



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT**

I Background Information:

A 510(k) Number

K254262

B Applicant

Ortho Clinical Diagnostics, Inc. (QuidelOrtho)

C Proprietary and Established Names

Sofia Influenza A+B FIA

Sofia RSV FIA

Sofia Strep A+ FIA

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
PSZ	Class II	21 CFR 866.3328 Influenza virus antigen detection test system	Microbiology
GQG	Class I	21 CFR 866.3480 Respiratory syncytial virus serological reagents	Microbiology
GTY	Class I	21 CFR 866.3740 <i>Streptococcus spp.</i> serological reagents	Microbiology
KHO	Class I, exempt	21 CFR 862.2560 - Fluorometer, For Clinical Use	Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

To obtain a substantial equivalence determination for the Sofia Influenza A+B FIA, Sofia RSV FIA, and Sofia Strep A+ FIA assays as performed on the Sofia 2 analyzer using an updated software version (v.2.0.14).

B Measurand:**Sofia Influenza A+B FIA:**

Influenza A and influenza B viral nucleoprotein antigens

Sofia RSV FIA:

Respiratory syncytial virus (RSV) nucleoprotein antigen

Sofia Strep A+ FIA:

Group A Streptococcal (GAS) antigens

C Type of Test:**Sofia Influenza A+B FIA:**

Lateral flow fluorescent immunoassay (FIA)

Sofia RSV FIA:

Lateral flow fluorescent immunoassay (FIA)

Sofia Strep A+ FIA:

Lateral flow fluorescent immunoassay (FIA)

III Intended Use/Indications for Use:**A Intended Use(s):**

See Indications for Use below.

B Indication(s) for Use:**Sofia Influenza A+B FIA**

The Sofia Influenza A+B FIA employs immunofluorescence to detect influenza A and influenza B viral nucleoprotein antigens in direct nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens and nasopharyngeal swab and nasopharyngeal aspirate/wash specimens in transport media from symptomatic patients. This qualitative test is intended for use as an aid in the rapid differential diagnosis of acute influenza A and influenza B viral infections. The test is not intended to detect influenza C antigens. A negative test is presumptive and it is recommended these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infections and should not be used as the sole basis for treatment or other patient management decisions.

The Sofia Influenza A+B FIA may be used with Sofia or Sofia 2.

Performance characteristics for influenza A and B were established during February through March 2011 when influenza viruses A/California/7/2009 (2009 H1N1), A/Perth/16/2009 (H3N2), and B/Brisbane/60/2008 (Victoria-Like) were the predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled “Update:

Influenza Activity--United States, 2010-2011 Season, and Composition of the 2011-2012 Influenza Vaccine.” Performance characteristics may vary against other emerging influenza viruses.

If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, samples 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 samples.

Sofia RSV FIA

The Sofia RSV FIA employs immunofluorescence for detection of respiratory syncytial virus (RSV) nucleoprotein antigen in nasopharyngeal swab and nasopharyngeal aspirate/wash specimens taken directly from symptomatic patients. This qualitative test is intended for use as an aid in the rapid diagnosis of acute RSV infections in pediatric patients. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative result is presumptive, and it is recommended these results be confirmed by viral culture or an FDA-cleared RSV molecular assay.

The Sofia RSV FIA may be used with Sofia or Sofia 2.

Sofia Strep A+ FIA

The Sofia Strep A+ FIA detects Group A Streptococcal antigens from throat swabs from patients with signs and symptoms of pharyngitis, such as sore throat. All negative test results should be confirmed by either bacterial culture or an FDA-cleared molecular assay because negative results do not preclude Group A Strep infection and should not be used as the sole basis for treatment. The test is intended for use as an aid in the diagnosis of Group A Streptococcal infection.

The Sofia Strep A+ FIA may be used with Sofia or Sofia 2.

C Special Conditions for Use Statement(s):

For Prescription Use Only

D Special Instrument Requirements:

Sofia 2 v. 2.0.14

IV Device/System Characteristics:

A Device Description:

Sofia Influenza A+B FIA

The Sofia Influenza A+B FIA is a rapid lateral flow immunoassay for the qualitative detection of influenza A and influenza B nucleoprotein in direct nasal swab (NS), nasopharyngeal swab (NP), and nasopharyngeal aspirate/wash (NA/W) specimens and NP and NA/W specimens in transport

media collected from patients with signs and symptoms of respiratory infection. The Sofia Influenza A+B FIA components have not been modified; detailed description of the lateral flow device is available in [K153012](#), [K112177](#), and [K162438](#) Decision Summaries describing the Sofia Influenza A+B FIA.

The Sofia 2 analyzer may be set to one of two operating modes: Walk Away or Read Now. Time to results for the Sofia 2 analyzer v. 2.0.14 are described below.

- Walk Away Mode: Sofia 2 analyzer scans the test cassette periodically during the test development time and displays a positive test result between 3 and 15 minutes. If the test is negative, the result will be displayed after 15 minutes. Failure to detect influenza A and B coinfection may occur when running the test on Sofia 2 analyzer in Walk Away mode.
- Read Now Mode: the user incubates the test cassette on the benchtop for 15 minutes before inserting the cassette into the Sofia 2 analyzer. Positive and negative test results are displayed within 1 minute. The Sofia 2 analyzer is able to report dual positive results (positive for Flu A and Flu B) in Read Now mode only.

Once testing is complete, Sofia 2 will display the test results (Influenza A Positive, Influenza B Positive Negative, Influenza A and B Positive or Invalid) on the screen. If an invalid test result is reported, the Sofia Influenza A+B FIA assay should be repeated with a new patient sample and a new test cassette. The fluorescence signal obtained with this assay is invisible to the unaided eye. The test results can only be obtained with the proper use of Sofia 2. Each Sofia Influenza A+B FIA kit will contain one Influenza A and Influenza B Positive and one Negative Control swab.

Sofia RSV FIA

The Sofia RSV FIA is a rapid lateral flow immunoassay for the qualitative detection of RSV A and RSV B nucleoprotein from nasopharyngeal (NP) swab and nasopharyngeal aspirate/wash (NA/W) specimens collected from pediatric patients with signs and symptoms of respiratory infection. The Sofia RSV FIA components have not been modified; detailed description of the lateral flow device is available in [K130398](#) and [K162911](#) Decision Summaries.

Sofia 2 analyzer may be set to one of two operating modes: Walk Away or Read Now. Time to results for the Sofia 2 analyzer are described below.

- Walk away mode: Sofia 2 analyzer images the test cassette at 3, 5, 8, 10, and 15 minutes and reports a positive test result at the time RSV is detected. If the test is negative, the result will be displayed after 15 minutes.
- Read now mode: The user incubates the test cassette on the benchtop for 15 minutes before inserting the cassette into the Sofia 2 analyzer. Positive and negative test results are displayed within 1 minute.

Once testing is complete, Sofia 2 will display the test results (Positive, Negative, or Invalid) on the screen. If an invalid test result is reported, the Sofia RSV FIA assay should be repeated with a new patient sample and a new test cassette. The fluorescence signal obtained with this assay is invisible to the unaided eye. The test results can only be obtained with the proper use of Sofia 2. Each Sofia RSV FIA kit will contain one RSV Positive Control and one Negative Control swab.

Sofia Strep A+ FIA

The Sofia Strep A+ FIA is a rapid lateral flow immunoassay for the qualitative detection of Group A Streptococcal (GAS) antigens from throat swabs collected from patients with signs and symptoms of pharyngitis. The Sofia Strep A+ FIA components have not been modified; a detailed description of the lateral flow device is available in [K141775](#) and [K171976](#) Decision Summaries.

There are three possible test results for the Sofia Strep A+ FIA: Strep A positive, Strep A negative, and invalid. If an invalid test result is reported, the Sofia Strep A+ FIA should be repeated with a new patient sample and a new test cassette.

Sofia 2 analyzer may be set to one of two operating modes: Walk Away or Read Now. Time to results for the Sofia 2 analyzer are described below.

- Walk Away Mode: Sofia 2 analyzer automatically times the test development and provides positive or negative test results after 5 minutes.
- Read Now Mode: The user incubates the test cassette on the benchtop for 5 minutes before inserting the cassette into the analyzer. Positive and negative test results are displayed within 1 minute.

Once testing is complete, Sofia 2 will display the test results (Positive, Negative, or Invalid) on the screen. If an invalid test result is reported, the Sofia Strep A+ FIA assay should be repeated with a new patient sample and a new test cassette. The fluorescence signal obtained with this assay is invisible to the unaided eye. The test results can only be obtained with the proper use of Sofia 2. Each Sofia Strep A+ FIA kit will contain one Strep A Positive and one Negative Control swab.

B Principle of Operation:

Sofia 2 family assays employ immunofluorescence-based lateral flow technology to perform qualitative detection of analytes in human clinical samples.

C Instrument Description Information:

1. Instrument Name:

Sofia 2

2. Specimen Identification:

The Sofia 2 analyzer supports specimen identification through two methods: Barcode entry and manual entry.

3. Specimen Sampling and Handling:

The Sofia 2 analyzer supports multiple specimen types depending on the assay.

Specimen collection is performed using the sterile swab or collection device provided or recommended in the test kit following the procedures specified in the assay-specific labeling.

4. Calibration:

The Sofia 2 analyzer uses an automated calibration system to ensure stable optical performance and minimize signal drift. A Calibration Check must be performed at least every 30 days, or as otherwise specified in the applicable assay labeling.

5. Quality Control:

The Sofia 2 analyzer uses Positive and Negative External Controls provided in each assay kit. External QC demonstrates that assay reagents, test cassettes, and procedures are functioning properly.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Sofia Influenza A+B FIA

B Predicate 510(k) Number(s):

K162438

C Comparison with Predicates:

Device & Predicate Device(s):	<u>Proposed Device</u> <u>K254262</u>			<u>Predicate Device</u> <u>K162438</u>
	Device Trade Name	Sofia Influenza A+B FIA	Sofia RSV FIA	Sofia Strep A+ FIA
General Device Characteristic Similarities				
Intended Use/Indications For Use	Same	See section III.B	See section III.B	The Sofia Influenza A+B FIA employs immunofluorescence to detect influenza A and influenza B viral nucleoprotein antigens in direct nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens and nasopharyngeal swab and nasopharyngeal aspirate/wash specimens in transport media from symptomatic patients. This qualitative test is intended for use as an aid in the rapid differential diagnosis of acute influenza A and influenza B viral infections. The test is not intended to detect influenza C antigens. A negative test is

Device & Predicate Device(s):	Proposed Device <u>K254262</u>			Predicate Device <u>K162438</u>
				presumptive and it is recommended these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Negative results do not preclude influenza virus infections and should not be used as the sole basis for treatment or other patient management decisions. This test is intended for professional and laboratory use. The Sofia Influenza A+B FIA may be used with Sofia or Sofia 2. Performance characteristics for influenza A and B were established during February through March 2011 when influenza viruses A/California/7/2009 (2009 H1N1), A/Perth/16/2009 (H3N2), and B/Brisbane/60/2008 (Victoria-Like) were the predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled "Update: Influenza Activity--United States, 2010-2011 Season, and Composition of the 2011-2012 Influenza Vaccine." Performance characteristics may vary against other emerging influenza viruses. If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, samples 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 samples.
Analyzer	Sofia 2			Same
Development Modes	Walk-Away and Read Now modes			Same

Device & Predicate Device(s):	<u>Proposed Device</u> <u>K254262</u>	<u>Predicate Device</u> <u>K162438</u>
Development time	Walk away mode: 3-15 minutes Read now mode: 1 minute	Same
Barcode Scanner (cassette)	Integrated barcode scanner	Same
Assay/instrument interface	Drawer (manual)	Same
User Interface	4-inch color LCD touchscreen display	Same
User Types	Operator user, Supervisor, Service level	Same
General Device Characteristic Differences		
Software version	v2.0.14	v1.2.0
Software	The software has been reengineered to enhance usability and to modernize the device drivers, without requiring any hardware modifications.	The firmware provides a Graphical User Inter-face and manages the workflow, algorithms, hardware integration (camera, sensors, screen, touch, power), and all interoperability functions.
Assay Framework	Existing assays were refactored to have algorithms, graphical user interface screens, and AMF components migrated into an assay-specific plugin that can be deployed independently of the firmware. Assay-related workflows (e.g., operator workflows and assay calculations) will no longer reside within the firmware. This architecture provides greater flexibility for allowing algorithms and user interface screens to be tailored to each individual assay.	Algorithms and screens reside in the firmware and are configured with an Assay Method File (AMF). Assay related workflows (such as operator workflows and assay calculations) reside inside of the firmware.
Assay Data Files	Assay plugin format	Assay Method File (AMF)
Operating System	Linux operating system Kernel version 5.4	Linux operating system Kernel version 4.1
Programming Language	C++	Python
Security - Data Encryption	Encryption was added for database and clinical data	Database and clinical data not encrypted
Security - User Authentication	Enhanced support for unique and complex user identification and password	Combination user identification and password available
Security - Export Files	Encryption of export setting files to USB i.e., instrument settings	Export setting files to USB were not encrypted

VI Standards/Guidance Documents Referenced:

- Content of Premarket Submissions for Device Software Functions (June 14, 2023)
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (February 2026)
- Bundling Multiple Devices or Multiple Indications in a Single Submission (June 22, 2007)

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

For the purposes of the analytical and comparison studies, previous software versions of the Sofia 2 analyzer (v1.2.0) are collectively referred to as “software version 1” and the updated software version (v2.0.14) is referred to as “software version 2”.

1. Precision/Reproducibility:

The precision and reproducibility studies of the Sofia Influenza A+B FIA were previously assessed in K162438. Refer to [K162438](#) Decision Summary for additional details.

The precision and reproducibility studies of the Sofia RSV FIA were previously assessed in K130398. Refer to [K130398](#) Decision Summary for additional details.

The precision and reproducibility studies of the Sofia Strep A+ FIA were previously assessed in K171976. Refer to [K171976](#) Decision Summary for additional details.

2. Linearity:

Not applicable

3. Analytical Specificity/Interference:

The analytical specificity/interference studies of the Sofia Influenza A+B FIA were previously assessed in K162438. Refer to [K162438](#) Decision Summary for additional details.

The analytical specificity/interference studies of the Sofia RSV FIA were previously assessed in K130398. Refer to [K130398](#) Decision Summary for additional details.

The analytical specificity/interference studies of the Sofia Strep A+ FIA were previously assessed in K171976. Refer to [K171976](#) Decision Summary for additional details.

4. Detection Limit and Assay Reportable Range:

The purpose of these studies is to demonstrate that the Limit of Detection (LoD) is equivalent for Sofia Influenza A+B FIA, Sofia RSV FIA, and Sofia Strep A+ FIA assays when run on the Sofia 2 analyzer using software version 2 and Sofia 2 software version 1. A calibration check of the Sofia 2 analyzers was performed prior to the beginning of the study. Positive and negative controls were tested on each analyzer prior to the testing. The control results were 100% as expected.

Sofia Influenza A+B FIA:

Contrived positive samples were prepared by spiking Influenza A/Victoria/2570/19 (Part no: 0810663CF) and Influenza B/Yamagata/Utah/09/14 (part no: 0810516CF) in negative nasal matrix (NNM), that was confirmed to be negative using a highly sensitive RT-PCR Influenza A+B Assay. 50 µL of sample was applied onto swabs for testing.

Ten (10) analyzers with software version 1 and ten (10) analyzers with software version 2 of the Sofia 2 and five (5) analyzers per influenza virus type were used in Read Now mode to

test all replicates. In an initial range-finding study, a 1:5 dilution series was prepared and five replicates at each dilution were tested on one assay lot. The preliminary LoD was defined as the lowest concentration that all five replicates were detected and was determined to be 1.9×10^2 TCID₅₀/mL for Influenza A/Victoria/2570/19 and 8.1×10^1 TCID₅₀/mL for Influenza B/Yamagata/Utah/09/14, for both software versions. To confirm the LoD, replicates at 2-fold dilution level above and below the preliminary LoD were tested with twenty replicates each on one lot of the Sofia Influenza A+B FIA assay. The LoD was confirmed to be 1.9×10^2 TCID₅₀/mL for Influenza A/Victoria/2570/19 and 1.6×10^2 TCID₅₀/mL for Influenza B/Yamagata/Utah/09/14, for both software versions.

Table 1. Performance of the Sofia Influenza A+B FIA – Summary Results

Influenza A								
Test Phase	Conc. (CFU/mL)	n	Sofia 2 Software Version 1			Sofia 2 Software Version 2		
			Invalid	Neg.	Pos. (%)	Invalid	Neg.	Pos. (%)
Blank Negative	N/A	5	0	5	0 (0)	0	5	0 (0)
Initial	2.3E+04	5	0	0	5 (100)	0	0	5 (100)
	4.7E+03	5	0	0	5 (100)	0	0	5 (100)
	9.4E+02	5	0	0	5 (100)	0	0	5 (100)
	1.9E+02	5	0	0	5 (100)	0	0	5 (100)
	3.7E+01	5	0	5	0 (0)	0	5	0 (0)
Confirmation	3.7E+02	20	0	0	20 (100)	0	0	20 (100)
	1.9E+02	20	0	0	20 (100)	0	0	20 (100)
	9.4E+01	20	0	16	4 (20)	0	17	3 (15)
Influenza B								
Test Phase	Conc. (CFU/mL)	n	Sofia 2 Software Version 1			Sofia 2 Software Version 2		
			Invalid	Neg.	Pos. (%)	Invalid	Neg.	Pos. (%)
Blank Negative	N/A	5	0	5	0 (0)	0	5	0 (0)
Initial	2.5E+05	5	0	0	5 (100)	0	0	5 (100)
	5.4E+04	5	0	0	5 (100)	0	0	5 (100)
	1.0E+04	5	0	0	5 (100)	0	0	5 (100)
	2.0E+03	5	0	0	5 (100)	0	0	5 (100)
	4.0E+02	5	0	0	5 (100)	0	0	5 (100)
	8.1E+01	5	0	0	5 (100)	0	0	5 (100)
	1.6E+01	5	0	5	0 (0)	0	5	0 (0)
Confirmation	3.2E+02	20	0	0	20 (100)	0	0	20 (100)
	1.6E+02	20	0	0	20 (100)	0	0	20 (100)
	8.1E+01	20	0	14	6 (30)	0	16	4 (20)

Sofia RSV FIA:

Contrived positive samples were prepared by spiking RSV Type A (A2) and RSV Type B (18537 B-Washington) in negative nasopharyngeal matrix (NNPM). 50 µL of sample was applied onto swabs for testing.

Ten (10) analyzers with software version 1 and ten (10) analyzers with software version 2 of the Sofia 2, five (5) analyzers per RSV type, were used in Read Now mode to test all replicates. In an initial range-finding study, a 1:5 dilution series was prepared and five replicates at each dilution were tested on one assay lot. The preliminary LoD was defined as

the lowest concentration that all five replicates were detected and was determined to be 5.0×10^4 TCID₅₀/mL for RSV Type A (A2) and 2.7×10^4 TCID₅₀/mL for RSV Type B (18537 B-Washington), for both software versions. To confirm the LoD, replicates at 2-fold dilution level above and below the preliminary LoD were tested with twenty replicates each on one lot of the Sofia RSV FIA assay. The LoD was confirmed to be 5.0×10^4 TCID₅₀/mL for RSV Type A (A2) and 2.7×10^4 TCID₅₀/mL for RSV Type B (18537 B-Washington), for both software versions.

Table 2. Performance of the Sofia RSV FIA – Summary Results

RSV A								
Test Phase	Conc. (TCID ₅₀ /mL)	n	Sofia 2 Software Version 1			Sofia 2 Software Version 2		
			Invalid	Neg.	Pos. (%)	Invalid	Neg.	Pos. (%)
Blank Negative	N/A	5	0	5	0 (0)	0	5	0 (0)
Initial	1.3E+06	5	0	0	5 (100)	0	0	5 (100)
	2.5E+05	5	0	0	5 (100)	0	0	5 (100)
	5.0E+04	5	0	0	5 (100)	0	0	5 (100)
	1.0E+04	5	0	5	0 (0)	0	5	0 (0)
	2.0E+03	5	0	5	0 (0)	0	5	0 (0)
Confirmation	1.0E+05	20	0	0	20 (100)	0	0	20 (100)
	5.0E+04	20	0	0	20 (100)	0	0	20 (100)
	2.5E+04	20	0	20	0 (0)	0	19	1 (5)
RSV B								
Test Phase	Conc. (CFU/mL)	n	Sofia 2 Software Version 1			Sofia 2 Software Version 2		
			Invalid	Neg.	Pos. (%)	Invalid	Neg.	Pos. (%)
Blank Negative	N/A	5	0	5	0 (0)	0	5	0 (0)
Initial	6.7E+05	5	0	0	5 (100)	0	0	5 (100)
	1.3E+05	5	0	0	5 (100)	0	0	5 (100)
	2.7E+04	5	0	0	5 (100)	0	0	5 (100)
	5.4E+03	5	0	5	0 (0)	0	5	0 (0)
	1.1E+03	5	0	5	0 (0)	0	5	0 (0)
Confirmation	5.4E+04	20	0	0	20 (100)	0	0	20 (100)
	2.7E+04	20	0	0	20 (100)	0	0	20 (100)
	1.3E+04	20	0	14	6 (30)	0	13	7 (35)

Sofia Strep A+ FIA:

Contrived positive samples were prepared by spiking *Streptococcus pyogenes* (strain: Bruno) in negative oropharyngeal test matrix (NOTM) and applying 50 µL onto swabs for testing.

Five (5) analyzers software version 1 and five (5) analyzers with software version 2 of the Sofia 2 were used in Read Now mode to test all replicates. In an initial range-finding study, a 1:5 dilution series was prepared and five replicates at each dilution were tested on one assay lot. The preliminary LoD was defined as the lowest concentration that all five replicate were detected and was determined to be 2.3×10^5 CFU/mL for both software versions. To confirm the LoD, replicates at 2-fold dilution level above and below the preliminary LoD were tested with twenty replicates each on one lot of the Sofia Strep A+ FIA assay. The LoD was confirmed to be 1.2×10^5 CFU/mL for both software versions.

Table 3. Performance of the Sofia Strep A+ FIA – Summary Results

Test Phase	Conc. (CFU/mL)	n	Sofia 2 Software Version 1			Sofia 2 Software Version 2		
			Invalid	Neg.	Pos. (%)	Invalid	Neg.	Pos. (%)
Blank Negative	N/A	5	0	5	0 (0)	0	5	0 (0)
Initial	1.2E+06	5	0	0	5 (100)	0	0	5 (100)
	2.3E+05	5	0	0	5 (100)	0	0	5 (100)
	4.6E+04	5	0	5	0 (00)	0	5	0 (00)
	9.2E+03	5	0	5	0 (00)	0	5	0 (00)
	1.8E+03	5	0	5	0 (00)	0	5	0 (00)
Confirmation	2.3E+05	20	0	0	20 (100)	0	0	20 (100)
	1.2E+05	20	0	0	20 (100)	0	0	20 (100)
	5.8E+04	20	0	20	0 (0)	0	19	1 (5)

The results of LoD equivalency studies for Sofia Influenza A+B FIA, Sofia RSV FIA, and Sofia Strep A+ FIA, obtained using Sofia 2 analyzer with v1 and v.2, are acceptable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Not applicable

6. Assay Cut-Off:

Not applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:

The performance of the Sofia Influenza A+B FIA, Sofia RSV FIA, and Strep A+ FIA was evaluated by performing a method comparison study with the Sofia 2 analyzer with software version 1 and version 2. Contrived positive and negative samples were prepared in negative clinical matrix (see sections below). The test panel consisted of 30 negative samples and 50 positive samples. Positive samples were comprised of 18 low positive samples (1-3x LoD), 17 moderate positive samples (3-5x LoD), and 15 moderate to high positive samples (5-10x LoD) per analyte. Prior to testing, all samples were coded and randomized and confirmed on the Sofia 2 analyzer using software version 1. Testing was performed on ten (10) Sofia 2 analyzers (5 per software version) operating in Read Now mode using a single lot.

Specific sample preparation information and method comparison study results are presented for Sofia Influenza A+B FIA, Sofia RSV FIA, and Sofia Strep A+ FIA below.

Sofia Influenza A+B FIA:

Contrived positive samples were prepared by spiking Influenza A/Victoria/2570/19 (Part no: 0810663CF) and Influenza B/Yamagata/Utah/09/14 (part no: 0810516CF) in NNM. Negative samples were NNM only. 50 µL of sample was applied onto swabs for testing.

All positive and negative samples yielded 100% agreement with the expected result with the Sofia 2 analyzer software version 1 and version 2 for Influenza A/Victoria/2570/19 and Influenza B/Yamagata/Utah/09/14. Results demonstrated equivalent performance of Sofia Influenza A+B FIA using the Sofia 2 analyzer with both software versions for Influenza A/Victoria/2570/19 and Influenza B/Yamagata/Utah/09/14 strains.

Sofia RSV FIA:

Contrived positive samples were prepared by spiking RSV Type A (A2) and RSV Type B (18537 B-Washington) in NNPM. Negative samples were NNPM only. 50 µL of sample was applied onto swabs for testing.

All negative and moderate and high positive samples yielded 100% agreement with the expected result with the Sofia 2 analyzer software version 1 and version 2 for RSV Type A (A2) and RSV Type B (18537 B-Washington). The low positive samples yielded 94% agreement with the expected result with the Sofia 2 analyzer software version 1 and version 2 for RSV Type A (A2) and yielded 100% for RSV Type B (18537 B-Washington). Results demonstrated equivalent performance of Sofia RSV FIA using the Sofia 2 analyzer with both software versions for RSV Type A (A2) and RSV Type B (18537 B-Washington) strains.

Sofia Strep A+ FIA:

Contrived positive samples were prepared by spiking *S. pyogenes* (strain: Bruno) into NOTM. Negative samples were NOTM only. 50 µL of each sample was applied to swabs for testing.

All positive and negative samples yielded 100% agreement with the expected result with the Sofia 2 analyzer software version 1 and version 2 for *S. pyogenes* (strain: Bruno). Results demonstrated equivalent performance of Sofia Strep A+ FIA using the Sofia 2 analyzer with both software versions for *S. pyogenes* (strain: Bruno).

2. Matrix Comparison:

Not applicable

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable

2. Clinical Specificity:

Not applicable

3. Clinical Cut-Off

Not applicable

4. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Performance Near Cut-Off

To evaluate performance near the assay cut-off for the Sofia Influenza A+B FIA, Sofia RSV FIA, and Sofia Strep A+ FIA, a panel of negative, low positive (1.5x LoD), and moderate positive (4x LoD) contrived samples were tested with the Sofia 2 analyzer software version 1 and version 2, in Read Now mode. Samples were tested in triplicate over five (5) days, two (2) runs per day, with at least two (2) operators, yielding 30 replicates per sample at a single site. Testing was performed on 20 analyzers (10 per software version) using one lot of each assay kit.

Specific sample preparation information and near cut-off performance results are presented for Sofia Influenza A+B FIA, Sofia RSV FIA, and Sofia Strep A+ FIA below.

Sofia Influenza A+B FIA:

Contrived positive samples were prepared by spiking Influenza A/Victoria/2570/19 (Part no: 0810663CF) and Influenza B/Yamagata/Utah/09/14 (part no: 0810516CF) in NNM. Negative samples were NNM only. 50 µL of sample was applied onto swabs for testing.

Table 4. Sofia Influenza A+B FIA Near Cut-off Performance with Sofia 2 v1 and v2

Sample	Concentration	Sofia 2 v1		Sofia 2 v2	
		% Agmt* (n/N)	95% CI**	% Agmt (n/N)	95% CI
Influenza A Victoria/2570/19	Negative	100.0% (30/30)	88.6 – 100.0%	100.0% (30/30)	88.6 – 100.0%
	1.5x LoD	100.0% (30/30)	88.6 – 100.0%	100.0% (30/30)	88.6 – 100.0%
	4x LoD	100.0% (30/30)	88.6 – 100.0%	100.0% (30/30)	88.6 – 100.0%
Influenza B Yamagata/Utah/09/14	Negative	100.0% (30/30)	88.6 – 100.0%	100.0% (30/30)	88.6 – 100.0%
	1.5x LoD	100.0% (30/30)	88.6 – 100.0%	100.0% (30/30)	88.6 – 100.0%
	4x LoD	100.0% (30/30)	88.6 – 100.0%	100.0% (30/30)	88.6 – 100.0%

*Agmt= Agreement, ** Confidence interval.

All positive and negative samples yielded 100% agreement with the expected result with the Sofia 2 analyzer software version 1 and version 2 for Influenza A Victoria/2570/19 and Influenza B Yamagata/Utah/09/14. Performance of the Sofia Influenza A+B FIA near the assay cut-off was equivalent between Sofia 2 analyzer software version 1 and version 2 for the influenza strains evaluated.

Sofia RSV FIA:

Contrived positive samples were prepared by spiking RSV Type A (A2) and RSV Type B (18537 B-Washington) in NNPM. Negative samples were NNPM only. 50 µL of sample was applied onto swabs for testing.

Table 5. Sofia RSV FIA Near Cut-off Performance with Sofia 2 v1 and v2

Sample	Concentration	Sofia 2 v1		Sofia 2 v2	
		% Agmt* (n/N)	95% CI**	% Agmt (n/N)	95% CI
RSV Type A (A2)	Negative	100.0% (30/30)	88.6 – 100.0%	100.0% (30/30)	88.6 – 100.0%
	1.5x LoD	100.0% (30/30)	88.6 – 100.0%	100.0% (30/30)	88.6 – 100.0%
	4x LoD	100.0% (30/30)	88.6 – 100.0%	100.0% (30/30)	88.6 – 100.0%
RSV Type B (18537 B-Washington),	Negative	100.0% (30/30)	88.6 – 100.0%	100.0% (30/30)	88.6 – 100.0%
	1.5x LoD	100.0% (30/30)	88.6 – 100.0%	100.0% (30/30)	88.6 – 100.0%
	4x LoD	100.0% (30/30)	88.6 – 100.0%	100.0% (30/30)	88.6 – 100.0%

*Agmt= Agreement, ** Confidence interval.

All positive and negative samples yielded 100% agreement with the expected result with the Sofia 2 analyzer software version 1 and version 2 for RSV Type A (A2) and RSV Type B (18537 B-Washington). Performance of the Sofia RSV FIA near the assay cut-off was equivalent between Sofia 2 analyzer software version 1 and version 2 for the RSV strains evaluated.

Sofia Strep A+ FIA:

Contrived positive samples were prepared by spiking *S. pyogenes* (strain: Bruno) into NOTM. Negative samples were NOTM only. 50 µL of each sample was applied to swabs for testing.

Table 6. Sofia Strep A+ FIA Near Cut-off Performance with Sofia 2 v1 and v2

Sample	Concentration	Sofia 2 v1		Sofia 2 v2	
		% Agmt* (n/N)	95% CI**	% Agmt (n/N)	95% CI
<i>S. pyogenes</i>	Negative	100.0% (30/30)	88.6 – 100.0%	100.0% (30/30)	88.6 – 100.0%
	1.5x LoD	100.0% (30/30)	88.6 – 100.0%	100.0% (30/30)	88.6 – 100.0%
	4x LoD	100.0% (30/30)	88.6 – 100.0%	100.0% (30/30)	88.6 – 100.0%

*Agmt= Agreement, ** Confidence interval.

All positive and negative samples yielded 100% agreement with the expected result with the Sofia 2 analyzer software version 1 and version 2 for *S. pyogenes*. Performance of the Sofia Strep A+ FIA near the assay cut-off was equivalent between Sofia 2 analyzer software version 1 and version 2 for the *S. pyogenes* evaluated.

D Expected Values/Reference Range:

Sofia Influenza A+B FIA:

A patient sample is expected to be negative for Influenza A and B.

Sofia RSV FIA:

A patient sample is expected to be negative for RSV.

Sofia Strep A+ FIA:

A patient sample is expected to be negative for Strep A.

E Other Supportive Instrument Performance Characteristics Data:

1) Electromagnetic compatibility

Electrical safety and electromagnetic compatibility (EMC) testing were performed, and the new test system was found to be acceptable.

2) Software and cybersecurity

Software and cybersecurity documentation was reviewed and found to be acceptable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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