K071188

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7 510(k) Summary

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Idaho Technology Inc. JBAIDS Anthrax Detection System

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitted by: Idaho Technology Inc.
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Contact Person: Beth Lingenfelter, ext. 407

Date Prepared: April 27, 2007

Device Name: Trade Name:

JBAIDS Anthrax Detection System

Common Name:

Real-time PCR amplification and detection system for targeted *Bacillus anthracis* DNA sequences

Classification Name:

System: Microorganism differentiation and identification device; 21 CFR 866.2660

Instrument: Micro Chemistry Analyzer for Clinical Use; 21 CFR 862.2170, product code JJF

Reagent Kit: (*B. anthracis*) NHT

Device Description: The Joint Biological Agent Identification and Diagnostic System (JBAIDS) Anthrax Detection System is a fully integrated *in vitro* diagnostic (IVD) system composed of the following:

- JBAIDS instrument with laptop computer
- Software
- Two different freeze-dried reagent assays (in one kit) for the qualitative detection of pathogenic *Bacillus anthracis*
- Four different sample preparation protocols, two for isolating target DNA from whole blood, one for processing blood culture, and another for processing colonies.

The JBAIDS instrument, using Polymerase Chain Reaction (PCR) technology, is a portable thermocycler and real-time fluorimeter. The JBAIDS Anthrax Detection Kit is specially designed for PCR in glass capillaries using the JBAIDS instrument and hydrolysis probes for sequence-specific detection of *B. anthracis* DNA found on the pX01 plasmid (Target 1) and the pX02 plasmid (Target 2).

The reagent kit contains four different types of freeze-dried reagent vials: Positive Controls, Negative Controls, Inhibition Controls, and Unknowns (used for testing the patient sample). Each JBAIDS assay requires a Positive and Negative Control, and each sample is tested using both an Inhibition Control vial and an Unknown reagent vial.

Before testing, whole-blood samples are purified using the Idaho Technology IT 1-2-3™ FLOW or QFLOW^{dna} Sample Purification Kit (or validated equivalent), while blood culture and direct culture specimens are prepared using the IT 1-2-3 SWIPE Sample Purification Kit (or validated equivalent). The resulting purified sample is added to an Unknown reagent vial and an Inhibition Control reagent vial, along with reconstitution buffer. A Positive Control and a Negative Control vial are prepared using reconstitution buffer and reagent grade water. Aliquots from each reagent vial are transferred to two reaction capillaries that are tested together in the JBAIDS instrument. The instrument is programmed to perform heating and cooling cycles that drive the PCR process. The heating and cooling cycles are generated using a heating coil and varying fan speeds. Fluorescence emission is monitored over one of three wavelengths, and the instrument software interprets the change in fluorescence to determine whether the target DNA is present.

When the organism is present, a fragment of *B. anthracis* DNA is amplified using specific primers. The amplicon is detected by fluorescence using a specific hydrolysis probe. The hydrolysis probe contains a short oligonucleotide that hybridizes to an internal sequence of the amplified fragment during the annealing phase of the PCR cycle. This probe has the 5' and 3' ends labeled with a reporter dye and a quenching dye, respectively. When the probe hybridizes to the specific DNA target, the Taq polymerase enzyme, replicating the target-specific DNA, hydrolyzes the probe, which separates the two fluorophores, thus allowing the reporter dye to fluoresce.

The level of fluorescence from each unknown sample and control is measured by the JBAIDS instrument. JBAIDS Software analyzes fluorescence amplification curves and reports results as "Positive," "Negative," "Inhibited," or "Uncertain." A failure of the Positive or Negative Control will result in the entire run being called "Invalid." Failure of the Inhibition Control yields an Inhibited result for the associated sample and requires retesting of that sample.

Intended Use: The JBAIDS Anthrax Detection System is intended for the qualitative IVD detection of targeted DNA sequences on the pX01 plasmid (Target 1) and the pX02 plasmid (Target 2) from the *Bacillus anthracis* pathogen. The system can be used to test human whole blood collected in sodium citrate, positive blood cultures, and cultured organisms grown on blood agar plates.

The JBAIDS Anthrax Target 1 Assay, when run on the JBAIDS instrument, is a qualitative IVD test for the detection of one of two DNA sequence targets, both of which are essential for the organism's pathogenicity. The JBAIDS Anthrax Target 2 Assay, when run on the JBAIDS instrument, is a qualitative IVD test for the detection of the second DNA sequence target and is run as a confirmatory test after obtaining a Positive result from the Target 1 Assay. The results from these tests are used in conjunction with culture and other laboratory tests and clinical information as an aid in the diagnosis of systemic anthrax infection in individuals suspected of having the disease.

These tests must be run on the JBAIDS instrument using the Diagnostic option for valid clinical results. Reports from the instrument are identified with the phrase "For In Vitro Diagnostic Use" when the Diagnostic option is used. Results that are not so identified should *not* be reported or used in patient diagnosis decisions.

Predicate Device: The JBAIDS Anthrax Detection System is substantially equivalent to unmodified system 510(k) number K0561713.

Table 1 Provides a comparison between the modified and unmodified device.

Table 1. Comparison of the modified and unmodified JBAIDS Anthrax Detection System.

ELEMENT	PREDICATE: Unmodified JBAIDS Anthrax Detection System (K051713)	New Device: Modified JBAIDS Anthrax Detection System
Intended Use	Identification of anthrax infection through the detection of 2 DNA sequence targets, which are both essential for *Bacillus anthracis* pathogenicity. 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.	Same
Specimen	Whole blood (collected in 3.2% sodium citrate), blood culture (grown in soybean-casein digest broth), or bacterial culture (grown on blood agar)	Same

ELEMENT	PREDICATE: Unmodified JBAIDS Anthrax Detection System (K051713)	New Device: Modified JBAIDS Anthrax Detection System
Specimen Preparation	Purified with IT 1-2-3 FLOW Sample Purification Kit or IT 1-2-3 SWIPE Sample Purification Kit (or validated equivalent)	Same, plus the addition of the IT 1-2-3 QFLOW^{dna} Sample Purification Kit as an alternate method for the purification of whole blood samples.
Testing Platform	The JBAIDS instrument which is a real-time PCR thermocycler.	Same
Time Required for Analysis of Specimen	Less than 3 hours	Same
Physical Properties	Freeze dried reagents with reconstitution water and buffer provided in kit	Same
Test Result	Identification of two plasmids required for pathogenicity of the organism; both plasmids are found together in virulent strains of *B. anthracis*.	Same

Performance Summary:

A method comparison and carry-over study were performed and demonstrated that whole blood samples purified using the IT 1-2-3 QFLOW^{dna} Sample Purification Kit provide equivalent results as whole blood samples purified using the IT 1-2-3 FLOW Sample Purification Kit.

Method Comparison:

Six (6) citrated whole blood samples spiked at the assay's limit of detection (LOD) with *B. anthracis* were processed using the IT 1-2-3 QFLOW^{dna} Sample Purification Kit and the IT 1-2-3 FLOW Sample Purification Kit. All six samples processed using both methods were positive with the both the *B. anthracis* Target 1 and Target 2 assays. Samples purified using the IT 1-2-3 QFLOW^{dna} protocol demonstrated equivalent, or better, recovery and purity of DNA.

Citrated whole blood samples from 16 normal healthy donors were processed using the IT 1-2-3 QFLOW^{dna} and IT 1-2-3 FLOW Sample Purification Kits and then tested using both assays for the JBAIDS Anthrax Detection Kit. All samples (100%) processed using the IT 1-2-3 QFLOW^{dna} protocol gave negative test results for both assays. One sample processed using the IT 1-2-3 FLOW protocol gave an inhibited result with the Target 1 assay while the other 15 were negative. All 16 samples gave negative results with the Target 2 assay.

Carry-over:

To determine the rate of carry-over for the two sample purification kits, strongly positive samples (spiked at 5 x 10^6 CFU/mL) were purified next to negative (unspiked) samples. The negative samples were tested using both the Target 1 and Target 2 assays. For samples purified using the QFLOW^{dna} protocol, carry-over was observed in 2.4% (1/42) of negative capillaries for the Target 1 assay and 0% (0/42) for the Target 2 assay. The carry-over rate for the same samples processed using the FLOW protocol was 0% (0/42) for both the Target 1 and Target 2 assays. The rate of carry-over observed using the two sample purification methods was determined to be equivalent and is also equivalent to the reported carry-over rate reported for blood culture samples purified using the IT 1-2-3 SWIPE Sample purification kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Beth Lingenfelter
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Idaho Technology Inc.
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Salt Lake City, UT 84108

MAY 2 1 2007

Re: k071188
Trade/Device Name: JBAIDS Anthrax Detection System
Regulation Number: 21 CFR 866.2660
Regulation Name: Microorganism differentiation and identification device
Regulatory Class: Class II
Product Code: NHT
Dated: April 27, 2007
Received: April 30, 2007

Dear Ms. Lingenfelter:

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.

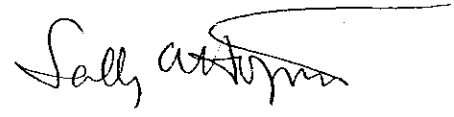
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
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Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____
Device Name: JBAIDS Anthrax Detection System
Indications for 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.

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:

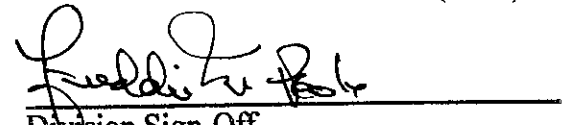
- The diagnosis of anthrax infection must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence, in addition to the identification of pXO1 and pXO2 targets either from cultures or from direct blood specimens.
- The assays have not been evaluated with blood from 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.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K071188