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

Quidel Corporation
Ronald H. Lollar
Sr. Director, Clinical, Regulatory and Scientific Affairs
2005 East State Street, Suite 100
Athens, OH 45701

October 16, 2017

Re: K171974
Trade/Device Name: Solana RSV+hMPV Assay
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory viral panel multiplex nucleic acid assay
Regulatory Class: II
Product Code: OCC
Dated: September 15, 2017
Received: September 18, 2017

Dear Mr. Lollar:

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)*
K171974

Device Name
Solana RSV+hMPV Assay

Indications for Use *(Describe)*
The Solana RSV+hMPV Assay is a qualitative *in vitro* diagnostic test for the detection and differentiation of RSV and hMPV viral RNA in nasal and nasopharyngeal swabs from patients with signs and symptoms of respiratory infection. This test is intended for use as an aid in the differential diagnosis of RSV and hMPV viral infections in humans in conjunction with clinical and epidemiological risk factors. This test is not intended to differentiate the two subtypes of RSV or the four genetic sub-lineages of hMPV.

Negative results do not preclude RSV infection and/or hMPV infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

Conversely, positive results do not rule-out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. The use of additional laboratory testing and clinical presentation must be considered in order to obtain the final diagnosis of respiratory viral infection.

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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510(k) Summary

Applicant:

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Date of preparation of 510(k) summary:

June 29, 2017

A. 510(k) Number:

K171974

B. Purpose for Submission:

To obtain substantial equivalence for the Solana® RSV+hMPV Assay when performed on the Solana® instrument

C. Measurand:

RSV: Matrix Gene;
hMPV: Fusion Protein Gene

D. Type of Test:

Reverse Transcriptase - Helicase-Dependent Amplification (RT-HDA)

510(k) Summary

E. Applicant:

Quidel Corporation

F. Proprietary and Established Names:

Solana® RSV+hMPV Assay

G. Regulatory Information:

Table 1. Regulatory Information

Product Code	Classification	Regulation Section	Panel
OCC	Class II	21 CFR 866.3980 Respiratory viral panel multiplex nucleic acid assay	Microbiology (83)
OEM		21 CFR 866.3980 Human Metapneumovirus (Hmpv) Rna Assay System	

H. Intended Use:

1. Intended Use(s):

The Solana® RSV+hMPV Assay is a qualitative *in vitro* diagnostic test for the detection and differentiation of RSV and hMPV viral RNA in nasal and nasopharyngeal swabs from patients with signs and symptoms of respiratory infection. This test is intended for use as an aid in the differential diagnosis of RSV and hMPV viral infections in humans in conjunction with clinical and epidemiological risk factors. This test is not intended to differentiate the two subtypes of RSV or the four genetic sub-lineages of hMPV.

Negative results do not preclude RSV infection and/or hMPV infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

Conversely, positive results do not rule-out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. The use of additional laboratory testing and clinical presentation must be considered in order to obtain the final diagnosis of respiratory viral infection.

510(k) Summary

2. Indication(s) for Use:

   Same as Intended Use

3. Special conditions for use statement(s):

   - For *in vitro* diagnostic use only
   - For prescription use only

4. Special instrument requirements:

   Solana® Instrument

I. Device Description:

The Solana RSV+hMPV Assay amplifies and detects viral RNA present in viral transport media containing nasopharyngeal or nasal swab specimens obtained from symptomatic patients.

The assay consists of two major steps: 1) specimen preparation, and 2) amplification and detection of target sequences specific to RSV and/or hMPV using isothermal Reverse Transcriptase - Helicase-Dependent Amplification (RT-HDA) in the presence of target-specific fluorescence probes.

A patient nasal or nasopharyngeal swab specimen in viral transport media is transferred to a Process Buffer Tube, subjected to heat treatment at 95°C for 5 minutes and mixed. The processed sample is transferred to a Reaction Tube. The Reaction Tube contains lyophilized RT-HDA reagents, dNTPs, primers and probes. Once rehydrated with the processed sample, the Reaction Tube is placed in Solana for amplification and detection of RSV and hMPV - specific target sequences. In Solana, the target sequences are amplified by RSV and hMPV specific primers and detected by RSV and hMPV specific fluorescence probes, respectively. A process control (PRC) is included in the Process Buffer Tube to monitor sample processing, inhibitory substances in clinical samples, reagent failure or device failure. The PRC target is amplified by RSV and hMPV specific primers and detected by a PRC specific fluorescence probe.

The two target probes and PRC probe are labeled with a quencher on one end and a fluorophore on the other end. In addition, the two target probes and PRC probe incorporate one or more RNA bases. Upon annealing to RSV, hMPV or PRC amplicons, the fluorescence probes are cleaved by RNaseH2 and the fluorescence signal increases due to physical separation of fluorophore from quencher. Solana measures and interprets the

fluorescent signal, using on-board method-specific algorithms. Solana then reports the test results to the user on its display screen, and it can print out the results via an attached printer.

Materials Provided:

Solana® RSV+hMPV Assay Kit: M306
48 Tests per kit

Table 2. Kit Components

Component	Quantity	Storage
Process Buffer	48 tubes/kit 1.55 mL	2°C to 8°C
Reaction Tubes	48 tubes/kit	2°C to 8°C

Materials required but not provided:

- External controls for RSV and hMPV (e.g. Solana RSV+hMPV Control Set, which contains positive and negative controls, serves as an external processing control)
- Sterile DNase-free filter-blocked positive displacement micropipettor tips
- Micropipettor
- Stopwatch or timer
- Scissors or a blade
- Workflow tray
- Transfer Rack
- Heat block capable of 95 ± 2°C temperature
- Thermometer
- Solana instrument
- Transport Media (BD/Copan UTM, Remel M4, Remel M4RT, Remel M5, Remel M6, or Copan eSwab)

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Lyra® RSV+hMPV Assay

2. Predicate 510(k) number(s):
   K131813

510(k) Summary

3. Comparison with predicate:

Table 3. **Similarities**		
Item	**Solana® RSV+hMPV Assay**	**Lyra® RSV+hMPV Assay (k131813)**
Intended Use	The Solana® RSV+hMPV Assay is a qualitative *in vitro* diagnostic test for the detection and differentiation of RSV and hMPV viral RNA in nasal and nasopharyngeal swabs from patients with signs and symptoms of respiratory infection. This test is intended for use as an aid in the differential diagnosis of RSV and hMPV viral infections in humans in conjunction with clinical and epidemiological risk factors. This test is not intended to differentiate the two subtypes of RSV or the four genetic sub-lineages of hMPV. Negative results do not preclude RSV infection and/or hMPV infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Conversely, positive results do not rule-out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. The use of additional laboratory testing and clinical presentation must be considered in order to obtain the final diagnosis of respiratory viral infection.	The Lyra RSV + hMPV Assay is a multiplex Real-Time PCR (RT-PCR) assay for the qualitative detection and identification of respiratory syncytial virus (RSV) and human metapneumovirus (hMPV) ribonucleic acid (RNA) extracted from nasal and nasopharyngeal swab specimens from patients with signs and symptoms of respiratory infection. This in vitro diagnostic test is intended to aid in the differential diagnosis of RSV and hMPV infections in humans in conjunction with clinical and epidemiological risk factors. This test is not intended to differentiate the two subtypes of RSV or the four genetic sub-lineages of hMPV. Negative results do not preclude RSV infection and/or hMPV infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Conversely, positive results do not rule-out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. The use

510(k) Summary

Table 3. Similarities		
Item	**Solana® RSV+hMPV Assay**	**Lyra® RSV+hMPV Assay (k131813)**
		of additional laboratory testing and clinical presentation must be considered in order to obtain the final diagnosis of respiratory viral infection. The Quidel Molecular RSV + hMPV Assay can be performed using either the Life Technologies QuantStudio™Dx RT-PCR Instrument, the Applied Biosystems® 7500 Fast Dx RT-PCR Instrument, or the Cepheid SmartCycler® II System.
Sample Types	nasal swab and nasopharyngeal swab	Same
Detection Techniques	Automated multiplex assay using different reporter dyes for each target	Same

Table 4. Differences		
Item	**Solana® RSV+hMPV Assay**	**Lyra® RSV+hMPV Assay (k131813)**
Viral Target	RSV: Matrix Gene; hMPV: Fusion Protein	RSV: L viral polymerase and NS2 genes hMPV: RNA polymerase gene
Amplification Technology	Reverse Transcriptase - Helicase-Dependent Amplification (RT-HDA)	Real Time PCR-based system for detecting the presence or absence of viral RNA in clinical specimens
Extraction Methods	None	bioMérieux easyMAG® Automated Magnetic Extraction Reagents
Instrument	Solana®	Life Technologies QuantStudio® Dx, the Applied Biosystems® 7500 Fast Dx, or the Cepheid SmartCycler® II

K. Standard/Guidance Document Referenced (if applicable):

Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Respiratory Viral Panel Multiplex Nucleic Acid Assay - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm180307.htm

Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Testing for Human Metapneumovirus (hMPV) Using Nucleic Acid Assays – https://www.fda.gov/RegulatoryInformation/Guidances/ucm180308.htm

Guidance for Industry and FDA Staff: Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests (Final, 3/13/2007) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071287.pdf

Guidance on Informed Consent for In Vitro Diagnostic Device Studies Leftover Human Specimens that are Not Individually Identifiable (April 2006) – http://www.fda.gov/cdrh/oivd/guidance/1588.pdf.

Guidance for Industry and Food and Drug Administration Staff - eCopy Program for Medical Device (December 2012) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf

L. Test Principle:

The Solana RSV+hMPV Assay amplifies and detects viral RNA present in viral transport media containing nasopharyngeal or nasal swab specimens obtained from symptomatic patients.

The assay consists of two major steps: 1) specimen preparation, and 2) amplification and detection of target sequences specific to RSV and/or hMPV using isothermal Reverse

Transcriptase - Helicase-Dependent Amplification (RT-HDA) in the presence of target-specific fluorescence probes.

A patient nasal or nasopharyngeal swab specimen in viral transport media is transferred to a Process Buffer Tube, subjected to heat treatment at 95°C for 5 minutes and mixed. The processed sample is transferred to a Reaction Tube. The Reaction Tube contains lyophilized RT-HDA reagents, dNTPs, primers and probes. Once rehydrated with the processed sample, the Reaction Tube is placed in Solana for amplification and detection of RSV and hMPV - specific target sequences. In Solana, the target sequences are amplified by RSV and hMPV specific primers and detected by RSV and hMPV specific fluorescence probes, respectively. A competitive process control (PRC) is included in the Process Buffer Tube to monitor sample processing, inhibitory substances in clinical samples, reagent failure or device failure. The PRC target is amplified by RSV and hMPV specific primers and detected by a PRC specific fluorescence probe.

The two target probes and PRC probe are labeled with a quencher on one end and a fluorophore on the other end. In addition, the two target probes and PRC probe incorporate one or more RNA bases. Upon annealing to RSV, hMPV or PRC amplicons, the fluorescence probes are cleaved by RNaseH2 and the fluorescence signal increases due to physical separation of fluorophore from quencher. Solana measures and interprets the fluorescent signal, using on-board method-specific algorithms. Solana then reports the test results to the user on its display screen, and it can print out the results via an attached printer.

M. Performance Characteristics:

1. Analytical performance:

   a. Precision/Reproducibility:

   Reproducibility
   A four-sample panel consisting of three levels of a combined RSV and hMPV (two (2) strains of each virus) contrived samples and a negative contrived sample were tested in this study. RSV A strain A2 (VR-1540) and hMPV 20 Type A2 (IA14-2003 G gene) (Set 1), or RSV B strain Wash/18537/62 (VR-1580) and hMPV 4 Type B2 (Peru1-2002, B2) (Set 2) were diluted in negative nasal matrix to 2x LOD for moderate positive, 1x LOD for low positive and diluted to C20 to C80 for high negative / low positive. Negative nasal matrix without spiked virus was used for the negative sample. Positive and negative controls were run in triplicate along with the panels. The panels were run by two operators at each testing site for five (5) non-consecutive days. The study was completed by the in-house laboratory (Athens facility of Quidel Corp), Lab Alliance, and Medical Center of Wisconsin. The Solana RSV+hMPV assay was used per the instructions for use.

510(k) Summary

Panels and controls were tested at each site by two operators per instrument for five days, each sample tested in three (3) replicates, for a total of 45 results per level for each virus strain (2 operators x 5 days x 3 sites x 3 replicates).

Table 5. Reproducibility Summary

	SITE						Overall Percent Agreement		95% Confidence Interval
	Site #1		Site #2		Site #3				
	# Expected Result/# tested	*% Agreement with Expected Result*	*# Expected Result/# tested*	*% Agreement with Expected Result*	*# Expected Result/# tested*	*% Agreement with Expected Result*			
RSV A strain A2 (VR-1540) High Negative (0.2x LOD ($1.6x10^3$ TCID50/mL)*	8/15	53.3	14/15	93.3	10/15	66.7	32/45	71.1	56.6 to 82.3
RSV A strain A2 (VR-1540) Low Positive (1x LOD) ($7.9x10^3$ TCID50/mL)	15/15	100	15/15	100	15/15	100	45/45	100	92.1 to 100
RSV A strain A2 (VR-1540) Moderate Positive (2x LOD) ($1.6x10^4$ TCID50/mL)	15/15	100	15/15	100	15/15	100	45/45	100	92.1 to 100
RSV B strain Wash/18537/62 (VR-1580) High Negative (0.2x LOD ($1.4 x10^2$ TCID50/mL)*	6/15	40.0	10/15	66.7	6/15	40	22/45	48.9	30.9 to 58.8
RSV B strain Wash/18537/62 (VR-1580) Low Positive (1x LOD) ($4.7x10^2$ TCID50/mL)	15/15	100	15/15	100	15/15	100	45/45	100	92.1 to 100
RSV B strain Wash/18537/62 (VR-1580) Moderate Positive (2x LOD) ($9.4x10^2$ TCID50/mL)	15/15	100	15/15	100	15/15	100	45/45	100	92.1 to 100
Negative	0/30	100	0/30	100	0/30	100	0/90	100	96.0 to 100
RSV Positive Control	30/30	100	30/30	100	30/30	100	90/90	100	96.0 to 100
RSV Negative Control	0/30	100	0/30	100	0/30	100	0/90	100	96.0 to 100

* An expected result for the high negative sample is a negative result.

510(k) Summary

Table 5: Reproducibility Summary									
	SITE						Overall Percent Agreement With Expected Results		95% Confidence Interval
	Site #1		Site #2		Site #3				
	# Expected Result/# tested	*% Agreement with Expected Result*	*# Expected Result/# tested*	*% Agreement with Expected Result*	*# Expected Result/# tested*	*% Agreement with Expected Result*			
hMPV 20 Type A2 (IA14-2003 G gene) High Negative (0.2x LOD ($2.4x10^2$ $TCID_{50}$/mL)*	11/15	73.3	14/15	93.3	10/15	66.7	35/45	77.8	63.7 to 87.5
hMPV 20 Type A2 (IA14-2003 G gene) Low Positive (1x LOD) ($1.2x10^4$ $TCID_{50}$/mL)	15/15	100	15/15	100	15/15	100	45/45	100	92.1 to 100
hMPV 20 Type A2 (IA14-2003 G gene) Moderate Positive (2x LOD) ($2.4x10^4$ $TCID_{50}$/mL)	15/15	100	15/15	100	15/15	100	45/45	100	92.1 to 100
hMPV 4 Type B2 (Peru1-2002, B2) High Negative (0.2x LOD ($4.6x10^2$ $TCID_{50}$/mL)*	9/15	60	9/15	60	9/15	60	27/45	60.0	45.5 to 73.0
hMPV 4 Type B2 (Peru1-2002, B2) Low Positive (1x LOD) ($2.3x10^3$ $TCID_{50}$/mL)	15/15	100	15/15	100	15/15	100	45/45	100	92.1 to 100
hMPV 4 Type B2 (Peru1-2002, B2) Moderate Positive (2x LOD) ($4.6x10^3$ $TCID_{50}$/mL)	15/15	100	15/15	100	15/15	100	45/45	100	92.1 to 100
Negative	0/30	100	0/30	100	0/30	100	0/90	100	96.0 to 100
hMPV Positive Control	30/30	100	30/30	100	30/30	100	90/90	100	96.0 to 100
hMPV Negative Control	0/30	100	0/30	100	0/30	100	0/90	100	96.0 to 100

* An expected result for the high negative sample is a negative result.

The results suggest that there are no significant differences between different users and different sites on different days.

b. Linearity/assay reportable range:

Not applicable – This assay is qualitative.

510(k) Summary

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability:

Not applicable. This assay is qualitative.

Specimen Stability:

RSV (RSV A, A2 (VR-1540) and RSV B, Wash/18537/62 (VR-1580)) and hMPV (hMPV 16 Type A1, IA10-2003 and hMPV 5 Type B1, Peru3-2003) were formulated in six (6) transport media pooled negative matrix (Copan UTM, Remel M4, Remel M5, Remel M6, Remel M4RT or Copan ESwab transport media) at a final concentration of 2 to 3x LOD level.

The transport media systems containing the contrived samples were stored at 2° to 8°C up to 9 days or -70°C up to 5 weeks. The samples were processed per the instructions for use. Each transport media was tested in 3 replicates at Day 0, 24 hours, 48 hours, 72 hours, Day 7 and Day 9 for 2 to 8°C storage or Day 0, week 1, week 2, week 3, week 4 and week 5 for -70°C storage.

RSV and hMPV are stable in transport media BD UTM, Remel M4, Remel M4RT, Remel M5, Remel M6 and Copan eSwab at 2° to 8°C for up to 8 days and at -70°C for up to 10 weeks.

Controls:

Controls (Solana RSV+hMPV Control Set, which contains positive and negative controls and serves as an external processing control) were run on the Solana® RSV+hMPV Assay each day of testing. These controls are described as follows:

a. The process control is used to monitor sample processing, to detect HDA inhibitory specimens, to confirm the integrity of assay reagents and the operation of the Solana instrument. The process control is included in the Reaction Mix tube.

b. The external positive control may be treated as a patient specimen. The control should be sampled and tested as if it were a patient specimen and processed as described above in the Assay Procedure. The external positive control is intended to monitor substantial reagent and instrument failure.

c. The external negative control may be treated as a patient specimen. The control should be sampled and tested as if it were a patient specimen and processed as described above in the Assay Procedure. The external negative control is used to detect reagent or environmental contamination (or carry-over) by RSV and hMPV RNA or amplicon.

It is recommended that the reactivity of each new lot and each new shipment of the Solana RSV+hMPV Assay be verified on receipt and before use. External control tests should be performed thereafter in accordance with appropriate federal, state and local guidelines. The Solana RSV+hMPV Assay should not be used in patient testing if the external controls do not produce the correct results.

d. Detection limit:

The analytical sensitivity (limit of detection or LOD) of the Solana RSV+hMPV Assay was determined using quantified ($TCID_{50}$/mL) cultures of one RSV A, one RSV B, one hMPV A1, one hMPV A2, one hMPV B1 and one hMPV B2 strain, serially diluted in negative nasopharyngeal matrix. Each dilution was run as 20 replicates in the Solana RSV+hMPV assay. Analytical sensitivity (LOD) is defined as the lowest concentration at which at least 95% of all replicates tested positive. The demonstrated LOD for each strain tested is shown below:

Table 6.LOD Summary

Virus	$TCID_{50}$/mL
RSV	
RSV A, A2 (VR-1540)	$7.9x10^3$
RSV B, Wash/18537/62 (VR-1580)	$3.9x10^2$
hMPV	
hMPV 16 Type A1, IA10-2003	$3.7x10^2$
hMPV 20 Type A2 IA14-2003 G gene	$1.2x10^4$
hMPV 5 Type B1, Peru3-2003	$3.8x10^3$
hMPV 4 Type B2, Peru1-2002	$2.3x10^3$

e. Analytical specificity:

Cross Reactivity:

A study was performed to evaluate the cross-reactivity of the Solana RSV+hMPV Assay with forty-six (46) microorganisms (25 bacteria, 1 yeast, 20 viruses) potentially

found in specimens that are collected from patients symptomatic for RSV and/or hMPV. Each microorganism was diluted in negative nasal matrix to the desired concentration (10^6 or higher CFU/mL for bacteria, yeast and 10^5 or higher pfu/mL or $TCID_{50}$/mL for viruses) and tested with the Solana RSV+hMPV Assay. No cross reactivity was observed with the organisms at concentrations shown in the table below.

Table 7. Potential Cross-reactive Organisms

Organism	Concentration Tested	Units
Adenovirus 1	1.00E+05	$TCID_{50}$/mL
Adenovirus 11	1.00E+05	$TCID_{50}$/mL
Bordetella bronchiseptica	1.00E+06	CFU/mL
Bordetella pertussis	1.00E+06	CFU/mL
Candida albicans	1.00E+06	CFU/mL
Chlamydophila pneumoniae	1.00E+06	IFU/mL
Chlamydia trachomatis	1.00E+06	IFU/mL
Coronavirus 229E	1.00E+05	$TCID_{50}$/mL
Corynebacterium diptheriae	1.00E+06	CFU/mL
Coxsackievirus B5/10/2006	1.00E+05	$TCID_{50}$/mL
Cytomegalovirus (VR-977)	1.00E+05	TCID50/mL
Echovirus 11	1.00E+05	$TCID_{50}$/mL
Echovirus 6	1.00E+05	$TCID_{50}$/mL
Enterovirus, Type 71	1.00E+05	TCID50/mL
Epstein Barr virus	1.00E+05	$TCID_{50}$/mL
Escherichia coli	1.00E+06	CFU/mL
Haemophilus influenzae	1.00E+06	CFU/mL
HSV 2 G strain	1.00E+05	$TCID_{50}$/mL
hMPV Peru1-2002, B2[1]	1.00E+05	$TCID_{50}$/mL
Influenza A/Texas/50/2012	1.00E+05	$TCID_{50}$/mL
Influenza B/Panama/45/90	1.00E+05	$TCID_{50}$/mL
Klebsiella pneumoniae	1.00E+06	CFU/mL
Lactobacillus plantarum	1.00E+06	CFU/mL
Legionella pneumophila	1.00E+06	CFU/mL
Measles	1.00E+05	$TCID_{50}$/mL
Moraxella catarrhalis	1.00E+06	CFU/mL
Mumps	1.00E+05	$TCID_{50}$/mL

510(k) Summary

Table 7. Potential Cross-reactive Organisms		
Organism	**Concentration Tested**	**Units**
Mycobacterium avium	1.00E+06	CFU/mL
Mycobacterium tuberculosis	1.00E+06	CFU/mL
Mycoplasma pneumoniae	1.00E+06	CFU/mL
Neisseria gonorrhoeae	1.00E+06	CFU/mL
Neisseria meningitidis	1.00E+06	CFU/mL
Parainfluenza Type 1	1.00E+05	$TCID_{50}$/mL
Parainfluenza Type 2	1.00E+05	$TCID_{50}$/mL
Parainfluenza Type 3	1.00E+05	$TCID_{50}$/mL
Proteus mirabilis	1.00E+06	CFU/mL
Proteus vulgaris	1.00E+06	CFU/mL
Pseudomonas aeruginosa	1.00E+06	CFU/mL
Rhinovirus Type 7	1.00E+05	TCID50/mL
RSV A2 (VR-1540)[2]	1.00E+05	$TCID_{50}$/mL
Staphylococcus aureus	1.00E+06	CFU/mL
Staphylococcus epidermidis	1.00E+06	CFU/mL
Streptococcus mutans	1.00E+06	CFU/mL
Streptococcus pneumoniae	1.00E+06	CFU/mL
Streptococcus pyogenes	1.00E+06	CFU/mL
Streptococcus salivarius	1.00E+06	CFU/mL

[1]All three replicates tested positive for hMPV and negative for RSV in the Solana RSV+hMPV assay.
[2]All three replicates tested negative for hMPV and positive for RSV in the Solana RSV+hMPV assay

No cross-reactivity was observed with the forty-six (46) microorganisms (25 bacteria, 1 yeast, 20 viruses) tested with the Solana® RSV+hMPV Assay.

Interference:

The performance of Solana RSV+hMPV Assay was evaluated with twenty (20) potentially interfering substances that may be present in nasal and nasopharyngeal specimens. The potentially interfering substances were evaluated with RSV (RSV A, A2 (VR-1540) and RSV B, Wash/18537/62 (VR-1580)) and hMPV (hMPV 16 Type A1, IA10-2003 and hMPV 5 Type B1, Peru3-2003) at concentrations of 3x LOD. There was no evidence of interference caused by the substances tested at the concentrations shown below.

Table 8. Interfering Substances		
Substance	**Active Ingredient**	**Concentration Tested**

510(k) Summary

Table 8. Interfering Substances		
Substance	**Active Ingredient**	**Concentration Tested**
Purified mucin protein	Mucin protein	2.5 mg/mL
Blood (human)	Blood	5.0%
Afrin – nasal spray	Oxymetazoline	5.0%
Saline nasal spray	Sodium Chloride	15.0%
Neo-Synephrine	Phenylephrine hydrochloride	15.0%
Flonase	Fluticasone	5.0%
Zicam Gentle Allergy Relief NasalGel	*Galphimia glauca*, *Histaminum hydrochloricum*, *Luffa operculata*, Sulfur	5.0%
Bactroban	Mupirocin	12.0 mg/mL
TamiFlu	Oseltamivir	2.2 µg/mL
Relenza	Zanamivir	282.0 ng/mL
Tobramycin	Tobramycin Sulfate	2.5 mg/mL
Chloraseptic spray	Benzocaine, Menthol	0.68 g/mL
SYMMETREL®	Amantadine hydrochloride	282.0 ng/mL
Nasocort Allergy 24 hour	Triamcinolone	5.0%
Sinus Buster Nasal Spray	*Capsicum annuum* (Capsaicin)	5.0%
NasalCrom Nasal Allergy Spray	Cromolyn Sodium	5.0%
Rhinocort	Budesonide (Glucocorticoid)	5.0%
Air-Vita Allergy Multi-Symptom Relief	Allium cepa, Ambrosia artemisiaefolia, Apis mellifica, Chamomilla, Eucalyptol, Eucalyptus globulus, Euphrasia officinalis, Galphimia glauca, Histaminum hydrochloricum, Natrum muriaticum, Nux vomica, Quercus robur, Silicea, Wyethia helenioides	5.0%
Atrovent® Nasal Spray	Ipratropium bromide	10.0 mg/mL

Table 8. Interfering Substances		
Substance	**Active Ingredient**	**Concentration Tested**
Patanase Nasal Spray	Olopatadine hydrochloride	10.0 mg/mL

Analytical Reactivity (Inclusivity):

The reactivity of the Solana® RSV+hMPV Assay was evaluated against four (4) additional strains of RSV, which include two (2) RSV A and two (2) RSV B and four (4) additional strains of hMPV, which include one (1) each of hMPV A1, hMPV A2, hMPV B1 and hMPV B2 at concentrations near the level of detection (LOD) of the assay.

Table 9. Inclusivity Strains		
Strain	$TCID_{50}$/mL	Inclusive (Yes or No)
RSV		
RSV A, strain Long (VR-26)	$1.6x10^4$	Yes
RSV A, strain 4/2015 Isolate #1	$1.6x10^4$	Yes
RSV B, strain 9320 (VR-955)	$7.9x10^2$	Yes
RSV B, strain WV/14617/85 (VR-1400)	$7.9x10^2$	Yes
hMPV		
hMPV 9 Type A1, strain IA3-2002	$7.4x10^2$	Yes
hMPV 27 Type A2, strain IA27-2004	$2.4x10^4$	Yes
hMPV 3 Type B1, strain Peru2-2002	$7.6x10^3$	Yes
hMPV 18 Type B2, strain IA18-2003	$4.5x10^3$	Yes

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

510(k) Summary

3. Clinical studies:

a. Clinical Sensitivity:

Performance characteristics of the Solana RSV+hMPV Assay were established during a prospective study with specimens collected between January and May 2017. Two thousand sixty-four (2064) specimens prospectively collected specimens have been included in this study at six (6) sites across the United States. Specimens were tested fresh (773) or after freezing (1291) at -70°C. A single nasal or nasopharyngeal swab specimen (300 and 1760, respectively) was collected per patient in viral transport media (BD/Copan UTM, Remel M5, Remel M6). Four (4) of the fresh specimens were removed from the study due to protocol deviations (inappropriate specimen type). All specimens were transported to a central location for extraction with the NucliSENS® easyMAG® and testing with a FDA-cleared RSV+hMPV molecular assay. The specimens were processed and tested with Solana RSV+hMPV Assay (frozen (1291) and fresh (769)) on the Solana instrument at one of the six (6) sites.

COMPARISON WITH A FDA-CLEARED RSV+HMPV MOLECULAR ASSAY

Two thousand sixty (2060) specimens were processed using the NucliSENS® easyMAG® and tested with a FDA-cleared RSV+hMPV molecular assay per the assay's package insert.

Of 2060 specimens evaluated in the study, 769 specimens were tested fresh (nonfrozen) using the Solana RSV+hMPV Assay and the Lyra RSV+hMPV Assay for the presence of RSV and hMPV. One thousand two hundred ninety-one (1291) specimens were frozen after collection and stored at -70°C prior to testing with the Solana® RSV+hMPV Assay and the Lyra RSV+hMPV Assay for the presence of RSV and hMPV. Fourteen (14) specimens (9 fresh and 5 frozen) were invalid in the Solana® Assay when initially tested and upon repeat testing (invalid rate of 0.7%, with 95% CI 0.4% to 1.1%). These fourteen (14) specimens have been excluded from further analysis.

Table 10 details the positive percent agreement (PPA) and the negative percent agreement (NPA) of the Solana RSV+hMPV Assay results for RSV, as compared with an FDA cleared molecular comparator, for the remaining two thousand forty-six (2046) specimens.

510(k) Summary

Table 10. Percent Agreement of the Solana® RSV+hMPV Assay for RSV Compared to an FDA cleared RSV+hMPV Molecular Assay (Across all Sites Combined)							
Source Category	N	TP	FP	TN	FN	PPA (95% CI)	NPA (95% CI)
Fresh	760	12	0	747	1	92.3 (66.7 to 98.6)	100 (99.5 to 100)
Frozen	1286	136	1	1143	6	95.8 (91.1 to 98.0)	99.9 (99.5 to 100)
All	2046	148	1	1890	7	95.5 (91.0 to 97.8)	99.9 (91.0 to 97.8)

There were a total of eight (8) discordant specimens among the two thousand forty-six (2046) specimens evaluated. The one (1) discordant specimens (Solana Positive/Comparator Negative) reported in Table 10 was positive by an alternative FDA-cleared molecular device. Of the seven (7) discordant specimens (Solana Negative/ Comparator Positive) reported in Table 10, six (6) of these specimens were positive by an alternative FDA-cleared molecular device.

Table 11 details the positive percent agreement (PPA) and the negative percent agreement (NPA) of the Solana RSV+hMPV Assay results for hMPV, as compared with an FDA cleared molecular comparator, for the remaining two thousand forty-six (2046) specimens.

Table 11. Percent Agreement of the Solana® RSV+hMPV Assay for hMPV Compared to an FDA-cleared RSV+hMPV Molecular Assay (Across all Sites Combined)							
Source Category	N	TP	FP	TN	FN	PPA (95% CI)	NPA (95% CI)
Fresh	760	24	2	733	1	96.0 (80.5 to 99.3)	99.7 (99.0 to 99.9)
Frozen	1286	62	1	1220	3	95.4 (87.3 to 98.4)	99.9 (99.5 to 100)
All	2046	86	3	1953	4	95.6 (89.1 to 98.3)	99.8 (99.6 to 99.9)

There were a total of seven (7) discordant specimens among the two thousand forty-six (2046) specimens evaluated. Of the three (3) discordant specimens (Solana Positive/ Comparator Negative) reported in Table 11, all of these specimens were negative by an alternative FDA-cleared molecular device. Of the four (4) discordant specimens (Solana Negative/ Comparator Positive) reported in Table 11, all of these specimens were positive by an alternative FDA-cleared molecular device.

b. Clinical specificity:

See Section 3a**.**

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

510(k) Summary

4. Clinical cut-off**:**

Not applicable

5. Expected values:

The expected values of the Solana RSV+hMPV Assay were established during a prospective study conducted between January and May 2017. Two thousand sixty-four (2064) specimens (fresh (773) and frozen (1291)) have been included in this study at six (6) sites across the United States. Four (4) of the fresh specimens were removed from the study due to protocol deviations (inappropriate specimen type). A single specimen was collected per patient. The specimens were processed and tested with Solana RSV+hMPV Assay on the Solana instrument at the sites.

The expected value of RSV and hMPV with the Solana RSV+hMPV Assay has been calculated for the combined sites based on the age of the patient.

Eighteen (18) of the two thousand sixty-four (2064) specimens were removed from analysis: (four (4) specimens were removed from the study due to protocol deviations (inappropriate specimen type); fourteen (14) specimens were invalid). Table 12 provides the percentage of RSV and hMPV positive cases per specified age group, as determined by the Solana RSV+hMPV Assay, for the remaining two thousand forty-six (2046) specimens.

Table 12. Expected Values (N=2046) (January to May 2017)

Age Group	RSV			hMPV		
	Number of Patients	Number of Positives	Positive Detection rate	Number of Patients	Number of Positives	Positive Detection rate
<1 year	235	46	19.6%	235	15	6.4%
1 to 5 years	390	41	10.5%	390	30	7.7%
6 to 10 years	186	6	3.2%	186	11	5.9%
11 to 15 years	125	5	4.0%	125	4	3.2%
16 to 21 years	109	2	1.8%	109	0	0.0%
22 to 50 years	358	11	3.1%	358	11	3.1%
51 to 65 years	259	15	5.8%	259	7	2.7%
> 65 years	384	23	6.0%	384	11	2.9%
Combined Age Groups	2046	149	7.3%	2046	89	4.3%

N. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Instrument: Solana® Instrument

510(k) Summary

O. System Descriptions:

1. Modes of Operation:

The Solana instrument heats each reaction tube to 58°C. If present, the target RNA sequence is reverse transcribed into cDNA by the Reverse Transcriptase and RSV or hMPV specific primers that are present in the reaction mix. After the completion of the Reverse Transcriptase step, the Solana instrument heats each reaction tube to 65°C where the isothermal DNA polymerase amplifies the cDNA strands using the RSV or hMPV specific primers. RSV or hMPV specific fluorescence probes are also included in the Reaction Tube. The target probes are labeled with a quencher on one end and a fluorophore specific for the recognition sequence on the other end. In addition, the target probes carry a ribonucleic acid. Upon annealing to amplicons, the fluorescence probes are cleaved by RNaseH2 and the fluorescence signal increases due to physical separation of fluorophore from quencher. The Solana instrument measures and interprets the fluorescent signal, using on-board method-specific algorithms. Solana instrument will then report the test results to the user on its display screen, and it can print out the results via a printer.

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes ____X_____ No _____

P. Proposed Labeling:

The labeling satisfies the requirements of 21 CFR Part 809.10, 21 CFR 801.109, and the special controls.