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, Inc.
Irene Guzman
Senior Regulatory Affairs Specialist
11331 Valley View Street
Cypress, CA 90630

September 21, 2015

Re: K152408
Trade/Device Name: Simplexa™ Flu A/B & RSV Direct and Simplexa™ Flu A/B & RSV Positive Control Pack
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory viral panel multiplex nucleic acid assay
Regulatory Class: II
Product Code: OCC
Dated: August 24, 2015
Received: August 25, 2015

Dear Ms. Guzman:

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,

Tamara V. Feldblyum - S for

Uwe Scherf, 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)*
K152408

Device Name
Simplexa™ Flu A/B & RSV Direct REF MOL2650 and Simplexa™ Flu A/B & RSV Positive Control Pack REF MOL2660

Indications for Use *(Describe)*

Simplexa™ Flu A/B & RSV Direct REF MOL2650

The Focus Diagnostics Simplexa™ Flu A/B & RSV Direct assay is intended for use on the 3M Integrated Cycler instrument for the in vitro qualitative detection and differentiation of influenza A virus, influenza B virus, and respiratory syncytial virus (RSV) RNA in nasopharyngeal swabs (NPS) from human patients with signs and symptoms of respiratory tract infection in conjunction with clinical and epidemiological risk factors. This test is intended for use as an aid in the differential diagnosis of influenza A, influenza B, and RSV viral infections in humans and is not intended to detect influenza C.

Negative results do not preclude influenza virus or RSV infection and should not be used as the sole basis for treatment or other patient management decisions.

Performance characteristics for influenza A were established with clinical specimens collected during the 2010/2011 influenza season when 2009 H1N1 influenza and H3N2 were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to the state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Simplexa™ Flu A/B & RSV Positive Control Pack REF MOL2660

Focus Diagnostics' Simplexa™ Flu A/B & RSV Positive Control Pack is intended to be used as a control with the Simplexa™ Flu A/B & RSV 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Applicant	Focus Diagnostics, Inc. 11331 Valley View Street Cypress, California 90630 USA
Establishment Registration No.	2023365
Contact Person	Irene M. Guzman tel 562.240.6133 fax 562.240.6530 iguzman@focusdx.com
Summary Date	August 24, 2015
Proprietary Name	Simplexa™ Flu A/B & RSV Direct and Simplexa™ Flu A/B & RSV Positive Control Pack
Generic Name	Respiratory viral panel nucleic acid
Classification	Class II
US Product Code	OCC - Respiratory Viral Panel Nucleic Acid Assay System OOI - Real Time Nucleic Acid Amplification System
Regulation Number	21 CFR § 866.3980
Predicate Device	K142365 Simplexa™ Flu A/B & RSV Direct and Simplexa™ Flu A/B & RSV Positive Control Pack

510(k) SUBMISSION PURPOSE

The purpose of this Special 510(k) is to expand the analytical reactivity to add 53 additional strains.

INTENDED USE

Simplexa™ Flu A/B & RSV Direct REF MOL2650

The Focus Diagnostics Simplexa™ Flu A/B & RSV Direct assay is intended for use on the 3M Integrated Cycler instrument for the *in vitro* qualitative detection and differentiation of influenza A virus, influenza B virus, and respiratory syncytial virus (RSV) RNA in nasopharyngeal swabs (NPS) from human patients with signs and symptoms of respiratory tract infection in conjunction with clinical and epidemiological risk factors. This test is intended for use as an aid in the differential diagnosis of influenza A, influenza B, and RSV viral infections in humans and is not intended to detect influenza C.

Negative results do not preclude influenza virus or RSV infection and should not be used as the sole basis for treatment or other patient management decisions.

Performance characteristics for influenza A were established with clinical specimens collected during the 2010/2011 influenza season when 2009 H1N1 influenza and H3N2 were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to the state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Simplexa™ Flu A/B & RSV Positive Control Pack REF MOL2660

Focus Diagnostics' Simplexa™ Flu A/B & RSV Positive Control Pack is intended to be used as a control with the Simplexa™ Flu A/B & RSV Direct kit. This control is not intended for use with other assays or systems.

DEVICE DESCRIPTION

The Simplexa™ Flu A/B & RSV Direct assay system is a real-time RT-PCR system that enables the direct amplification, detection and differentiation of human influenza A (Flu A) virus RNA, human influenza B (Flu B) virus RNA and RSV RNA from unprocessed nasopharyngeal swabs that have not undergone nucleic acid extraction. The system consists of the Simplexa™ Flu A/B & RSV Direct assay, the 3M Integrated Cycler (with Integrated Cycler Studio Software), the Direct Amplification Disc and associated accessories.

In the Simplexa™ Flu A/B & RSV Direct assay, bi-functional fluorescent probe-primers are used together with corresponding reverse primers to amplify Flu A, Flu B, RSV and internal control RNA. The assay provides three results; conserved regions of influenza A viruses (matrix gene), influenza B viruses (matrix gene) and RSV (M gene) are targeted to identify these viruses in the specimen. An RNA internal control is used to detect RT-PCR failure and/or inhibition.

COMPARISON TO PREDICATE

Similarities

Feature	Predicate K142365	Proposed Product
Intended Use	**Simplexa™ Flu A/B & RSV Direct REF MOL2650** The Focus Diagnostics Simplexa™ Flu A/B & RSV Direct assay is intended for use on the 3M Integrated Cycler instrument for the *in vitro* qualitative detection and differentiation of influenza A virus, influenza B virus, and respiratory syncytial virus (RSV) RNA in nasopharyngeal swabs (NPS) from human patients with signs and symptoms of respiratory tract infection in conjunction with clinical and epidemiological risk factors. This test is intended for use as an aid in the differential diagnosis of influenza A, influenza B, and RSV viral infections in humans and is not intended to detect influenza C. Negative results do not preclude influenza virus or RSV infection and should not be used as the sole basis for treatment or other patient management decisions. Performance characteristics for influenza A were established with clinical specimens collected during the 2010/2011 influenza season when 2009 H1N1 influenza and H3N2 were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary. If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to the state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens. **Simplexa™ Flu A/B & RSV Positive Control Pack REF MOL2660** Focus Diagnostics' Simplexa™ Flu A/B & RSV Positive Control Pack is intended to be used as a control with the Simplexa™ Flu A/B & RSV Direct kit. This control is not intended for use with other assays or systems.	Same

Feature	Predicate K142365	Proposed Product
Technology	The Simplexa™ Flu A/B & RSV Direct assay system is a real-time RT-PCR system that enables the direct amplification, detection and differentiation of human influenza A (Flu A) virus RNA, human influenza B (Flu B) virus RNA and RSV RNA from unprocessed nasopharyngeal swabs that have not undergone nucleic acid extraction. The system consists of the Simplexa™ Flu A/B & RSV Direct assay, the 3M Integrated Cycler (with Integrated Cycler Studio Software), the Direct Amplification Disc and associated accessories. In the Simplexa™ Flu A/B & RSV Direct assay, bi-functional fluorescent probe-primers are used together with corresponding reverse primers to amplify Flu A, Flu B, RSV and internal control RNA. The assay provides three results; conserved regions of influenza A viruses (matrix gene), influenza B viruses (matrix gene) and RSV (M gene) are targeted to identify these viruses in the specimen. An RNA internal control is used to detect RT-PCR failure and/or inhibition.	Same
Instrument	3M Integrated Cycler	Same
Specimen Type	Unprocessed nasopharyngeal swabs that have not undergone nucleic acid extraction	Same
Influenza A Viral Target	Well conserved region of the matrix gene	Same
Influenza B Viral Target	Well conserved region of the matrix gene	Same
Respiratory Syncytial Viral Target	M gene	Same
Assay Type	Qualitative	Same

Differences

	Subject Device
Add 53 additional influenza strains to Analytical Reactivity. **Thirty-seven (37) Strains of Influenza A** **Nine (9) Strains of Influenza B** **Seven (7) strains of RSV**	Fifty (53) additional influenza strains were tested and included in the analytical reactivity table. **Influenza A (37 Strains)** (H1N1) pdm09 - A/California/4/2009, (H1N1) pdm09 - A/Massachusetts/15/2013, (H1N1) pdm09 - A/Mexico/4108/2009, (H1N1) pdm09 - A/New York/18/2009, H1N1 - A/Hawaii/15/2001, H2N2 - A/Japan/305/57, H3N2 - A/California/02/2014, H3N2 - A/New York/55/2004, H3N2 - A/Rhode Island/01/2010, H3N2 - A/Santiago/7981/2006, H3N2 - A/Switzerland/9715293/2013, H5N1 - A/Egypt/N03072/2010(H5N1)-PR8-IDCDC-RG29, H5N1 - A/Hubei/1/2010(H5N1)-PR8-IDCDC-RG30, H5N1 - A/India/NIV/2006(H5N1)-PR8-IBCDC-RG7, H9N2 - A/Hong Kong/33982/2009(H9N2)-PR8-IDCDC_RG26 Avian Influenza A Viruses H1N3 - A/shorebird/Delaware Bay/211/1994, H1N8 - A/red knot/Delaware Bay/240/1994, H3N6 - A/redhead/Alberta/192/2002, H3N8 - A/duck/Chabarovsk/1610/1972, H4N6 - A/duck/Czechoslovakia/1956, H4N6 - A/red knot/Delaware/541/1988, H5N1 - A/chicken/Vietnam/NCVD-016/2008(H5N1)-PR8-IDCDC-RG12, H5N2 - A/pheasant/New Jersey/1355/1998(H5N2)-PR8-IBCDC-4, H6N2 - A/turkey/Massachusetts/3740/1965, H7N2 - A/turkey/Virginia/4529/2002 (H7N2)xPR8-IBCDC-5, H7N7 - A/mallard/Netherlands/12/2000(H7N7)/PR8-IBCDC-1, H10N1 - A/mallard/Wisconsin/4230/2009, H10N7 - A/chicken/Germany/N/49, H10N7 - A/mallard/Illinois/10OS4334/2010, H10N8 - A/quail/Italy/1117/1965, H11N9 - A/American green-winged teal/Mississippi/300/2010, H12N5 - A/mallard/Wisconsin/4218/2009, H12N6 -A/duck/Wisconsin/480/1979, H13N6 - A/black-legged kittiwake/Quebec/02838-1/2009, H16N3 - A/shorebird/Delaware/172/2006, Swine Influenza A Viruses H1N2 - A/swine/Ohio/09SW1477/2009, H3N2 - A/swine/Ohio/09SW83E/2009 **Influenza B (9 Strains)** Victoria - B/Brisbane/33/2008, Yamagata - B/Christchurch/33/2004, Yamagata-B/Guangdong-Liwan/1133/2014,Yamagata - B/Massachusetts/2/2012, Victoria - B/Nevada/03/2011, Yamagata - B/Phuket/3073/2013, Victoria - B/Texas/02/2013, Yamagata - B/Utah/9/2014, Victoria - B/Victoria/304/2006 **RSV (7 Strains)** ATCC-2012-10, A 1997/12-35, A 1998/12-21, A 1998/3-2, A 2000/3-4, A 2001/2-20, A 2001/3-12

CLINICAL AGREEMENT – PROSPECTIVE STUDY

No Change. Refer to K142365.

CLINICAL AGREEMENT – RETROSPECTIVE STUDY

No Change. Refer to K142365.

REPRODUCIBILITY

No Change. Refer to K142365.

ANALYTICAL SENSITIVITY / LIMIT OF DETECTION

No Change. Refer to K142365.

ANALYTICAL REACTIVITY/ CROSS REACTIVITY

Analytical Reactivity - Simplexa™ Flu A/B & RSV Direct

Multiple strains of influenza A (H1, H2, H3, H5 and H9 subtypes), avian influenza A (H1, H3, H4, H5, H6, H7, H10, H11, H12, H13 and H16 subtypes), swine influenza A (H1 and H3 subtypes), influenza B (Victoria and Yamagata lineages) and RSV (A subtypes) were evaluated. The most recent strains and geographically diverse strains were chosen. Quantified viral material was spiked into negative swab matrix at a single dilution at the concentrations below. Each was assayed in triplicate. The Ct values obtained indicate all viral strains were detected at the concentrations tested.

Influenza A Viruses			
Subtype	**Organism**	**Concentration Tested**	**Result**
(H1N1) pdm09	A/California/4/2009	100 $TCID_{50}$/mL	Flu A Detected
(H1N1) pdm09	A/Massachusetts/15/2013	1000 $CEID_{50}$/mL[2]	Flu A Detected
(H1N1) pdm09	A/Mexico/4108/2009	100 $CEID_{50}$/mL[2]	Flu A Detected
(H1N1) pdm09	A/New York/18/2009	100 $CEID_{50}$/mL[2]	Flu A Detected
H1N1	A/Hawaii/15/2001	100 $CEID_{50}$/mL[2]	Flu A Detected
H2N2	A/Japan/305/57	3.26E-01 ng/µL[3]	Flu A Detected
H3N2	A/California/02/2014	100 $TCID_{50}$/mL	Flu A Detected
H3N2	A/New York/55/2004	100 $CEID_{50}$/mL[2]	Flu A Detected
H3N2	A/Rhode Island/01/2010	400 $CEID_{50}$/mL[2]	Flu A Detected
H3N2	A/Santiago/7981/2006	100 $CEID_{50}$/mL[2]	Flu A Detected
H3N2	A/Switzerland/9715293/2013	200 $CEID_{50}$/mL[2]	Flu A Detected
H5N1	A/Egypt/N03072/2010(H5N1)-PR8-IDCDC-RG29	1:100,000[4]	Flu A Detected
H5N1	A/Hubei/1/2010(H5N1)-PR8-IDCDC-RG30	1:100,000[4]	Flu A Detected
H5N1	A/India/NIV/2006(H5N1)-PR8-IBCDC-RG7	1:100,000[4]	Flu A Detected
H9N2	A/Hong Kong/33982/2009(H9N2)-PR8-IDCDC_RG26	100 $CEID_{50}$/mL[2]	Flu A Detected

[1]Infectious Units/mL
[2]$CEID_{50}$/mL: Chicken Embryo Infectious Dose
[3]1xTE was used for dilution. Japan/305/57 (H2N2) is purified RNA, not virus like the rest of the panel.
[4]Inactivated virus was diluted and tested
[5] EID_{50}/mL: Egg Infectious Dose

Avian Influenza A Viruses			
Subtype	**Organism**	**Concentration Tested**	**Result**
H1N3	A/shorebird/Delaware Bay/211/1994	100 $CEID_{50}$/mL[1]	Flu A Detected
H1N8	A/red knot/Delaware Bay/240/1994	200 $CEID_{50}$/mL[1]	Flu A Detected
H3N6	A/redhead/Alberta/192/2002	100 $CEID_{50}$/mL[1]	Flu A Detected
H3N8	A/duck/Chabarovsk/1610/1972	400 $CEID_{50}$/mL[1]	Flu A Detected
H4N6	A/duck/Czechoslovakia/1956	100 $CEID_{50}$/mL[1]	Flu A Detected
H4N6	A/red knot/Delaware/541/1988	100 $CEID_{50}$/mL[1]	Flu A Detected
H5N1	A/chicken/Vietnam/NCVD-016/2008(H5N1)-PR8-IDCDC-RG12	1:100,000[2]	Flu A Detected
H5N2	A/pheasant/New Jersey/1355/1998(H5N2)-PR8-IBCDC-4	1:100,000[2]	Flu A Detected

Avian Influenza A Viruses (Continued)			
Subtype	**Organism**	**Concentration Tested**	**Result**
H6N2	A/turkey/Massachusetts/3740/1965	200 $CEID_{50}$/mL[1]	Flu A Detected
H7N2	A/turkey/Virginia/4529/2002 (H7N2)xPR8-IBCDC-5	1:100,000[2]	Flu A Detected
H7N7	A/mallard/Netherlands/12/2000(H7N7)/PR8-IBCDC-1	1:100,000[2]	Flu A Detected
H10N1	A/mallard/Wisconsin/4230/2009	100 $CEID_{50}$/mL[1]	Flu A Detected
H10N7	A/chicken/Germany/N/49	100 $CEID_{50}$/mL[1]	Flu A Detected
H10N7	A/mallard/Illinois/10OS4334/2010	100 $CEID_{50}$/mL[1]	Flu A Detected
H10N8	A/quail/Italy/1117/1965	100 $CEID_{50}$/mL[1]	Flu A Detected
H11N9	A/American green-winged teal/Mississippi/300/2010	100 $CEID_{50}$/mL[1]	Flu A Detected
H12N5	A/mallard/Wisconsin/4218/2009	100 $CEID_{50}$/mL[1]	Flu A Detected
H12N6	A/duck/Wisconsin/480/1979	100 $CEID_{50}$/mL[1]	Flu A Detected
H13N6	A/black-legged kittiwake/Quebec/02838-1/2009	200 $CEID_{50}$/mL[1]	Flu A Detected
H16N3	A/shorebird/Delaware/172/2006	400 $CEID_{50}$/mL[1]	Flu A Detected

[1]$CEID_{50}$/mL: Chicken Embryo Infectious Dose

[2]Inactivated virus was diluted and tested

NOTE: Although this test has been shown to detect novel avian influenza A (H7N9) and H3N2v cultured viruses, the performance characteristics of this device with clinical specimens that are positive for novel avian influenza A (H7N9) and H3N2v influenza viruses have not been established.

Swine Influenza A Viruses			
Subtype	**Organism**	**Concentration Tested**	**Result**
H1N2	A/swine/Ohio/09SW1477/2009	100 $TCID_{50}$/mL	Flu A Detected
H3N2	A/swine/Ohio/09SW83E/2009	400 $CEID_{50}$/mL[1]	Flu A Detected

[1]$CEID_{50}$/mL: Chicken Embryo Infectious Dose

Influenza B Viruses			
Lineage	**Organism**	**Concentration Tested**	**Result**
Victoria	B/Brisbane/33/2008	20 $CEID_{50}$/mL[1]	Flu B Detected
Victoria	B/Nevada/03/2011	100 $CEID_{50}$/mL[1]	Flu B Detected
Victoria	B/Texas/02/2013	100 $TCID_{50}$/mL	Flu B Detected
Victoria	B/Victoria/304/2006	20 $CEID_{50}$/mL[1]	Flu B Detected
Yamagata	B/Christchurch/33/2004	100 $TCID_{50}$/mL	Flu B Detected
Yamagata	B/Guangdong-Liwan/1133/2014	400 $CEID_{50}$/mL[1]	Flu B Detected
Yamagata	B/Massachusetts/2/2012	100 IU/mL[2]	Flu B Detected
Yamagata	B/Phuket/3073/2013	100 $CEID_{50}$/mL[1]	Flu B Detected
Yamagata	B/Utah/9/2014	100 $CEID_{50}$/mL[1]	Flu B Detected

[1]$CEID_{50}$/mL: Chicken Embryo Infectious Dose

[2]Infectious Units/mL

RSV			
Subtype	**Organism**	**Concentration Tested**	**Result**
N/A	ATCC-2012-10	100 PFU/mL	RSV Detected
A	A 1997/12-35	100 $TCID_{50}$/mL	RSV Detected
A	A 1998/12-21	100 $TCID_{50}$/mL	RSV Detected
A	A 1998/3-2	100 $TCID_{50}$/mL	RSV Detected
A	A 2000/3-4	100 $TCID_{50}$/mL	RSV Detected
A	A 2001/2-20	100 $TCID_{50}$/mL	RSV Detected
A	A 2001/3-12	100 $TCID_{50}$/mL	RSV Detected

CROSS REACTIVITY (Analytical Specificity)

No Change. Refer to K142365.

INTERFERENCE

No Change. Refer to K142365.

COMPETITIVE INTERFERENCE

No Change. Refer to K142365.

INHIBITION BY OTHER MICROORGANISMS

No Change. Refer to K142365.

ADDITIONAL PERFORMANCE STUDIES

Please refer to the previously FDA cleared 510(k) K142365 for additional information.

CONCLUSION

Fifty-three strains met the established acceptance criteria and passed validation testing. Analytical Reactivity will be expanded to add 53 additional strains.