510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:

k151917

B. Purpose for Submission:

New instrument for use with the ARIES® HSV 1&2 Assay cleared under k151906

C. Manufacturer and Instrument Name:

Luminex Corporation, ARIES® System

D. Type of Test or Tests Performed:

Nucleic-acid amplification testing

E. System Descriptions:

1. Device Description:

The ARIES® System is a clinical multiplex test system that automates and integrates extraction of nucleic acid from a clinical sample, performs real -time PCR, and measuring and sorting multiple signals generated in an in vitro diagnostic assay. The instrument system is used with specific IVD assays to measure multiple analytes. The device includes a signal reader unit, raw data storage mechanisms, data acquisition software and software to process detected signals. The ARIES® System is for in vitro diagnostic use by trained laboratory professionals in a controlled laboratory environment and is not intended for patient contact.

The ARIES® System consists of the following;

- a bench top instrument with two separate modules each with a magazine rack to accommodate six disposable single-use assay cassettes
- methods for manipulating sample and reagent movement within the cassette
- heaters for lysis, elution and nucleic acid amplification
- 6 optical channels
- fluorometer for real-time PCR fluorescence detection and melt analysis
- methods for thermal and optical calibration
- software for running and analyzing IVD assays

2. Principles of Operation:

a. Device Features Controlled by Software:

The ARIES® SYSTEM instrument uses the ARIES® Software 1.0 software and the ARIES® Assay Protocol file for data acquisition, analysis, and reporting.

The ARIES® instrument software is installed on the embedded PC and controls the two modules housed in the instrument. The ARIES® Instrument is a Real Time PCR Instrument. The ARIES® instrument software provides the interface between the ARIES® Software 1.0 and the ARIES® system hardware. The ARIES® system software communicates to the instrument software to manage operations of the system, including manipulation of sample and reagent movement within the cassette, control of heaters for lysis, elution and nucleic acid amplification, controlling the fluorimeter for real-time PCR bulk fluorescence detection and melt analysis, controlling thermal and optical calibration and data analysis for IVD assays run on the system.

The ARIES® Software 1.0 software is installed in an embedded computer and provides the graphical user interface (GUI) application that is intended to be the end-user interface to the ARIES® instrument. The ARIES® Software 1.0 software is responsible for providing the environment in which an end-user runs and reports assays, administers, maintains, and sets default settings for the system.

The ARIES® Assay Protocol Software is a framework that allows running assays and generating reports on an ARIES® instrument. The ARIES® Assay Protocol Software is contained within an assay protocol template. This template is a read-only type of assay protocol file that contains a specific script, data reduction, assay editor tool, and reports, and default assay parameters and blank call logic. The ARIES® Assay Protocol file that is generated contains assay logic (rules that specify clinical outcomes), data reduction runtime files (DLL), and assay configuration parameters (script parameters that control the instrument for running a sample in a cassette and data reduction algorithm parameters).

b. Operational Environment (Off-the-Shelf Software):

The ARIES® Software 1.0 software uses some commercial off-the-shelf software components. The sponsor provided detailed documentation for the OTS used, including validation, for both the ARIES® Software 1.0 software and the ARIES® Assay Protocol Software.

For the ARIES® Assay Protocol Software used by Luminex, the recommended configuration for each computer is:

- Windows 7 Professional SP1 (US English, 32 bit or 64 bit)
- 2.8 GHz Intel Dual Core (or higher)
- 4 Gb RAM (or higher)
- 160 GB hard drive (or higher)

The programming language used to develop the ARIES® Software 1.0 software was

Microsoft Visual C#. Instrument control software was written in a combination and C# and C++.

3. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes ___x_____ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes _____ or No ___x_____

4. Specimen Identification:

   A barcode reader may be used for entry of sample IDs, or they may be entered manually.

5. Specimen Sampling and Handling:

   Samples are manually prepared according to assay manufacturer's suggestions and are transferred to an assay specific cassette for analysis.

6. Calibration:

   Calibration is performed by Luminex service personnel using ARIES® System Verification Cassettes.

7. Quality Control:

   Each ARIES® assay cassette includes a Sample Process Control (SPC). The SPC has a known melting temperature (Tm) range and cycle threshold (Ct) range. Each time an assay is run, the system measures the temperature and fluorescence intensity of the SPC control to ensure the thermal and optical subsystems have remained in calibration.

8. Software:

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

   Yes_____x___ or No_____

F. Regulatory Information:

1. Regulation section:

   21 CFR 862.2570 Instrumentation for clinical multiplex test systems

2. Classification:

   Class II (special controls)

3 Product code:

   OOI – Real-time nucleic acid amplification

4. Panel:

   Chemistry (75)

G. Intended Use:

1. Indication(s) for Use:

   The Luminex ARIES® System is an in vitro diagnostic (IVD) platform that performs nucleic acid based tests in clinical laboratories. The Luminex ARIES® System is capable of automated extraction and purification of nucleic acids from multiple sample types as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR.

2. Special Conditions for Use Statement(s):

   For prescription use only.

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

   BD Diagnostics (Becton, Dickinson and Company), BD MAX System
   K111860

2. Comparison with Predicate Device:

Similarities		
Item	**New Device: Luminex ARIES® System**	**Predicate Device: BD Max System (k111860)**
Intended Use	The Luminex ARIES® System is an in vitro	Same

Similarities		
Item	**New Device: Luminex ARIES® System**	**Predicate Device: BD Max System (k111860)**
	diagnostic (IVD) platform that performs nucleic acid based tests in clinical laboratories. The Luminex ARIES® System is capable of automated extraction and purification of nucleic acids from multiple sample types as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based PCR.	
Sample Preparation Method	Automated nucleic acid lysis and extraction by the ARIES® system	Same
Assay Format	Amplification: Real Time PCR Detection: Fluorgenic	Same
Interpretation of Test Results	Automated (Diagnostic software of Luminex ARIES® System)	Same

Differences		
Item	**New Device: Luminex ARIES® System**	**Predicate Device: BD Max System (k111860)**
Fluidics	Self-contained	Manual sample preparation
Assay Cartridge	• Cartridge is closed to the environment • Single Use	• Reagent strips are open to the environment • Can be used twice
Fluorescence Channels	Six (6) channels	Five (5) channels
Software	Software resides on the ARIES® System	Software resides on an all-in-one computer

I. Special Control/Guidance Document Referenced (if applicable):

- IEC60825 – Safety of laser products, 2nd edition, 2007
- IEC62304, - Medical Device Software – Software Life Cycle Processes, 2006
- ISO 14971 – Medical Devices – Applications of Risk Management, 2007
- ISO15223-1 – Medical Devices – Symbols to be used with Medical Device Labels, Labelling, and Information to be Supplied, 2007

J. Performance Characteristics*:*

1. Analytical Performance:

   Performance for the ARIES® System was established in the clearance of the assay, the ARIES® HSV1&2 Assay (*k151906*).

   a. Accuracy:

   See *k151906*

   b. Precision/Reproducibility:

   See *k151906*

   c. Linearity:

   See *k151906*

   d. Carryover:

   See *k151906*

   e. Interfering Substances:

   See *k151906*

2. Other Supportive Instrument Performance Data Not Covered Above:

   Not applicable

K. Proposed Labeling:

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

L. Conclusion:

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