

**SPECIAL 510(k): Device Modification  
OIR Review Memorandum**

**To:** THE FILE

**RE:** DOCUMENT NUMBER K141458

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):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.  
 Proprietary Name: Simplexa™ HSV 1 & 2 Direct and Simplexa™ HSV 1 & 2 Positive Control Pack  
 510(k) number: K133621
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED**. There is a change in labeling which is described below.
3. A description of the device **MODIFICATION(S)**, in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.  
**This change was for:**
  - a) An update to the already cleared 3M Integrated Cyler Studio system to version 6.0 that addresses the software vulnerability in version 5.0 that allowed end-users to manually enter dye spectra for the dyes used in IVD assays (software incident #10042). The system was already cleared under K100148, K102314, and K120413. Version 5.0 of the software was the most recent version cleared in K133621.
  - b) Modifications to the labeling to reflect the change in the software, remove warning and limitations related to the software vulnerability concern in the previous software version 5.0. Finally, the labeling was separated to generate a separate labeling for the Controls, this resulted in removing the indications for use, and all of the labeling information specific for the controls from the device labeling to a separate labeling for the Simplexa™ HSV 1 & 2 Positive Control Pack. The indications for use and performance information for the Simplexa™ HSV 1 & 2 Positive Control Pack were reviewed in the original 510(k) K133621.
4. **Comparison Information** (similarities and differences) to the legally marketed predicate device

Feature	Predicate device	Modified Device
Intended Use/ Indications for Use	The Focus Diagnostics Simplexa™ HSV 1 & 2 Direct is intended for use on the 3M Integrated Cyler instrument for the qualitative detection and differentiation of HSV-1 and HSV-2 DNA in cerebrospinal fluid (CSF) samples from patients suspected of Herpes Simplex Virus (HSV) infections of the central nervous system (CNS). This test is intended as an aid in the diagnosis of HSV-1 and HSV-2 infections of	Same except the intended use for the Simplexa Positive Control Pack was separated to a separate labeling

	<p>the CNS.</p> <p>Negative results do not preclude HSV-1 or HSV-2 infection and should not be used as the sole basis for treatment or other patient management decisions.</p> <p>The assay is not intended for use as a donor screening test. The assay is for professional use only.</p> <p>The Positive Control is intended to be used as a control with the Simplexa™ HSV 1 &amp; 2 Direct. This control is not intended for use with other assays or systems.</p>	
Technology	Real-time PCR that enables the direct amplification, detection and differentiation of HSV-1 and/or HSV-2 DNA from unprocessed CSF specimens without nucleic acid extraction.	Same

Differences

Feature	Predicate device	Modified Device
Integrated Cyler Studio Software	Integrated Cyler Studio Software version 5.0 or higher.	<p>Integrated Cyler Studio Software version 6.0 or higher.</p> <p>Software changes were made to restrict manual modification of the spectral matrix and to resolve anomalies.</p>

5. A **Design Control Activities Summary** which includes:

Design controls in accordance with §21 CFR 820.30 were conducted to modify the device.

a) Risk Analysis:

A Failure Modes and Effects Analysis was used to facilitate, capture and quantify potential impacts of the software configuration, 3M Integrated Cyler Studio Software Release 6.0 PCR13-021 running on Windows XP (SP3) professional and Windows 7 operating systems. The changes

made to the Integrated Cyclor Studio software version 6.0 were assessed using risk management. Risk management involved analysis of the characteristics of Integrated Cyclor Studio software version 6.0, the characteristics of the process that might create a hazard with the Integrated Cyclor Studio software version 6.0, and the possible hazards associated with the use of the Integrated Cyclor Studio software version 6.0. The risk management process consisted of risk analysis, risk evaluation, risk control, risk benefit and evaluation of residual risk acceptability. A thorough review was performed to ensure all risk control measures identified from all hazardous situations were considered to assess if previously estimated risks were affected. After risk control measures were applied, any residual risk(s) were evaluated. Acceptability of overall residual risk took into consideration whether anticipated medical benefits outweighed the overall residual risks of a product placed on the market for its intended use.

b) Verification and Validation activities:

Verification activities for the Integrated Cyclor Studio software version 6.0 included development of verification test plans with defined acceptance criteria (design inputs), conducting and documenting verification testing and review of the verification results as they compared to the verification test plans predetermined acceptance criteria (design outputs). Integrated Cyclor Studio software version 6.0 was validated in a similar fashion with the development of validation test plans with defined acceptance criteria (design inputs), conducting and documenting validation testing and review of the validation results as they compared to the validation test plans predetermined acceptance criteria (design outputs). The results of verification and validation of Integrated Cyclor Studio software version 6.0 show the results met the predetermined acceptance criteria. The results of assays ran with the Integrated Cyclor Studio software version 6.0 demonstrate that the results obtained with the previously released versions of Integrated Cyclor Studio software were equivalent to the results obtained using Integrated Cyclor Studio software version 6.0.

c) Declaration of Conformity

A declaration of conformity to design controls in accordance to §21 CFR 820.30 is included in the K141458 Simplexa™ HSV 1 & 2 Direct REF MOL2150 and Simplexa™ HSV 1 & 2 Positive Control Pack REF MOL2160 Special 510(k) submission. The declaration of conformity was signed by the individuals responsible for the activities.

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 device.