint Biological Agent Identification and Diagnostic System (JBAIDS) Anthrax Detection System is a fully integrated IVD system composed of the portable JBAIDS instrument, laptop computer and software, the JBAIDS Anthrax Detection Kit with two different freeze-dried PCR assays for detection of pathogenic *Bacillus anthracis* DNA. The system has been validated using four different sample preparation kits for isolating DNA from whole blood (IT *1-2-3* Platinum Path, QFLOW^{DNA} Sample Purification Kits), positive blood cultures (IT *1-2-3*™ SWIPE Sample Purification

Kit), and plate cultures (IT *1-2-3* Platinum Path and SWIPE Sample Purification Kits). Use of the JBAIDS DNA Extraction Control Kit is also recommended.

Prior to testing, specimens are processed using BioFire Diagnostic's IT *1-2-3* Sample Purification Kits. The resulting purified sample is added to Target 1 Unknown and Target 1 Inhibition Control vials, along with reconstitution buffer. Target 1 Positive Control and Negative Control vials are prepared using reconstitution buffer and water. When *B. anthracis* DNA is present, a fragment of *B. anthracis* DNA is amplified. The amplicon is detected by fluorescence using a specific hydrolysis probe. Each probe is labeled on one end with a fluorescent reporter moiety (6-carboxyfluorescein (6-FAM)) and elsewhere with a quencher moiety (carboxy tetramethylrhodamine (TAMRA)). When the probe is intact, the quencher absorbs the light emitted by the reporter moiety. During PCR, the probe hybridizes to the target sequence before the exonuclease activity of Taq-polymerase hydrolyzes the probe, separating the fluorophore from the quencher and permitting detection of the fluorescent signal generated by the reporter. The fluorescent signal increases as additional templates are amplified and more probes are hydrolyzed.

JBAIDS Software analyzes the fluorescence amplification curves and reports results as positive, negative, uncertain or inhibited. A failure of the Positive or Negative Control will result in the entire run being called invalid. Retesting is required to resolve uncertain, invalid or inhibited results. The Target 2 assay is used as a supplementary test only after a positive result is obtained with the Target 1 assay.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   JBAIDS Anthrax Detection Kit

2. Predicate 510(k) number(s):

   K051713 and K071188

3. Comparison with predicate:

Similarities		
Item	**New Device JBAIDS Anthrax Detection Kit with addition of Platinum Path Sample Purification Kit**	**Predicate Device (K051713 and K071188) JBAIDS Anthrax Detection Kit**
Intended Use	Identification of anthrax infection through the detection of	Same

Similarities		
Item	**New Device JBAIDS Anthrax Detection Kit with addition of Platinum Path Sample Purification Kit**	**Predicate Device (K051713 and K071188) JBAIDS Anthrax Detection Kit**
	two DNA sequence targets for *Bacillus anthracis*. Results are used in conjunction with clinical information, culture, and other laboratory tests as an aid in the diagnosis of systemic anthrax infection in individuals suspected of having the disease.	
Technology	Real-time PCR using hydrolysis probes	Same
Organism Detected	Qualitative *in vitro* detection of *Bacillus anthracis* DNA	Same
Specimen Types	Whole blood (collected in 3.2% sodium citrate), blood culture (grown in soybean-casein digest broth) or bacterial culture (grown on blood agar)	Same
Platform	JBAIDS Instrument	Same
Time Required for Analysis of Specimen	Less than 3 hours	Same
DNA Extraction Method	Blood culture purified with IT *1-2-3* SWIPE Sample Purification Kit (or validated equivalent).	Same

Differences		
Item	**New Device**	**Predicate Device (K051713 and K071188)**
DNA Extraction	Whole blood purified with IT *1-2-3* Platinum	Whole blood purified with IT *1-2-3*

Differences		
Item	**New Device**	**Predicate Device (K051713 and K071188)**
Methods	Path or IT *1-2-3* QFLOW^{dna} Sample Purification Kits (or validated equivalent).	QFLOW^{DNA} Sample Purification Kit (or validated equivalent).
	Direct bacterial culture purified with IT *1-2-3* Platinum Path or IT *1-2-3* SWIPE Sample Purification Kit (or validated equivalent).	Direct bacterial culture purified with IT *1-2-3* SWIPE Sample Purification Kit (or validated equivalent).

K. Standard/Guidance Document Referenced (if applicable):

FDA 21 CFR 820: QSR, October 7, 1996

21CFR809.10, In Vitro Diagnostic Products for Human Use, Subpart B –Labeling, April 2012.

"Molecular Diagnostic Methods for Infectious Diseases," CLSI Approved Guideline, MM3-A2 (February 2006).

"Evaluation of Precision Performance of Quantitative Measurements Methods; Approved Guidance-Second Edition", CLSI Approved Guidance EP5-A2 (August 2004).

"Protocols for Determination of Limits of Detection and Limits of Quantitation", CLSI Approved Guidance EP17-A (2004).

L. Test Principle:

Refer to previously FDA-cleared 510(k) Premarket Notification: K051713 and K071188

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

Reproducibility

This study was designed to establish test result reproducibility using the Joint Biological Agent Identification and Diagnostic System (JBAIDS) Anthrax Detection Kit in conjunction with the IT *1-2-3* Platinum Path Sample Purification Kit (Platinum Path) accessory. This study was performed at three sites using contrived whole blood samples purified using the IT *1-2-3* Platinum Path Sample Purification Kit.
Qualitative Anthrax assay results were evaluated for reproducibility, and results are presented by sample, by day, by site, and across sites.

Contrived specimens were prepared by spiking freshly collected pooled human whole blood with inactivated *B. anthracis*. Spike levels consisted of the following:

- true negative samples
- low positive samples, spiked at the limit of detection (LoD*)
- medium positive samples, spiked at 5×LoD*
  * The LoD for inactivated organism was determined based upon previous studies where the Cp values obtained when testing dilutions of the inactivated organism stock and live organism stock (both concentrations reported in CFU/mL) indicate that the inactivated organism stock (i.e. the lot used in this study) contains approximately 4-fold more of the gene target than the live organism stock. To account for these differences, the inactivated organism was used at concentrations shown to provide similar PCR performance (i.e. similar Cp values) to live organism; the concentrations are reported in 'live equivalence'.

A panel of twelve pooled human whole blood samples, spiked with inactivated *B. anthracis* at the two concentrations noted above and tested twice each day for four days at each of three testing sites. There were 96 total replicates tested at each analyte level. On each testing day, two users at each site tested one aliquot of each of the twelve specimens. A minimum of two JBAIDS instruments were used at each site. Three lots of JBAIDS Anthrax reagents were used over the course of the 4 days of testing at each site. One set of DNA Extraction Controls (EC) including one positive EC sample and one negative EC sample, was prepared and purified during each round of sample purification.

Run control (NC and PC) results

Negative Control (NC) and Positive Control (PC) reactions were included in each JBAIDS run. These are freeze-dried reagent vials that either omit or include template DNA, respectively, for the target assays; they are set up using water in lieu of sample. In 50 out of 50 Anthrax Target 1 runs, the NC and PC reactions were successful. In 52 out of 53 Anthrax Target 2 runs, the

NC and PC reactions were successful. In the run that was unsuccessful, the entire rotor failed to amplify, correctly resulting in a failed PC. The run control results establish acceptable run-to-run reproducibility with standard deviations of less than one cycle for both target PCs.

Inhibition control (IC) results

A target-specific inhibition control assay (IC) is run with each sample. The IC result is "inhibited" when the associated IC assay is unsuccessful and the Anthrax target assay is not positive. Of the 300 processed samples, the Target 1 IC was positive for 300 samples and the Target 2 IC was positive for 299 samples. The sample with the inhibited test result for Target 2 was retested according to protocol undiluted and at a 1:10 dilution; both retested samples produced the expected final result of positive.

Extraction control (EC) results

A set of positive and negative DNA ECs was tested with each set of purified samples, and both controls were required to be successful for a successful Platinum Path purification. Based on the DNA EC results, there were 24/25 successful Platinum Path purifications reported. The sample associated with the failed extraction result needed to be re-purified in order to achieve a passing result.

Assay reproducibility results

Samples spiked at both the medium positive level (5×LoD) and the low positive level (LoD) yielded positive results 100% of the time for both assays. Samples that were not spiked with inactivated organism (true negatives) yielded negative results 100% of the time. There were no observed differences in qualitative reproducibility results of Anthrax assays between days, users, or between sites testing on at least two instruments. All ICs were successful on final test results for all samples.

Variability of the Cp values in each test run at each site was analyzed for all samples purified with the Platinum Path kit and tested with the Anthrax Target 1 and Target 2 assays. Overall, system variability, as measured by the coefficient of variation (% CV) of the Cp score, was below 3.5% for all samples spiked at or above the LoD, regardless of test site. The observed mean Cp values measured per site and per spike level were similar (within one SD) to the overall mean Cp value, and the observed variability of the mean Cp values across sites overlapped. The results of this study are acceptable to establish device variability between sites including multiple operators and multiple instruments.

b. Linearity/assay reportable range:

Not Applicable

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

There are no reported changes to the stability or expected values therefore no study was recommended during the presubmission for this assay. For information on stability and expected values refer to previously FDA-cleared 510(k) Premarket Notifications K051713 and K071188.

d. Detection limit:

This study was designed to establish the JBAIDS Anthrax Detection Kit when used in conjunction with the IT *1-2-3* Platinum Path sample purification kit (Platinum Path) for whole blood samples meets the previously established LoD of 95% positivity at 1000 CFU/mL. The study was performed in two phases:

Phase one was a direct comparison of the test result obtained with the previously validated purification kit (i.e. QFLOW^{DNA}), and the new purification kit utilizing whole blood samples spiked with live *B. anthracis* at three concentrations: 10×, 1×, and 0.1× the LoD previously confirmed at 1000 CFU/mL using the IT 1-2-3 FLOW and QFLOW^{DNA} Sample Purification Kits. These spiked whole blood samples were split and purified with the QFLOW kit as a reference and the Platinum Path kit under evaluation. Only positive test results were used to determine the mean Cp values at each bacterial spike concentration. A single Target 2 Inhibition Control (IC) was reconstituted using one of the four samples spiked at the lowest test concentration and processed with each of the sample purification kits. The spiked blood samples were derived from a pool, so a single IC performed for each set of samples processed with each purification kit was deemed sufficient. ICs for all runs and purification kits gave positive test results, indicating PCR was not inhibited in the pooled whole blood samples.

This first comparison run resulted in *B. anthracis* detection for all samples, including at the lowest concentration of 0.1×LoD. To estimate the concentration that Platinum Path processed samples are detected less than 100% of the time and to compare the qualitative detection of the two kits, a second comparison of the QFLOW^{DNA} and Platinum Path sample purification kits was performed for whole blood samples spiked to lower concentrations: 1×, 0.1×, and 0.01×LoD. These results are also shown in Table 2. In this second run, only three of the four Platinum Path processed samples spiked at 0.1×LoD gave positive results, even though all four of the samples spiked at this concentration had positive results in the first run. This indicates 0.1×LoD is at or near the spike level that qualitative detection of *B. anthracis* falls

below 100% for Platinum Path processed samples. For both purification methods, two out of four samples spiked at 0.01×LoD showed positive test results. The QFLOW and Platinum Path kits show similar qualitative results above, near and below LoD, indicating the JBAIDS Anthrax Target 2 sensitivity is similar whether evaluating samples processed with the QFLOW kit or with the Platinum Path kit.

Phase two was a confirmatory test using whole blood samples from individual donors spiked with live *B. anthracis* at 1000 CFU/mL and purified with the Platinum Path kit. Each set of 10 spiked samples was processed with an unspiked sample (matrix blank, MB) that served as a contamination control. Individual sample and overall mean Cp values were presented. Both matrix blanks gave negative results for both target assays, indicating no contamination by *B. anthracis* was observed. All ICs were positive except for one associated with Sample 13. Initially, sample 13 was called inhibited for target 2 due to a failure of the associated target 2 IC (one positive and one negative capillary). Upon retesting according to protocol, sample 13 was positive undiluted, as well as positive at the 1:10 dilution. Twenty out of 20 sample purified with the Platinum Path kit were positive for both Anthrax Target 1 and Target 2 assays when spiked at the established LoD of 1000 CFU/mL.

The results of the direct comparison between the QFLOW^{DNA} and Platinum Path whole blood purification methods used with the JBAIDS Anthrax Detection kit are acceptable to establish an LoD of 1000 CFU/mL.

e. Analytical reactivity/specificity:

No changes to the assay primers or probes are reported therefore no study was recommended during the presubmission for this assay. Analytical reactivity/specificity data for this assay can be found in K051713 and K071188.

f. Assay cut-off:

No changes in the assay cut-off are reported. For assay cut-off data, refer to previously FDA-cleared 510(k) Premarket Notifications K051713 and K071188.

h. Interfering species

There are no reported changes to the assay primers or probes therefore no interfering species study was recommended during the presubmission for this assay. Interfering species data for this assay can be found in K051713 and K071188.

i. Direct from culture testing

This study was designed to establish that the assays in the Joint Biological Agent Identification and Diagnostic System (JBAIDS) Anthrax Detection Kit is capable of detecting and identifying targets from direct culture samples processed using a modified IT *1-2-3* Platinum Path Sample Purification Kit protocol.

This study was performed in a BSL3 laboratory using a single strain for each of three live organism species: *B. anthracis* Ames, *Y. pestis* CO92, and *F. tularensis* Schu4. Each organism was grown on separate agar plates. Once colonies were at least 1.5 mm in diameter, 10 positive colonies (for the given test organism) and 10 negative colonies (5 from each of the remaining two organisms) were processed using a modified Platinum Path protocol and tested on JBAIDS. All NC and PC reactions for all assays in all runs were successful.

After all colonies had grown on agar plates, one isolated colony was used to "spike" each sample according to the modified Platinum Path protocol. Ten *B. anthracis* colonies were purified alongside five *Y. pestis* colonies and five *F. tularensis* colonies. All 20 samples were tested with JBAIDS Anthrax Target 1 and Target 2 reagents. *B. anthracis* was detected in all ten *B. anthracis* cultures, and all non- *B. anthracis* cultures produced negative results. The mean Cp values for both anthrax targets were approximately five cycles later than expected, yet within the detection range for the assays. Under the conditions of this study, these results indicate that the colony processing procedure using the Platinum Path kit can detect *B. anthracis* colonies.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

The clinical validation study was designed to validate the use of the Platinum Path kit to process clinical whole blood specimens for testing with the previously FDA-cleared JBAIDS Anthrax Detection Kit. Because clinical specimens from patients infected with *Bacillus anthracis* (Anthrax) are not available, spiked whole blood samples were used in the clinical evaluation. Prospectively collected

whole blood specimens collected in sodium citrate were obtained from patients with febrile illness and spiked with inactivated *B. anthracis*. These spiked samples were then purified in parallel using the new (Platinum Path) and old (QFLOW^{dna}) extraction methods, and tested with the JBAIDS Anthrax Detection Kit.

Subjects meeting the following criteria were invited to enroll in the multisite study after written informed consent was acquired:

Inclusion Criteria

- Subject experienced a fever of at least 100˚F within the previous 24 hours (recorded or self-reported).
- Subject was an adult.

Exclusion Criteria

- Adult volunteers who were incapacitated or otherwise unable to provide informed consent were excluded from the study.
- Individuals under the age of 18 were excluded from the study.

Whole blood specimens were collected at three sites that were selected for the quality of their personnel and their access to the desired subject populations. The study locations were representative of the intended use setting (military hospitals and field clinics), and specimen collection was performed by trained study personnel.

De-identified blood specimens were collected in two 5 mL sodium citrate tubes and stored at 2-8°C. Blood specimens were shipped on ice to BioFire Diagnostics labs twice a week. Upon arrival at the Firm, samples were assigned a new study code number and then spiked with inactivated *B. anthracis* (Ames strain) according to a randomized spiking plan. A total of one hundred (100) samples were spiked as shown in Table 1.

Table 1. Human whole blood sample spike levels and number of replicates

***B. anthracis* spike level**	**Live Organism in CFU/ml (Inactivated Organism Equivalent)***	**Number of Sample Replicates Processed with Each Sample Purification Kit**
No Spike	-	50
1× LoD	1000 (250)	20
5× LoD	5000 (1250)	10
10× LoD	10,000 (2500)	10
100× LoD	100,000 (25,000)	5

1,000× LoD	1,000,000 (250,000)	5
	Total	100

* Samples were spiked with inactivated organism at concentrations that were adjusted to match the PCR performance of live organism (i.e. four fold lower). The spike level is relative to the LoD confirmed for blood samples purified with the Platinum Path kit (1000 CFU/mL live).

Blood samples were spiked and tested within seven days of blood collection. Individuals who prepared the spiked samples were different from those who processed and tested the samples. Two aliquots from each prepared sample were purified, one with the Platinum Path kit and the other with the QFLOW^{DNA} kit. The purified samples were then tested with the JBAIDS Anthrax Detection Kit.

The combined Target 1 and Target 2 results obtained with the Platinum Path processed samples were compared to the combined Target 1 and Target 2 results obtained with the QFLOW^{DNA} processed samples, which were accepted as the correct results

Valid JBAIDS Anthrax detection results were obtained for all 100 contrived whole blood samples purified by both the Platinum Path and QFLOW^{DNA} Sample Purification Kits. Table 2 provides the JBAIDS Anthrax Target 1and Target 2 test results and Cp values stratified by *B. anthracis* spike level.

Table 2. Cp analysis of JBAIDS Anthrax Detection Kit testing of spiked whole blood samples processed with the IT 1-2-3 Platinum Path and QFLOW sample purification kits

***B. anthracis* Spike Level**	**Anthrax Target Assay**	**Sample Purification Kit**					
		Platinum Path			**QFLOW^{DNA}**		
		JABAIDS Positive/Total	**Mean Cp**	**SD**	**JABAIDS Positive/Total**	**Mean Cp**	**SD**
No Spike	**Target 1**	0/50			0/50		
	Target 2	0/50			0/50		
1X LoD	**Target 1**	20/20	32.10	0.93	20/20	30.05	0.53
	Target 2	20/20	32.55	0.92	20/20	30.52	0.48
5X LoD	**Target 1**	10/10	29.45	0.59	10/10	27.42	0.57
	Target 2	10/10	30.04	0.65	10/10	28.11	0.61
10X LoD	**Target 1**	10/10	29.13	1.07	10/10	27.08	0.69
	Target 2	10/10	29.60	1.02	10/10	27.61	0.69
100X LoD	**Target 1**	5/5	25.18	0.65	5/5	23.13	0.55
	Target 2	5/5	25.77	0.51	5/5	23.81	0.62
1,000X LoD	**Target 1**	5/5	22.19	0.67	5/5	20.23	0.39
	Target 2	5/5	22.98	0.77	5/5	20.77	0.54

Relative performance of both purification kits is shown in Table 3, where the result for a sample purified with the QFLOW^{DNA} kit was accepted as the correct result. The final Anthrax interpretation for samples purified using the Platinum

Path kit had a positive percent agreement (PPA) of 100% as compared to samples purified using QFLOW^{DNA} (50/50; 95% CI = 92.9-100%). The final JBAIDS Anthrax interpretation for samples purified using Platinum Path was negative for 50 out of 50 samples that were negative when purified using QFLOW^{DNA}. This represents a negative percent agreement (NPA) of 100% (50/50; 95% CI = 92.9-100%). Overall percent agreement between the two purification kits is 100% (100/100; 95% CI = 96.4-100%).

Table 3. JBAIDS Anthrax Detection Kit Performance on Spiked Whole Blood Samples Processed with the IT *1-2-3* Platinum Path and QFLOW^{DNA} Sample Purification Kits

		QFLOW Sample preparation method	
		Positive	**Negative**
Platinum Path sample preparation method	**Positive**	50	0
	Negative	0	50
		Two sided 95% confidence interval	
Positive percent agreement (PPA)	100 % (50/50)	92.9% - 100%	
Negative percent agreement (NPA)	100% (50/50)	92.9% - 100%	

4. Clinical cut-off**:**

   Not Applicable

5. Expected values/Reference range:

   Not applicable

N. Instrument Names:

Joint Biological Agent Identification and Diagnostic System

O. System Descriptions:

1. Modes of Operation:

   No changes in the mode of operation were reported. For information on the modes of operation refer to previously FDA-cleared 510(k) Premarket Notifications K051713 and K071188.

2. Software:

   No changes in the software were reported. For software information refer to previously FDA-cleared 510(k) Premarket Notifications K051713 and K071188.

3. Specimen Identification:

   No changes in the specimen identification were reported. For specimen identification information refer to previously FDA-cleared 510(k) Premarket Notifications K051713 and K071188.

4. Specimen Sampling and Handling:

   No changes in the specimen sampling and handling were reported. For specimen sampling and handling identification information refer to previously FDA-cleared 510(k) Premarket Notifications K051713 and K071188

5. Calibration:

   No changes in calibration were reported. For specimen calibration information refer to previously FDA-cleared 510(k) Premarket Notifications K051713 and K071188.

6. Quality Control:

   No changes in quality control were reported. For quality control information refer to previously FDA-cleared 510(k) Premarket Notifications K051713 and K071188.

P. Other Supportive Instrument Performance Characteristics Data Not Covered in the "Performance Characteristics" Section above:

None

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.