NOV 2 4 2010

Applicant	Focus Diagnostics, Inc. 11331 Valley View Street Cypress, California 90630 USA
Establishment Registration No.	2023365
Contact Person	Tara Viviani tel 714.822.2115 fax 714.822.3898 tviviani@focusdx.com
Summary Date	November 12, 2010
Proprietary Name	Simplexa™ Flu A/B & RSV
Generic Name	Respiratory Viral Panel
Classification	Class II, Special Controls
Predicate Devices	Prodesse, ProFlu+ Assay (K092500 , K081030, K073029)

Intended Use

The Focus Diagnostics Simplexa™ Flu A/B & RSV assay is intended for use on the 3M Integrated Cycler instrument for the in vitro qualitative detection and discrimination 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 during the 2010 influenza season when 2009 H1N1 influenza was the predominant influenza A virus 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 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.

Device Description

The test is a real-time RT-PCR amplification and detection system that utilizes a bi-functional fluorescent probe-primer for the detection and differentiation of human influenza A virus RNA, human influenza B virus RNA and respiratory syncytial virus RNA in nasopharyngeal swabs (NPS). The assay is composed of two principal steps: (1) extraction of RNA from patient specimens, (2) A bi-functional fluorescent probe-primer is used together with a reverse primer to amplify a specific target (for each analyte and the RNA internal control). 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 monitor the extraction process and to detect RT-PCR inhibition.

The 3M Integrated Cycler is a rapid real-time Polymerase Chain Reaction thermocycler used for the identification of nucleic acid from prepared biological samples. The instrument utilizes disk media to contain and to process samples. The instrument uses real time flourometric detection to identify targets within the sample wells. The instrument is controlled by an external computer running the Integrated Cycler Studio Software.

Predicate Device Information

Trade Name / Method	510(k) submitter	510(k) number	Decision Date	Panel	Product Code(s)
proFlu+	Prodesse	K092500, K081030, K073029	08/20/2009 05/02/2008 01/04/2008	Microbiology (83)	OCC

Comparison to Predicate

Item Name	Device Simplexa™ Flu A/B & RSV	Predicate ProFlu+
Intended Use	The Focus Diagnostics Simplexa™ Flu A/B & RSV assay is intended for use on the 3M Integrated Cycler instrument for the in vitro qualitative detection and discrimination 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 during the 2010 influenza season when 2009 H1N1 influenza was the predominant influenza A virus in circulation. When other influenza A viruses are	The ProFlu™+ Assay is a multiplex Real-Time PCR (RT-PCR) in vitro diagnostic test for the rapid and qualitative detection and discrimination of Influenza A Virus, Influenza B Virus, and Respiratory Syncytial Virus (RSV) nucleic acids isolated and purified from nasopharyngeal (NP) swab specimens obtained from symptomatic patients. This test is intended for use to 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 or RSV virus infection and should not be used as the sole basis for treatment or other management decisions. It is recommended that negative RSV results be confirmed by culture. Performance characteristics for Influenza A Virus were established when Influenza A/H3 and A/H1 were the predominant Influenza A viruses in circulation. When other Influenza A viruses are emerging, performance characteristics may vary.

Item Name	Device Simplexa™ Flu A/B & RSV	Predicate ProFlu+
	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 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.	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 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.
Assay Targets	Influenza A, Influenza B, RSV	Influenza A, Influenza B, RSV
Sample Types	NPS	NPS
Extraction Methods	Roche MagNA Pure LC Total Nucleic Acid Isolation Kit, Biomérieux NucliSENS easyMAG	Roche MagNA Pure LC Total Nucleic Acid Isolation Kit, Biomérieux NucliSENS easyMAG
Assay Methodology	PCR-based system for detecting the presence / absence of viral RNA in clinical specimens	PCR-based system for detecting the presence / absence of viral DNA/RNA in clinical specimens
Detection Techniques	Multiplex assay using different reporter dyes for each target.	Multiplex assay using different reporter dyes for each target.
Influenza A Viral Target	Well conserved region of the matrix gene	Matrix gene
Influenza B Viral Target	Well conserved region of the matrix gene	Non-structural NS1 and NS2
Respiratory Syncytial Viral Target	M gene	Polymerase

Reproducibility:

Three investigative sites assessed the device's inter-laboratory reproducibility and inter/intra-assay reproducibility. Each of the three laboratories tested eighteen samples, the Positive Control and the No Template Control, in triplicate on five different days. Each site had two operators who each ran the assay once per day, for a total of two runs per day. One site performed the extraction using the MagNA Pure LC Total Nucleic Acid Isolation Kit; two sites performed the extraction step using the Biomérieux NucliSENS easyMAG. Combined results for all sites are summarized below.

Influenza A = Total %CV of 0.8 to 2.1
Influenza B = Total %CV of 0.5 to 6.8
RSV = Total %CV of 2.1 to 4.5

Limit of Detection

Viral Strain	LoD MagNA Pure extraction ($TCID_{50}$/mL)	LoD NucliSENS easyMAG extraction ($TCID_{50}$/mL)
Influenza A/PR/8/34 (H1N1)	1.0×10^{-2}	1.0×10^{-2}
Influenza A/Hong Kong/8/68 (H3N2)	1.0×10^{1}	1.0×10^{1}
Influenza B/Great Lakes/1739/54	1.0×10^{0}	5.0×10^{0}
Influenza B/Malaysia/2506/2004	1.0×10^{1}	1.0×10^{1}
RSV A2	1.0×10^{0}	1.0×10^{0}
RSV B1	1.0×10^{0}	5.0×10^{0}

Analytical Reactivity

Viral Strain	Lowest Concentration Detected ($TCID_{50}$/mL)	Result
Influenza A/Wisconsin/67/05 H3	1.0×10^{2}	Positive for FLU A
Influenza A/New Caledonia/10/07 H1N1	1.0×10^{2}	Positive for FLU A
Influenza A/Brisbane/10/07 H3	1.0×10^{2}	Positive for FLU A
Influenza A/Solomon Island/03/06 H1	1.0×10^{2}	Positive for FLU A
Influenza A/Taiwan/42/06 H1N1	1.0×10^{2}	Positive for FLU A
Influenza A/Brisbane/59/07 H1	1.0×10^{2}	Positive for FLU A
Influenza A/Swine NY/02/2009 H1	1.0×10^{2}	Positive for FLU A
Influenza A/WS/33 H1N1	1.0×10^{2}	Positive for FLU A
Influenza A/Port Chalmers/1/73 H3N2	1.0×10^{2}	Positive for FLU A
Influenza A/California/7/2009 NYMC X-179A	1.0×10^{2}	Positive for FLU A
Influenza B/Florida/02/06	1.0×10^{2}	Positive for FLU B
Influenza B/Florida/04/06	2.0×10^{2}	Positive for FLU B
Influenza B/Florida/07/04	1.0×10^{2}	Positive for FLU B
Influenza B/Lee/40	1.0×10^{2}	Positive for FLU B
Influenza B/Maryland/1/59	1.0×10^{2}	Positive for FLU B
Influenza B/Hong Kong/5/72	1.0×10^{2}	Positive for FLU B
Influenza B/Allen/45	1.0×10^{2}	Positive for FLU B
Influenza B/Taiwan/2/62	2.0×10^{2}	Positive for FLU B
Influenza B/Panama/45/90	2.0×10^{2}	Positive for FLU B
RSV A-Long	1.0×10^{2}	Positive for RSV
RSV B-Wash/18537/62	1.0×10^{2}	Positive for RSV
RSV B-WV/14617/85	1.0×10^{2}	Positive for RSV
RSV B-9320	1.0×10^{2}	Positive for RSV

Cross-Reactivity

No cross reactivity was detected for Influenza A, Influenza B or RSV to organisms that are closely related to influenza or RSV, or cause similar clinical symptoms as influenza or RSV, or present as normal flora in the specimen types of interest.

Interference

The performance of this assay was evaluated with potentially interfering substances that may be present in nasopharyngeal swabs. The potentially interfering substances were evaluated in influenza A (influenza A/Hong Kong/8/68), and influenza B (influenza B/Malaysia/2506/2004) at a concentration of 50 $TCID_{50}$/mL and RSV A2 at a concentration of 5 $TCID_{50}$/mL. There was no evidence of interference caused by the substances tested.

Inhibition by Other Microorganisms

The Simplexa™ assay was evaluated by testing the ability to identify influenza A virus, influenza B virus and RSV when potentially inhibitory organisms are present. No inhibitory effects were confirmed for influenza A, influenza B or RSV.

Clinical Agreement

Three external testing sites participated in the Clinical Agreement Study. Reference results for influenza A and influenza B viruses were generated using a high performance FDA cleared nucleic acid test (NAT). Reference results for RSV were generated using culture/DFA. Culture/DFA results were carried forward from the results obtained at the time of sample collection or banking. A total of 735 nasopharyngeal swabs specimens were obtained from a combination of prospectively collected specimens (n = 558) from patients with signs and symptoms of viral respiratory tract infection and retrospectively banked specimens from patients with signs and symptoms of viral respiratory tract infection.

Influenza A Clinical Agreement Summary – Prospective Samples

*High Perf. NAT[1]		Simplexa		
	n	Detected	Not Detected	% Agreement
Detected	25	25	0	100%(25/25) 95% CI:86.7-100%
Not Detected	528	1	527	99.8%(527/528) 95% CI:98.9-100%

Culture/DFA		Simplexa		
	n	Detected	Not Detected	Sensitivity / Specificity
Detected	22	22	0	100%(22/22) 95% CI:85.1-100%
Not Detected	534	4	530	99.3%(530/534) 95% CI:98.1-99.7%

Influenza B Clinical Agreement Summary – Prospective Samples

*High Perf. NAT		Simplexa		
	n	Detected	Not Detected	% Agreement
Detected	2	1	1	50%(1/2) 95% CI:9.5-90.5%
Not Detected	551	1	550	99.8%(550/551) 95% CI:99-100%

Culture/DFA		Simplexa		
	n	Detected	Not Detected	Sensitivity / Specificity
Detected	1	1	0	100%(1/1) 95% CI:20.7-100%
Not Detected	555	1	554	99.8%(554/555) 95% CI:99-100%

RSV Clinical Agreement Summary – Prospective Samples

NAT		Simplexa		
	n	Detected	Not Detected	% Agreement
Detected	111	110	1	99.1%(110/111) 95% CI:95.1-99.8%
Not Detected	442	2	440	99.5%(440/442) 95% CI:98.4-99.9%

*Culture/DFA		Simplexa		
	n	Detected	Not Detected	Sensitivity / Specificity
Detected	100	98	2	98%(98/100) 95% CI:93-99.4%
Not Detected	455	14	441	96.9%(441/455) 95% CI:94.9-98.2%

Influenza A Clinical Agreement Summary – Retrospective Samples

*High Perf. NAT		Simplexa		
	n	Detected	Not Detected	% Agreement
Detected	79	79	0	100%(79/79) 95% CI:95.4-100%
Not Detected	98	1	97	99%(97/98) 95% CI:94.4-99.8%

Culture/DFA		Simplexa		
	n	Detected	Not Detected	Sensitivity / Specificity
Detected	80	80	0	100%(80/80) 95% CI:95.4-100%
Not Detected	50	0	50	100%(50/50) 95% CI:92.9-100%

Influenza B Clinical Agreement Summary – Retrospective Samples

*High Perf. NAT		Simplexa		
	n	Detected	Not Detected	% Agreement
Detected	50	50	0	100%(50/50) 95% CI:92.9-100%
Not Detected	127	0	127	100%(127/127) 95% CI:97.1-100%

Culture/DFA		Simplexa		
	n	Detected	Not Detected	Sensitivity / Specificity
Detected	50	50	0	100%(50/50) 95% CI:92.9-100%
Not Detected	93	0	93	100%(93/93) 95% CI:96-100%

RSV Clinical Agreement Summary – Retrospective Samples

NAT		Simplexa		
	n	Detected	Not Detected	% Agreement
Detected	22	22	0	100%(22/22) 95% CI:85.1-100%
Not Detected	155	1	154	99.4%(154/155) 95% CI:96.4-99.9%

*Culture/DFA		Simplexa		
	n	Detected	Not Detected	Sensitivity / Specificity
Detected	22	22	0	100%(22/22) 95% CI:85.1-100%
Not Detected	25	1	24	96%(24/25) 95% CI:80.5-99.3%

[1]High Perf. NAT = High Performance Nucleic Acid Test

*Reference method for clinical performance evaluation for 510(k) clearance.

Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Focus Diagnostics, Inc.
c/o Tara Viviani
Regulatory Affairs Project Manager
11331 Valley View St.
Cypress, California 90630

NOV 24 2010

Re: K102170

Trade/Device Name:	Simplexa™ Flu A/B & RSV
Regulation Number:	21 CFR §866.3980
Regulation Name:	Respiratory viral panel multiplex nucleic acid assay
Regulatory Class:	Class II
Product Code:	OCC
Dated:	November 11, 2010
Received:	November 12, 2010

Dear Ms. Viviani:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

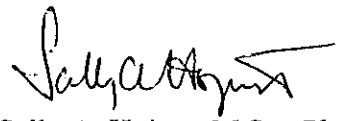
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102170

NOV 2 4 2010

Device Name: Simplexa™ Flu A/B & RSV

Indications for Use:

The Focus Diagnostics Simplexa™ Flu A/B & RSV assay is intended for use on the 3M Integrated Cycler instrument for the in vitro qualitative detection and discrimination 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 during the 2010 influenza season when 2009 H1N1 influenza was the predominant influenza A virus 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 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.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics (OIVD)

Uwe Scherf

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k102170