

SPECIAL 510(k): Device Modification
OIR Decision Memorandum

To: THE FILE

RE: K161495 - Luminex ARIES® System

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:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.
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 **MODIFICATIONS**, 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 modifications to the ARIES System to produce the ARIES M1 System with a reduced throughput. The ARIES System has the capacity to process up to 12 assays at a given time and the ARIES M1 System (modified device) will have the capacity to process up to 6 assays at a given time to address the needs of lower throughput laboratories.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and software is shown in the table below:

Device & Predicate Device:	<u>K161495</u>	<u>K160517</u> (Predicate)
General Device Characteristics		
Indications For Use	The Luminex® ARIES® M1 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.	The Luminex® ARIES® System is an in vitro diagnostic (IVD) platform that performs nucleic acid based tests in clinical laboratories. The Luminex ARIES M1 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	Same	Automated nucleic acid lysis and extraction by the ARIES System
Assay Format	Same	Amplification: Real Time PCR Detection: Fluorogenic

Device & Predicate Device:	<u>K161495</u>	<u>K160517</u> (Predicate)
Assay Controls	Same	Sample Processing Control (SPC)
Test Results Interpretation	Same	Automated (ARIES Software)
# of Assay Processing Modules	One assay processing module	Two (up to 12 cassette capacity). NOTE: Assay processing modules are interchangeable between systems
Hardware User Interface	Chassis sized to fit one assay processing module and a 12.1" LCD touchscreen	Chassis sized to fit two assay processing modules and a large touchscreen
Software User Interface	Chassis sized to fit one assay processing module and a 12.1" LCD touchscreen	Scaled to fit large ARIES System touchscreen

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

Risk analysis was performed to identify risks, their possible causes, and appropriate control mechanisms. The risk analysis identified no additional hazards, no additional causes, and no required additional controls.

The following studies were performed to validate the modified ARIES System and ensure the design outputs met the design input requirements:

- One study focused on user experience when interfacing with the ARIES M1 System. The study consisted of three operators executing a prescribed protocol on three separate ARIES M1 Systems in a user-simulated environment and completing a survey of their use experience. The study concluded that user needs were met when the ARIES M1 System was run in a user-simulated environment.
 - Precision and method comparison testing was performed by testing two lots of ARIES HSV 1&2 Assay Cassettes on four ARIES instruments (three M6V1 instruments (new) and one M12V6 instrument (old)) with two operators across 10 days with a total of 809 replicates. The panel used in this study was prepared with a moderate positive and low positive independently for HSV-1 and HSV-2 as well as a negative sample. The results of the precision and method comparison studies demonstrate 100% agreement between all 809 replicates tested by both operators across four ARIES instruments, three ARIES M1 Systems and one ARIES System.
 - Further, the precision in T_m (melting temperature) on the ARIES M1 System was evaluated. The standard deviation in adjusted T_m for HSV-1 moderate positive and HSV-1 low positive samples on each ARIES M1 System was 0.2. The standard deviation in adjusted T_m for HSV-2 moderate positive and HSV-2 low positive samples on each ARIES M1 System was 0.2, and the standard deviation in SPC T_m for HSV-1 and HSV-2 negative samples for each ARIES M1 System was ≤0.3.
6. 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 modifications 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 device.