SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE RE: DOCUMENT NUMBER K_071188____

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

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1. The name and 510(k) number of the SUBMITTER'S previously cleared device.
JBAIDS Anthrax Detection Kit K051713

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

This change was for

The addition of the IT 1-2-3™ QFLOW^{dna} Sample Purification kit to the JBAIDS Anthrax Detection kit.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and

	Similarities	Differences
	Predicate	Modified
Intended Use	To detect target DNA sequences of *B. anthracis*	Same
Labeling	Basic package insert with no information on the IT 1-2-3QFLOW™ Sample Purification kit, ASAY-ASY	Addition under Materials Required Not Provided: IT 1-2-3QFLOW™ Sample Purification kit, ASAY-ASY-0503 IT1-2-3RNA Module, ASAY-ASY-0501 Other updates to the following sections Specimen Collection and Preparation, Sample Purification Procedure, Interfering substances, and Quality Control Purification
System	Detection kit	Same

	FLOW (Predicate)	QFLOW^{dna} (Modified)
Lysis	3 ml of citrated whole blood	0.8 ml of citrated whole blood
Protease treatment	400 µLof protease, 5 min @ rm temp	60 µLof protease K, 10 µL of carrier RNA, and 600 µL of Qiagen Buffer Al @ 55-60˚C for 1 hr
Bind DNA to filter	9 mL of Buffer 1, centrifuge for 3 min at 3000g	Add 600 µLof ethanol and transfer 600 µL to a QIAamp spin column. Centrifuge for 1.5 min at 6000g. Repeat two more times.
Wash Filter	Add 9 mL of Buffer 2 and centrifuge for 3 min at 3000 g	Add 500 µL Qiagen AW1 buffer and centrifuge for 1.5 min at 6000g. Repeat with Qiagen AW2
Dry Spin and Heat	Centrifuge for 5 min at 3000 g, heat the spin filter for 5 min at 88-95˚C in a heat block or 70-75˚C in a water bath	Centrifuge QIAamp spin column for 3 min at 12,000 g.

Elute Sample	Add 1 mL of Buffer 3. Incubate for 5 min at rm temp; centrifuge for 5 min at 3000 g	Add 230 µL Qiagen Buffer AE heated to 68-72 ˚C. Incubate for 5 min at 68-72˚C; centrifuge for 1.5 min at 6000 g.
Dilution	Dilute purified sample 1:5 with Buffer 3 just before testing with the JBAIDS Anthrax Detection Kit	The purified sample is ready for testing with the JBAIDS Anthrax Detection Kit

5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

The design control activities performed

a. Assay Sensitivity
   Target 1, FLOW Cp 34.87 vs. QFLOW^{dna} Cp 31.46
   Target 2, FLOW Cp 34.68 vs. QFLOW^{dna} Cp 31.76
   The Cp values obtained for the QFLOW^{dna} processed sample set were earlier than that obtained for the FLOW processed sample set.

b. Quantity of DNA (Spectrophotometric method)
   FLOW 6.18 ng/ µL vs. QFLOW^{dna} 54.61 ng/ µL
   The quantity of total DNA is higher for sample processed using the QFLOW^{dna} protocol.

c. OD260/OD280 ratio
   FLOW 1.02 vs. QFLOW^{dna} 1.96
   The purity of DNA with regard to protein content is better for the QFLOW^{dna} processed samples.

d. Gel Analysis of Purified DNA
   The bands of the DNA purified using the QFLOW^{dna} procedure were brighter, indicating the quantity of DNA is higher.

e. Removal of Inhibitory Substances
   Citrated whole blood samples from 16 normal healthy donors were processed using the FLOW and the QFLOW^{dna} procedures and then tested using the Target 1 and

Target 2 assays.
Target 1, FLOW IC Cp 31.69 vs. QFLOW^{dna} IC Cp 31.80
Target 2, FLOW IC Cp 31.91 vs. QFLOW^{dna} IC Cp 32.04
There was adequate removal of PCR inhibitors from whole blood samples processed using the QFLOW^{dna} protocol.

f. Carry-Over
Strongly positive samples (spiked at 5x 10^6 CFU/mL) were purified, using FLOW and the QFLOW^{dna} procedures, next to negative (unspiked) samples. Both sets of negative samples were tested by the Target 1 and Target 2 assays.
Target 1, FLOW carry-over rate 0% (0/42) vs. QFLOW^{dna} 2.4% (1/42)
Target 2, FLOW carry-over rate 0% (0/42) vs. QFLOW^{dna} 0% (0/42)

6. A **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure (and Class III Summary for Class III devices).**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K071188

Reviewer: Alexandra Wong/Freddie Poole

Division/Branch: DMD/BACB

Device Name: JBAIDS Anthrax Detection kit

Product To Which Compared (510(K) Number If Known): k051713

		YES	NO	
1.	Is Product A Device	x		If **NO** = Stop
2.	Is Device Subject To 510(k)?	x		If **NO** = Stop
3.	Same Indication Statement?	x		If **YES** = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NE**
5.	Same Technological Characteristics?	x		If **YES** = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7.	Descriptive Characteristics Precise Enough?	x		If **NO** = Go To 10 If **YES** = Stop **SE**
8.	New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NE**
9.	Accepted Scientific Methods Exist?			If **NO** = Stop **NE**
10. Performance Data Available?				If **NO** = Request Data
11. Data Demonstrate Equivalence?				Final Decision: SE

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:

The 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 human whole blood collected in sodium citrate from individuals suspected of having anthrax, positive blood cultures, and 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.

JBAIDS Anthrax Target 1 and Target 2 Assays are run on the JBAIDS instrument using the Diagnostic Wizard.

2. **Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.**

The Joint Biological Agent Identification and Diagnostic System (JBAIDS) Anthrax Detection System is a fully integrated *in-vitro* diagnostic (IVD) system composed of the JBAIDS instrument with laptop computer, software, 2 different freeze-dried reagent assays (in one kit) for the qualitative detection of pathogenic *Bacillus anthracis*, and 4 different sample preparation protocols, **two** for isolating target DNA from whole blood, one for processing blood culture, and another for processing colonies. This submission is for a modification to the sample purification kit described below.

Device Modification

The modification consists in the addition of the QFLOW^{dna} Sample Purification Kit for the purification of whole blood samples. The QFLOW^{dna} protocol offers the advantages of requiring a smaller sample volume, and all processing steps can be performed using a smaller bench top centrifuge. The table below exhibits a summary of changes to the modified kit.

	FLOW (Predicate)	QFLOW^{dna} (Modified)
Lysis	3 ml of citrated whole blood	0.8 ml of citrated whole blood
Protease treatment	400 µLof protease, 5 min @ rm temp	60 µLof protease K, 10 µL of carrier RNA, and 600 µL of Qiagen Buffer Al @ 55-60˚C for 1 hr
Bind DNA to filter	9 mL of Buffer 1, centrifuge for 3 min at 3000g	Add 600 µLof ethanol and transfer 600 µL to a QIAamp spin column. Centrifuge for 1.5 min at 6000g. Repeat two more times.
Wash Filter	Add 9 mL of Buffer 2 and centrifuge for 3 min at 3000 g	Add 500 µL Qiagen AW1 buffer and centrifuge for 1.5 min at 6000g. Repeat with Qiagen AW2
Dry Spin and Heat	Centrifuge for 5 min at 3000 g, heat the spin	Centrifuge QIAamp spin column for 3 min at

	filter for 5 min at 88-95˚C in a heat block or 70-75˚C in a water bath	12,000 g.
Elute Sample	Add 1 mL of Buffer 3. Incubate for 5 min at rm temp; centrifuge for 5 min at 3000 g	Add 230 µL Qiagen Buffer AE heated to 68-72 ˚C. Incubate for 5 min at 68-72˚C; centrifuge for 1.5 min at 6000 g.
Dilution	Dilute purified sample 1:5 with Buffer 3 just before testing with the JBAIDS Anthrax Detection Kit	The purified sample is ready for testing with the JBAIDS Anthrax Detection Kit

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

The sponsor included all required information in the submission to meet the criteria for a Special 510(k). The sponsor submitted descriptions with explanations of the device modification, i.e., the addition of a new sample purification kit; and a summary of their design control validation studies.

ATTACH ADDITIONAL SUPPORTING INFORMATION