July 15, 2018

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

Re: K181029
Trade/Device Name: Solana Bordetella Complete Assay
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory viral panel multiplex nucleic acid assay
Regulatory Class: Class II
Product Code: OZZ
Dated: April 17, 2018
Received: April 18, 2018

Dear Ronald 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 Part 801 and Part 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Steven R. Gitterman -S for

Uwe Scherf, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181029

Device Name

Solana® Bordetella Complete Assay

Indications for Use *(Describe)*

The Solana Bordetella Complete Assay is an in vitro diagnostic test for the qualitative detection of *Bordetella pertussis* and *Bordetella parapertussis* nucleic acids isolated from nasopharyngeal swab specimens obtained from patients suspected of having respiratory tract infection attributable to *Bordetella pertussis* and *Bordetella parapertussis*.

The Solana Bordetella Complete Assay is an HDA-based duplex assay that targets the IS481 and IS1001 sequence of *Bordetella pertussis* (BP) and *Bordetella parapertussis* (BPP) genomes, respectively. The IS481 sequence may also be found in strains of other organisms (i.e., *B. holmesii* and *B. bronchiseptica*). The IS1001 sequence may also be found in strains of other organisms (i.e., *B. bronchiseptica*). *B. holmesii* infection may cause clinical illness similar to *B. pertussis*, and mixed outbreaks involving both *B. pertussis* and *B. holmesii* infection have been reported. Additional testing should be performed if necessary to differentiate *B. holmesii* and *B. pertussis*. *B. bronchiseptica* is a rare cause of infection in humans. When clinical factors suggest that *B. pertussis* or *B. parapertussis* may not be the cause of respiratory infection, other clinically appropriate investigation(s) should be carried out in accordance with published guidelines.

Negative results for the Solana Bordetella Complete Assay do not preclude *B. pertussis* or *B. parapertussis* infection and positive results do not rule out co-infection with other respiratory pathogens. Results from the Solana Bordetella Complete Assay should be used in conjunction with information obtained during the patient's clinical evaluation as an aid in diagnosis of *B. pertussis* and or *B. parapertussis* infection and should not be used as the sole basis for treatment or other patient management decisions.

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:

Quidel Corporation
12544 High Bluff Drive, Suite 200
San Diego, California 92130
Telephone: 858-552-7910
Fax: 858-646-8045

Contact Information:

Ronald H. Lollar, Senior Director, Clinical and Regulatory Affairs
2005 East State Street, Suite 100
Athens, Ohio 45701
740-589-3300 – Corporate number
740-589-3373 – Desk phone
858-552-6451– Fax
Ron.Lollar@quidel.com

Date of preparation of 510(k) summary:

June 18, 2018

A. 510(k) Number:

K181029

B. Purpose for Submission:

To obtain substantial equivalence for the Solana® Bordetella Complete Assay when performed on the Solana® instrument

C. Measurand:

Bordetella pertussis: IS481 Insertional Element sequence;
Bordetella parapertussis: IS1001 Insertional Element sequence

D. Type of Test:

Helicase-Dependent Amplification (HDA)

510(k) Summary

E. Applicant:

Quidel Corporation

F. Proprietary and Established Names:

Solana® Bordetella Complete Assay

G. Regulatory Information:

Table 1. Regulatory Information			
Product Code	**Classification**	**Regulation Section**	**Panel**
OZZ	Class II	21 CFR 866.3980 Respiratory viral panel multiplex nucleic acid assay	Microbiology (83)

H. Intended Use:

1. Intended Use(s):

The Solana Bordetella Complete Assay is an *in vitro* diagnostic test for the qualitative detection of *Bordetella pertussis* and *Bordetella parapertussis* nucleic acids isolated from nasopharyngeal swab specimens obtained from patients suspected of having respiratory tract infection attributable to *Bordetella pertussis* and *Bordetella parapertussis*.

The Solana Bordetella Complete Assay is an HDA-based duplex assay that targets the IS481 and IS1001 sequence of *Bordetella pertussis* (BP) and *Bordetella parapertussis* (BPP) genomes, respectively. The IS481 sequence may also be found in strains of other organisms (i.e., *B. holmesii* and *B. bronchiseptica*). The IS1001 sequence may also be found in strains of other organisms (i.e., *B. bronchiseptica*). *B. holmesii* infection may cause clinical illness similar to *B. pertussis*, and mixed outbreaks involving both *B. pertussis* and *B. holmesii* infection have been reported. Additional testing should be performed if necessary to differentiate *B. holmesii* and *B. pertussis*. *B. bronchiseptica* is a rare cause of infection in humans. When clinical factors suggest that *B. pertussis* or *B. parapertussis* may not be the cause of respiratory infection, other clinically appropriate investigation(s) should be carried out in accordance with published guidelines.

510(k) Summary

Negative results for the Solana Bordetella Complete Assay do not preclude *B. pertussis* or *B. parapertussis* infection and positive results do not rule out co-infection with other respiratory pathogens. Results from the Solana Bordetella Complete Assay should be used in conjunction with information obtained during the patient's clinical evaluation as an aid in diagnosis of *B. pertussis* and or *B. parapertussis* infection and should not be used as the sole basis for treatment or other patient management decisions.

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 Bordetella Complete Assay amplifies, detects and differentiates DNA of *Bordetella pertussis* and *Bordetella parapertussis* from nasopharyngeal swabs.

The assay consists of two major steps: 1) specimen preparation, and 2) amplification and detection of target sequences specific to *B. pertussis* and *B. parapertussis* using isothermal Helicase-Dependent Amplification (HDA) in the presence of target-specific fluorescence probes.

A patient nasopharyngeal swab specimen in 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 HDA reagents, dNTPs, primers and probes. Once rehydrated with the processed sample, the Reaction Tube is placed in Solana for amplification and detection of *B. pertussis* and *B. parapertussis*-specific target sequences. In Solana, the target sequences are amplified by *B. pertussis* and *B. parapertussis* specific primers and detected by *B. pertussis* and *B. parapertussis*-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 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 have one or more bases that are comprised of ribonucleic acid. Upon annealing to *B. pertussis* and *B. parapertussis* 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 Bordetella Complete Assay Kit: M308
48 Tests per kit

Table 2. Kit Components

Component	Quantity	Storage
Process Buffer	48 tubes/kit, 1.45 mL	2°C to 8°C
Reaction Tubes	48 tubes/kit	2°C to 8°C

Materials required but not provided:

- External controls for *B. pertussis* and *B. parapertussis* (e.g. Quidel Molecular Bordetella Control Set, Cat. No. M117 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

510(k) Summary

J. Substantial Equivalence Information:

1. Predicate device name(s):

   ARIES Bordetella Assay

2. Predicate 510(k) number(s):
   K163626

3. Comparison with predicate:

Table 3. Similarities

Item	Solana® Bordetella Complete Assay	ARIES Bordetella Assay (k163626)
Intended Use	The Solana Bordetella Complete Assay is an in vitro diagnostic test for the qualitative detection of *Bordetella pertussis* and *Bordetella parapertussis* nucleic acids isolated from nasopharyngeal swab specimens obtained from patients suspected of having respiratory tract infection attributable to *Bordetella pertussis* and *Bordetella parapertussis*. The Solana Bordetella Complete Assay is an HDA-based duplex assay that targets the IS481 and IS1001 sequence of *Bordetella pertussis* (BP) and *Bordetella parapertussis* (BPP) genomes, respectively. The IS481 sequence may also be found in strains of other organisms (i.e., *B. holmesii* and *B. bronchiseptica*). The IS1001 sequence may also be found in strains of other organisms (i.e., *B. bronchiseptica*). *B. holmesii* infection may cause clinical illness similar to *B. pertussis*, and mixed outbreaks involving both *B. pertussis* and *B. holmesii* infection have been reported.	The ARIES Bordetella Assay is a real-time polymerase chain reaction (PCR) based qualitative in vitro diagnostic test for the direct detection and identification of *Bordetella pertussis* (*B. pertussis*) and *Bordetella parapertussis* (*B. parapertussis*) nucleic acid in nasopharyngeal swab (NPS) specimens obtained from individuals suspected of having a respiratory tract infection attributable to *B. pertussis* or *B. parapertussis*. The ARIES Bordetella Assay targets the *B. pertussis* toxin promoter and the *B. parapertussis* IS1001 insertion element in the genomes. When clinical factors suggest that *B. pertussis* or *B. parapertussis* may not be the cause of respiratory infection, other clinically appropriate investigation(s) should be carried out in accordance with published guidelines.

510(k) Summary

Table 3. Similarities		
Item	**Solana® Bordetella Complete Assay**	**ARIES Bordetella Assay (k163626)**
	Additional testing should be performed if necessary to differentiate *B. holmesii* and *B. pertussis*. *B. bronchiseptica* is a rare cause of infection in humans. When clinical factors suggest that *B. pertussis* or *B. parapertussis* may not be the cause of respiratory infection, other clinically appropriate investigation(s) should be carried out in accordance with published guidelines. Negative results for the Solana Bordetella Complete Assay do not preclude *B. pertussis* or *B. parapertussis* infection and positive results do not rule out co-infection with other respiratory pathogens. Results from the Solana Bordetella Complete Assay should be used in conjunction with information obtained during the patient's clinical evaluation as an aid in diagnosis of *B. pertussis* and or *B. parapertussis* infection and should not be used as the sole basis for treatment or other patient management decisions.	Negative results for the ARIES Bordetella Assay do not preclude *B. pertussis* or *B. parapertussis* infection and positive results do not rule out co-infections with other respiratory pathogens. The direct detection and identification of *B. pertussis* and *B. parapertussis* nucleic acids from symptomatic patients aids in the diagnosis of *B. pertussis* and *B. parapertussis* respiratory infection in conjunction with other clinical findings and epidemiological information. The ARIES Bordetella Assay is indicated for use with the ARIES Systems.
Sample Types	nasopharyngeal swab	Same

Table 4. Differences		
Item	**Solana® Bordetella Complete Assay**	**ARIES Bordetella Assay (k163626)**
Target	*Bordetella pertussis*: IS481 Insertional Element sequence; *Bordetella parapertussis*: IS1001 Insertional Element sequence	*Bordetella pertussis*: Toxin promoter (ptxA-pr); *Bordetella parapertussis*: IS1001 sequence
Amplification Technology	Helicase-Dependent Amplification (HDA)	Real Time PCR

Table 4. Differences		
Item	**Solana® Bordetella Complete Assay**	**ARIES Bordetella Assay (k163626)**
Detection Techniques	Different fluorescent reporter dyes for each target. Fluorescence Emissions and Detection	Different fluorescent reporter dyes for each target and melt analysis. Fluorescence Emissions and Detection
Extraction Methods	None	Automated by the ARIES Systems
Instrument	Solana®	ARIES Systems

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: 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 assay consists of two major steps: 1) specimen preparation, and 2) amplification and detection of target sequences specific to *B. pertussis* and *B. parapertussis* using isothermal

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

A patient nasopharyngeal swab specimen in transport media is transferred to a Process Buffer Tube, subjected to heat treatment at 95° ± 2°C for 5 minutes and mixed. The processed sample is transferred to a Reaction Tube. The Reaction Tube contains lyophilized HDA reagents, dNTPs, primers and probes. Once rehydrated with the processed sample, the Reaction Tube is placed in Solana for amplification and detection of *B. pertussis* and *B. parapertussis*-specific target sequences. In Solana, the target sequences are amplified by *B. pertussis* and *B. parapertussis* specific primers and detected by *B. pertussis* and *B. parapertussis*-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 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 have one or more bases that are comprised of ribonucleic acid. Upon annealing to *B. pertussis* and *B. parapertussis* 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 BP and BPP (two (2) strains of each organism) contrived samples and a negative contrived sample were tested in this study. BP A639 and BPP A747 (Set 1), or BP E431 and BPP E838 (Set 2) were diluted in negative nasal matrix to 2x LOD for moderate positive, 1x LOD for low positive and diluted to concentrations below the LOD (i.e., C_{20} to C_{80}) for high negative samples. Negative nasal matrix without spiked organism was used for the negative sample. Positive and negative controls were run in triplicate along with the panels.

510(k) Summary

The panels were run by two (2) operators at each testing site for five (5) non-consecutive days. The Solana Bordetella Complete Assay was used per the instructions for use.

Panels and controls were tested at each site by two (2) operators per instrument for five (5) days, each sample tested in three (3) replicates, for a total of 45 results per level for each organism 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*			
BP strain A639 High Negative[1] (103 CFU/mL)	7/15	46.6	7/15	46.6	6/15	40.0	20/45	44.4	30.9 to 58.8
BP strain A639 Low Positive (1025 CFU/mL)	15/15	100	15/15	100	15/15	100	45/45	100	92.1 to 100
BP strain A639 Moderate Positive (2050 CFU/mL)	15/15	100	15/15	100	15/15	100	45/45	100	92.1 to 100
BP strain E431 High Negative (86 CFU/mL)	4/15	26.7	10/15	66.7	7/15	46.6	21/45	46.7	32.9 to 60.9
BP strain E431 Low Positive (862 CFU/mL)	15/15	100	15/15	100	15/15	100	45/45	100	92.1 to 100
BP strain E431 Moderate Positive (1724 CFU/mL)	15/15	100	15/15	100	15/15	100	45/45	100	92.1 to 100
BPP strain A747 High Negative[1] (462 CFU/mL)	6/15	40.0	7/15	46.6	1/15	6.7	12/45	26.7	16.0 to 41.0
BPP strain A747 Low Positive (4622 CFU/mL)	15/15	100	15/15	100	15/15	100	45/45	100	92.1 to 100
BPP strain A747 Moderate Positive (9244 CFU/mL)	15/15	100	15/15	100	15/15	100	45/45	100	92.1 to 100
BPP strain E838 High Negative (553CFU/mL)	6/15	40.0	8/15	53.3	3/15	20.0	17/45	37.8	25.1 to 52.4
BPP strain E838	15/15	100	15/15	100	15/15	100	45/45	100	92.1 to 100

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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*			
Low Positive (5533 CFU/mL)									
BPP strain E838 Moderate Positive (11,066 CFU/mL)	15/15	100	15/15	100	15/15	100	45/45	100	92.1 to 100
Negative Sample	0/30	100	0/30	100	0/30	100	0/90	100	95.9 to 100
BP Positive Control	30/30	100	30/30	100	30/30	100	90/90	100	95.9 to 100
BPP Positive Control	30/30	100	30/30	100	30/30	100	90/90	100	95.9 to 100
Negative Control	0/30	100	0/30	100	0/30	100	0/90	100	95.9 to 100

[1] An expected result for the high negative sample is percent positivity between 20 and 80%.

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.

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

Traceability:

Not applicable. This assay is qualitative.

Specimen Stability:

Specimens can be stored at 2° to 8°C for up to 97 hours, up to 49 hours at 25°C before processing, or up tp 5-months at ≤ -70°C.

Swabs can be eluted in either saline (0.85%), Tris EDTA, Molecular Grade Water, Amies liquid media (i.e. E-Swab), or UTM, M4, M4-RT, or M6 viral transport media.

510(k) Summary

A series of analytical studies were performed evaluating a number of routinely used transport media at a volume of 3 mL: M4, M4-RT, and M5. Molecular Grade Water, Saline (0.9%), Tris-EDTA, Amies transport media (Eswab) were also evaluated.

No significant difference in assay performance was seen between the four different types of viral transport media, saline (0.85%), Tris EDTA, Molecular Grade Water, or Amies.

NOTE: The M4, M4-RT, and M5 were only validated analytically.

Controls:

Controls (Quidel Molecular Bordetella Control Set, which contains positive and negative controls and serves as an external processing control) were run on the Solana Bordetella Complete 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 Process Buffer tube.

b. The Quidel Molecular Bordetella 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 Quidel Molecular Bordetella 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 *B. pertussis* and *B. parapertussis* DNA or amplicon.

It is recommended that the reactivity of each new lot and each new shipment of the Solana Bordetella Complete 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 Bordetella Complete 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 Bordetella Complete Assay was determined using quantified (CFU/mL) cultures of two (2) BP strains (A639 and E431) and two (2) BPP strains (A747 and E838) serially diluted in a negative nasal matrix.

Target Type	Target	Validation Lot	Determined LOD	
			CFU/mL	CFU/Assay
Fresh Cells	BP Strain: A639	1	1025	1.71
		2	1025	1.71
		3	1025	1.71
	BP Strain: E431	1	863	1.44
		2	863	1.44
		3	863	1.44
	BPP Strain: A747	1	4622	7.70
		2	4622	7.70
		3	4622	7.70
	BPP Strain: E838	1	5533	9.22
		2	5533	9.22
		3	5533	9.22
Assay LOD: BP			1025	1.71
Assay LOD: BPP			5533	9.22

e. Analytical specificity:

Cross Reactivity:

A study was performed to determine if eighty-three (83) microorganisms or viruses likely to be present in specimens collected to test for *Bordetella pertussis* (BP) and *Bordetella parapertussis* (BPP) infection cross-react with the Solana Bordetella Complete Assay. The microorganisms were tested above clinically relevant levels (bacteria/yeast ≥ $1x10^6$ CFU/mL, viruses $1x10^5 TCID_{50}$/mL).

Table 6. Organism - Bacteria		
Acinetobacter baumanii	*Bordetella pertussis A639*	*Legionella pneumophilia*
Arcanobacterium haemolyticum	*Bordetella petrii*	*Moraxella catarrhalis*
Bacteroides fragilis	*Bordetella trematum*	*Morganella morganii*

510(k) Summary

Table 6. Organism - Bacteria		
Bordetella avium	*Burkholderia cenocepacia*	*Mycobacterium avium*
Bordetella bronchiseptica (ATCC 780)	*Burkholderia cepacia*	*Mycobacterium tuberculosis (avirulent)*
Bordetella bronchiseptica (ZeptoMetrix 801649)	*Burkholderia multivorans*	*Mycoplasma pneumoniae*
Bordetella bronchiseptica (ATCC 4617)	*Burkholderia thailandensis*	*Neisseria gonorrhoeae*
Bordetella bronchiseptica (ATCC 10580)	*Chlamydia trachomatis*	*Neisseria meningitidis*
Bordetella bronchiseptica (ATCC BAA-588)	*Chlamydophila pneumoniae*	*Neisseria mucosa*
Bordetella bronchiseptica (ATCC 785)	*Corynebacterium diptheriae*	*Parvimonas micra*
Bordetella bronchiseptica (ATCC 786)	*Enterobacter aerogenes*	*Proteus mirabilis*
Bordetella bronchiseptica (ATCC 14064)	*Enterococcus faecalis*	*Proteus vulgaris*
Bordetella hinzii	*Escherichia coli*	*Pseudomonas aeruginosa*
Bordetella holmesii (ZeptoMetrix F061)	*Fusobacterium necrophorum*	*Staphylococcus aureus (MRSA)*
Bordetella holmesii (ATCC 51541)	*Haemophilus influenzae*	*Staphylococcus epidermidis*
Bordetella holmesii (ATCC 700053)	*Klebsiella pneumoniae*	*Stenotrophomonas maltophilia*
Bordetella holmesii (ATCC 700052)	*Lactobacillus acidophilus*	*Streptococcus pneumoniae*
Bordetella parapertussis E838	*Lactobacillus plantarum*	*Streptococcus pyogenes*
		Streptococcus salivarius

Table 7. Organism -Yeast
Candida albicans

Table 8. Organism - Virus	
Adenovirus 31	HSV Type 2 G strain
Coronavirus 229E	Influenza A/Mexico/4108/2009
Coronavirus NL63	Influenza B/Florida/04/2006
Coronavirus OC43	Measles virus
Coxsackievirus B4	Metapneumovirus A1

Table 8. Organism - Virus	
Coxsackievirus B5/10/2006	Mumps virus
Echovirus 6	Parainfluenza Type 1 (#2)
Echovirus 7	Parainfluenza Type 2 (Greer)
Echovirus 9	Parainfluenza Type 3 (C234)
Echovirus 11	Parainfluenza Type 4 (VR-1377)
Enterovirus 70	Respiratory Syncytial Virus A
Enterovirus 71	Rhinovirus 1A
Epstein-Barr Virus	Varicella Zoster Virus
HSV Type 1 Maclnytre strain	

Five (5) non-BP organisms tested positive for BP. The five organisms include 4 of 4 *Bordetella holmesii* strains (ZeptoMetrix F061, ATCC 51541, ATCC 700053, and ATCC 700052) and 1 of 8 *Bordetella bronchiseptica* strains (ATCC 4617). Cross reactivity with these organisms is expected due to the presence of the BP target sequence, IS481, in the genomes of these organisms.

None of the potentially cross-reactive organisms tested positive for BPP.

High levels of BP did not generate any BPP-positive results, and high levels of BPP did not generate any BP-positive results, which indicate that the Solana Bordetella Complete Assay is specific for each target.

Interference:

The performance of Solana Bordetella Complete Assay was evaluated with sixteen (16) potentially interfering substances that may be present in specimens collected to test for *Bordetella pertussis* (BP) and *Bordetella parapertussis* (BPP) infection. The substances were diluted in negative nasal matrix and tested in the absence or presence of 2x LOD BP (Strain A639 2050 CFU/mL) and 2x LOD BPP (Strain E838 11066 CFU/mL) in the Solana Bordetella Complete Assay.

Table 9. Interfering Substances			
Substance	**Concentration Tested**	**Substance**	**Concentration Tested**
Cepacol Sore Throat Lozenges	5% w/v	Neo-Synephrine	15% v/v

Table 9. Interfering Substances			
Substance	**Concentration Tested**	**Substance**	**Concentration Tested**
Halls Cherry Menthol-Lyptus Cough Drops	15% w/v	Afrin Nasal Spray Original	15% v/v
Children's Dimetapp	15% v/v	Zicam Non-Drowsy Allergy Relief Nasal Gel	5% v/v
Chloraseptic Sore Throat Lozenges	10% w/v	Rite Aid Brand Saline Nasal Spray	15% v/v
Ricola Original Swiss Sugar-Free Herb Cough Suppressant Throat Drops	15% w/v	Zanamivir (Relenza)	5 mg/mL
Sucrets Complete Lozenges - Vapor Cherry	5% w/v	Tobramycin	4 µg/mL
Mucin (Bovine Submaxillary Gland, Type I-S)	5 mg/mL	Mupirocin	10 mg/mL
Human Blood, EDTA anticoagulated	5% v/v	Oseltamivir Phosphate (Tamiflu)	10 mg/mL

Negative sample testing in the presence of each of the sixteen (16) substances produced negative results for 3 of 3 replicates. BP+BPP sample testing at 2x LOD levels in the presence of each of the 16 substances produced BP and BPP positive results for 3 of 3 replicates. Based on these results, the 16 substances tested in this study are considered to not interfere with the Solana Bordetella Complete Assay.

Analytical Reactivity (Inclusivity):

The reactivity of the Solana Bordetella Complete Assay was evaluated against an additional eight (8) *Bordetella pertussis* (BP) and eight (8) *Bordetella parapertussis* (BPP) strains that were not used for LOD determination. The testing was performed at 1x LOD (1025 CFU/mL and 5533 CFU/mL, respectively) level of the assay. All additional sixteen (16) strains were detected in the Solana Bordetella Complete Assay.

Table 10. Analytical Sensitivity - Inclusivity	
BP Strains Detected at 1X LOD (1025 CFU/mL)	**BPP Strains Detected at 1X LOD (5533 CFU/mL)**
ATCC 9340	ZeptoMetrix C510
ATCC 9797	ZeptoMetrix E595
ATCC BAA-1335	ATCC 15311
ATCC BAA-589	ATCC 15989
ATCC 51445	ATCC 53892
ATCC 10380	ATCC 53893
ATCC 8478	ATCC BAA-587
ATCC 12743	ATCC 15237

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

A multi-center study was performed to evaluate the Solana Bordetella Complete Assay using nasopharyngeal swab specimens obtained from patients suspected of having respiratory tract infection attributable to *Bordetella pertussis* or *Bordetella parapertussis*. The study was performed during the Winter of 2017 to 2018 (October, 2017 to January, 2018) at one (1) internal and four (4) external sites in the United States. The study used seven hundred forty-one (741) fresh specimens at four (4) sites, and two hundred thirty-three (233) frozen archival specimens at four (4) sites.

Clinical performance was based on comparison of the Solana Bordetella Complete Assay results to those obtained by a Composite Reference Method that included two (2) manufacturer validated, IS481-targeted real-time PCR assays and bi-directional sequencing. The PCR assay protocols included 37 amplification cycles. S

Combined Fresh Specimen Data

Seven hundred forty-one (741) fresh nasopharyngeal swab specimens, obtained from female and male patients suspected of having respiratory tract infection attributable to *Bordetella pertussis* or *Bordetella parapertussis,* were prospectively collected and transported to each laboratory for testing with the Solana Bordetella Complete Assay. Four (4) specimens (0.5%) were invalid (in both the initial and repeat test) and have been removed from further analysis. The tables below present the data for the remaining seven hundred thirty-seven (737) specimens.

Table 11. Prospective Study: Combined Site Fresh Specimens - Composite Reference Method versus Solana Bordetella Complete Assay for *B. pertussis*

	Composite Reference Method		
Solana Bordetella Complete Assay	Positive	Negative	Total
Positive	11	3	14
Negative	0	723	723
Total	12	725	737
			95% CI
Positive Percent Agreement	11/11	100%	74.1% to 100%
Negative Percent Agreement	723/726	99.6%	98.8% to 99.9%

Table 12. Prospective Study:Combined Site Fresh Specimens - Composite Reference Method versus Solana Bordetella Complete Assay for *B. parapertussis*

	Composite Reference Method		
Solana Bordetella Complete Assay	Positive	Negative	Total
Positive	10	0	10
Negative	0	727	727
Total	10	727	737
			95% CI
Positive Percent Agreement	10/10	100%	72.2% to 100%
Negative Percent Agreement	727/727	100%	99.5% to 100%

510(k) Summary

Combined Frozen Archival Specimen Data

Two hundred thirty-three (233) selected frozen archival nasopharyngeal swab specimens were obtained from female and male patients previously tested for the presence of *Bordetella pertussis* or *Bordetella parapertussis.* The specimens were tested with the Solana Bordetella Complete Assay and the Composite Reference Method. The tables below present the data for the specimens.

Table 13. Combined Site Archival Specimens - Composite Reference Method versus Solana Bordetella Complete Assay for *B. pertussis*

	Composite Reference Method		
Solana Bordetella Complete Assay	Positive	Negative	Total
Positive	155	6	161
Negative	3	69	72
Total	158	75	233
			95% CI
Positive Percent Agreement	155/158	98.1%	94.6% to 99.4%
Negative Percent Agreement	69/75	92.0%	83.6% to 96.3%

Table 14. Combined Site Archival Specimens - Composite Reference Method versus Solana Bordetella Complete Assay for *B. parapertussis*

	Composite Reference Method		
Solana Bordetella Complete Assay	Positive	Negative	Total
Positive	12	3	15
Negative	0	218	218
Total	12	221	233
			95% CI
Positive Percent Agreement	12/12	100%	75.7% to 100%
Negative Percent Agreement	218/221	98.6%	96.1% to 99.5%

An additional study was performed to demonstrate the sensitivity of Solana Bordetella Complete Assay using three (3) levels of *Bordetella parapertussis* (BPP) (two (2) strains) in negative specimen matrix at two (2) testing locations. Each individual specimen was prepared using a unique negative NP specimen matrix.

Table 15. Contrived *Bordetella parapertussis* Panel Result Summary			
Panel Members	**# of Samples**	**BPP Concentrations**	**Results**
Negative	20	0	Negative: 100% (20/20)
BPP Low Positive	 10 10	**2.5X LOD** BPP A747 (1.2 x10^4 CFU/mL) BPP E838 (1.4 x10^4 CFU/mL)	 100% (10/10) 100% (10/10)
BPP Moderate Positive	 6 6	**10X LOD** BPP A747 (4.6 x10^4 CFU/mL) BPP E838 (5.5 x10^4 CFU/mL)	 100% (6/6) 100% (6/6)
BPP High Positive	 4 4	**100X LOD** BPP A747 (4.6 x10^5 CFU/mL) BPP E838 (5.5 x10^5 CFU/mL)	 100% (4/4) 100% (4/4)
Negative Control	6	**N/A**	0% (0/6)
BPP Positive Control	6	**N/A**	100% (6/6)

The Solana Bordetella Complete Assay demonstrate sensitivity to three (3) concentrations of *Bordetella parapertussis* (BPP) (two (2) strains). This observation is based on the following findings:

- All negative samples generated negative results for BPP.
- The detection percentage of BPP Low samples was 100% (10/10)
- The detection percentage of BPP Moderate samples was 100% (6/6).
- The detection percentage of BPP High samples was 100% (4/4).
- The Positive and Negative controls performed as expected:
  - The detection percentage of BPP in the positive control was 100% (6/6);
  - The detection percentage of BP and BPP in the negative control was 0% (0/6)

b. Clinical specificity:

See Section 3a.

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

Not applicable

4. Clinical cut-off:

Not applicable

510(k) Summary

5. Expected values:

The expected values of the Solana Bordetella Complete Assay were established during a prospective study conducted between October 2017 to January 2018. Seven hundred forty-one (741) fresh nasopharyngeal swab specimens, obtained from female and male patients suspected of having respiratory tract infection attributable to *Bordetella pertussis* or *Bordetella parapertussis*, were collected and transported to four (4) laboratory for testing with the Solana Bordetella Complete Assay. A single specimen was collected per patient.

The prevalence of *Bordetella pertussis* and *Bordetella parapertussis* detected with the Solana Bordetella Complete Assay has been calculated for the combined sites based on the age of the patient. Four (4) specimens (0.5%) were invalid (in both the initial and repeat test) and have been removed from the Expected Values table. The table below presents the data for the remaining seven hundred thirty-seven (737) specimens.

Table 16. Combined Fresh Specimen Study Expected Values (N=737)

		Bordetella pertussis		***Bordetella parapertussis***	
Age	Total #	Total Positive	Prevalence	Total Positive	Prevalence
≤ 2 years	241*	3	1.2%	4	1.7%
3 to 12 years	210**	4	1.9%	6	2.9%
13 to 21 years	102	6	5.9%	0	0.0%
≥ 22 years	184	1	0.5%	0	0.0%

* Two (2) specimens were invalid
** Two (2) specimens were invalid

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

Instrument: Solana® Instrument

O. System Descriptions:

1. Modes of Operation:

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.