

SPECIAL 510(k): Device Modification  
OIR Decision Summary

To: THE FILE

RE: DOCUMENT NUMBER K160517

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II device requiring 510(k). The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device:  
ARIES<sup>®</sup> System (K151917) cleared with the ARIES<sup>®</sup> HSV 1&2 Assay (K151906)
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 and package labeling.

Submitter states in the submission that the intended use of the modified device has not changed from its predicate. The intended use in the labeling is the same.

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**.

The latest modifications to be submitted are for the:

- a. Addition of a new software functionality to the ARIES<sup>®</sup> System. The ARIES<sup>®</sup> System previously cleared in K151917 had the ability to interface with SYNCT Software (optional software); however SYNCT was not available at the time. This added capability to the ARIES<sup>®</sup> System gives users the ability to manage their test data with SYNCT. The SYNCT Software is a desktop application that can be utilized by an end-user on a standalone computer, providing users the ability to operate general functions such as Order Management, with or without a Laboratory Information System (LIS), viewing test results, reviewing and preparing test reports, performing software administrative functions, and providing security control for permitted functions.
  - b. Modification to allow the ARIES<sup>®</sup> System to function as a stand-alone clinical sample concentrator.
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.

<b>Similarities</b>		
<b>Item</b>	<b>Predicate Device ARIES<sup>®</sup> System (K151917)</b>	<b>Modified Device: ARIES<sup>®</sup> System (K160517)</b>
<i>Intended Use</i>	The Luminex ARIES <sup>®</sup> System is an in vitro diagnostic (IVD) platform that performs nucleic acid based tests in clinical laboratories. The Luminex ARIES <sup>®</sup> 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.	Same
<i>Sample Preparation Procedure</i>	Automated nucleic acid lysis and extraction by the ARIES <sup>®</sup>	Same

	System	
<i>Amplification Technology</i>	Real Time PCR	Same
<i>Assay Controls</i>	Sample Processing Control (SPC)	Same
<i>Test Interpretation</i>	Automated (Diagnostic software of Luminex ARIES <sup>®</sup> System)	Same
<i>Assay Cartridge</i>	Cartridge is closed to the environment; Single Use	Same
<b>Differences</b>		
<b>Item</b>	<b>Predicate Device ARIES<sup>®</sup> System (K151917)</b>	<b>Modified Device: ARIES<sup>®</sup> System (K160517)</b>
<i>Software</i>	Ability to interface with SYNCT software–SYNCT not yet available	Ability to interface with SYNCT software–SYNCT software available

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.

Submitter states in the submission that the ARIES<sup>®</sup> System device is not being changed. Similar to the risk management activities (traceability of hazards, risk evaluation, implementation/verification of risk controls) for the ARIES<sup>®</sup> System cleared in K151917, the final assessment indicates that the residual risks are at an acceptable level.

- 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.

Verification and Validation studies of SYNCT Software version 1.1 update 1 were conducted to verify that none of the IVD functions (for NxTAG and ARIES<sup>®</sup> assays/workflow) were adversely affected by the non-IVD functions, i.e. UDP module.

6) Conclusion

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 demonstrates 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.