JUL 0 1 2014 **K141458**

510(k) Summary

Simplexa™ HSV 1 & 2 Direct REF MOL2150
Simplexa™ HSV 1 & 2 Positive Control Pack REF MOL2160
Prepared Date: July 1, 2014

Applicant	Focus Diagnostics, Inc. 11331 Valley View Street Cypress, California 90630 USA
Establishment Registration No.	2023365
Contact Person	Sharon Young tel 562.240.6680 fax 562.240.6529 syoung@focusdx.com
Summary Date	July 1, 2014
Proprietary Name	Simplexa™ HSV 1 & 2 Direct and Simplexa™ HSV 1 & 2 Positive Control Pack
Generic Name	HSV-1 & HSV-2 DNA detection
Classification	Class II
US Product Code	PGH - HSV-1 and HSV-2 CNS Nucleic-Acid based panel
Regulation Number	§21 CFR 866.3307
Predicate Device	K133621

INTENDED USE

The Focus Diagnostics Simplexa™ HSV 1 & 2 Direct is intended for use on the 3M Integrated Cycler 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 the CNS.

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.

The assay is not intended for use as a donor screening test. The assay is for professional use only.

INTENDED USE

The Simplexa™ HSV 1 & 2 Positive Control Pack is intended to be used as a control with the Simplexa™ HSV 1 & 2 Direct kit. This control is not intended for use with other assays or systems.

DEVICE DESCRIPTION

The Simplexa™ HSV 1 & 2 Direct assay system is a 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. The system consists of the Simplexa™ HSV 1 & 2 Direct assay, the 3M Integrated Cycler (with 3M Integrated Cycler Studio Software), the Direct Amplification Disc and associated accessories.

In the Simplexa™ HSV 1 & 2 Direct assay, bi-functional fluorescent probe-primers are used together with corresponding reverse primers to amplify HSV-1, HSV-2 and internal control targets. Well conserved regions of the HSV-1 and HSV-2 DNA polymerase genes are targeted to identify HSV-1 and HSV-2 DNA respectively in the specimen. An internal control is used to detect PCR failure and/or inhibition.

Simplexa™ HSV 1 & 2 Direct REF MOL2150

Kit Description

Component Name	REF	EC SYMBOL ON LABEL		Abbreviated Name	Cap Color	Number of Vials	Reactions per Vial/Kit	Volume per Vial
Simplexa™ HSV 1 & 2 Direct Reaction Mix	**MOL2151**	**REAG**	**A**	**RM**	Brown	24	1/24	50 µL

Component Description

Kit Component	Contents
Simplexa™ HSV 1 & 2 Direct Reaction Mix (RM)	DNA polymerase, buffer, dNTPs, template DNA (Internal Control) dye-labeled fluorescent probe-primers specific for detection of HSV-1 and/or HSV-2 and for the DNA Internal Control.

Target	Probe Fluorophore (Dye)	Excitation (nm)	Emission (nm)	Targeted Gene
HSV-1	CFR610	590	610	HSV-1 DNA polymerase
HSV-2	FAM	495	520	HSV-2 DNA polymerase
DNA Internal Control	Q670	644	670	NA

Simplexa™ HSV 1 & 2 Kit Barcode Card	Assay specific parameters.

Simplexa™ HSV 1 & 2 Positive Control Pack REF MOL2160

Product Description

Component Name	REF	Description	Cap Color	Number of Vials	Reactions per Vial/Kit	Volume per Vial
Simplexa™ HSV 1 & 2 Direct Positive Control	**MOL2161**	Inactivated HSV-1 Virus, Inactivated HSV-2 Virus	Red	10	1/10	100 µL

MATERIALS SUPPLIED SEPARATLY

1. Direct Amplification Disc Kit (REF MOL1455)
   a. Direct Amplification Discs for use on the 3M Integrated Cycler.

COMPARISON TO PREDICATE

Similarities

Feature	Predicate K133621	Modified Device K141458
Intended Use	The Focus Diagnostics Simplexa™ HSV 1 & 2 Direct is intended for use on the 3M Integrated Cycler 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 the CNS. 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. The assay is not intended for use as a donor screening test. The assay is for professional use only. The Positive Control is intended to be used as a control with the Simplexa™ HSV 1 & 2 Direct. This control is not intended for use with other assays or systems.	Same
Technology	The Simplexa™ HSV 1 & 2 Direct assay system is a 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
Analyte	HSV-1 & HSV-2 DNA.	Same
Assay Type	Qualitative.	Same

Differences

	Predicate	Modified Device
Integrated Cycler Studio Software	Integrated Cycler Studio Software version 5.0 or higher.	Integrated Cycler Studio Software version 6.0 or higher. Software changes were made to restrict manual modification of the spectral matrix and to resolve anomalies.

SUMMARY OF DESIGN CONTROL ACTIVITIES

Design controls in accordance with §21 CFR 820.30 were conducted to modify the device. Verification activities for the Integrated Cycler 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 Cycler 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 Cycler Studio software version 6.0 show the results met the predetermined acceptance criteria. The results of assays ran with the Integrated Cycler Studio software version 6.0 demonstrate that the results obtained with the previously released versions of Integrated Cycler Studio software were equivalent to the results obtained using Integrated Cycler Studio software version 6.0.

The changes made to the Integrated Cycler Studio software version 6.0 were assessed using risk management. Risk management involved analysis of the characteristics of Integrated Cycler Studio software version 6.0, the characteristics of the process that might create a hazard with the Integrated Cycler Studio software version 6.0, and the possible hazards associated with the use of the Integrated Cycler 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.

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

FOCUS DIAGNOSTICS
SHARON YOUNG
11331 VALLEY VIEW STREET
CYPRESS, CA 90630

July 1, 2014

Re: K141458
Trade/Device Name: Simplexa™ HSV 1 & 2 Direct and
Simplexa™ HSV 1 & 2 Positive Control Pack
Regulation Number: 21 CFR 866.3307
Regulation Name: Herpes simplex virus nucleic acid-based assay for central nervous system infections
Regulatory Class: II
Product Code: PGH
Dated: May 29, 2014
Received: June 2, 2014

Dear Ms. Young:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Stephen J. Lovell -S for

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141458

Device Name
Simplexa™ HSV 1 & 2 Direct
Simplexa™ HSV 1 & 2 Positive Control Pack

Indications for Use *(Describe)*

Simplexa™ HSV 1 & 2 Direct (MOL2150)
The Focus Diagnostics Simplexa™ HSV 1 & 2 Direct is intended for use on the 3M Integrated Cycler 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 the CNS.

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.

The assay is not intended for use as a donor screening test. The assay is for professional use only.

Simplexa™ HSV 1 & 2 Positive Control Pack (MOL2160)
The Simplexa™ HSV 1 & 2 Positive Control Pack is intended to be used as a control with the Simplexa™ HSV 1 & 2 Direct kit. This control is not intended for use with other assays or systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Stephen J. Lovell -S
2014.07.01 14:37:03 -04'00'

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