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

October 25, 2016

QUIDEL CORPORATION
RONALD LOLLAR
SENIOR DIRECTOR, CLINICAL REGULATORY, SCIENTIFIC AFFAIRS
2005 EAST STATE STREET, SUITE 100
ATHENS OH 45701

Re: K162274
Trade/Device Name: Solana Strep Complete Assay
Regulation Number: 21 CFR 866.2680
Regulation Name: Streptococcus spp. nucleic acid-based assay
Regulatory Class: II
Product Code: PGX
Dated: August 10, 2016
Received: August 12, 2016

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,

Ribhi Shawar -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)*
K162274

Device Name
Solana® Strep Complete Assay

Indications for Use *(Describe)*
The Solana® Strep Complete Assay is a rapid in vitro diagnostic test, using isothermal amplification technology (helicase-dependent amplification, HDA), for the qualitative detection and differentiation of Streptococcus pyogenes (Group A β-hemolytic Streptococcus) and Streptococcus dysgalactiae (pyogenic Group C and G β-hemolytic Streptococcus) nucleic acids isolated from throat swab specimens obtained from patients with signs and symptoms of pharyngitis, such as sore throat. The Solana® Strep Complete Assay is intended for use only with the the Solana® instrument.

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:

August 10, 2016

A. 510(k) Number:

K162274

B. Purpose for Submission:

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

C. Measurand:

DNase B (*sdaB*) sequence of *Streptococcus pyogenes* (Group A Streptococcus)
Protein G gene of *Streptococcus dysgalactiae* (pyogenic Group C and G β-hemolytic Streptococcus)

D. Type of Test:

Helicase-dependent amplification (HDA)

510(k) Summary

E. Applicant:

Quidel Corporation

F. Proprietary and Established Names:

Solana® Strep Complete Assay

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
PGX – Groups A, C and G Beta-Hemolytic *Streptococcus* Nucleic Acid Amplification	Class II (Non-exempt)	21 CFR 866.2680 – *Streptococcus spp*. Nucleic Acid-Based Assay	Microbiology (83)

H. Intended Use:

1. Intended Use(s):

   The Solana® Strep Complete Assay is a rapid *in vitro* diagnostic test, using isothermal amplification technology (helicase-dependent amplification, HDA), for the qualitative detection and differentiation of *Streptococcus pyogenes* (Group A β-hemolytic Streptococcus) and *Streptococcus dysgalactiae* (pyogenic Group C and G β-hemolytic Streptococcus) nucleic acids isolated from throat swab specimens obtained from patients with signs and symptoms of pharyngitis, such as sore throat. The Solana® Strep Complete Assay is intended for use only with the Solana® instrument.

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

510(k) Summary

4. Special instrument requirements:

   Solana® instrument

I. Device Description:

The Solana Strep Complete Assay amplifies, detects and differentiates *Streptococcus pyogenes* DNA and *Streptococcus dysgalactiae* DNA present in throat swab specimens obtained from symptomatic patients.

The assay consists of two major steps: 1) specimen preparation, and 2) amplification and detection of target sequence specific to *S. pyogenes* (GAS) and *S. dysgalactiae* (C/G) using isothermal Helicase-Dependent Amplification (HDA) in the presence of target-specific fluorescence probe.

Patient specimen on a throat swab is transferred to a Lysis Tube and subjected to heat-treatment at 95±°C for 5 minutes. The heat-treated sample is added to a Dilution Tube, and then transferred to two Reaction Tubes, GAS Reaction Tube and Strep C/G Reaction Tube. GAS Reaction Tube contains white lyophilized HDA reagents, dNTPs, primers and probes specific for the amplification and detection of *S. pyogenes* target sequence, while C/G Reaction Tube contains blue lyophilized HDA reagents, dNTPs, primers and probes specific for the amplification and detection of *S. dysgalactiae* target sequence. Once rehydrated with the diluted sample, the Reaction Tubes are placed in a Solana Instrument for amplification and detection of the target sequences. In Solana, the target sequences are amplified by specific primers and detected by a specific fluorescence probe included in each Reaction Tube. Two competitive process controls (PRCs) are included in the Lysis Tube to monitor sample processing, inhibitory substances in clinical samples, reagent failure or device failure for each target. PRCs are amplified by the target-specific primers and detected by a PRC specific fluorescence probe.

The target and PRC probes are labeled with a quencher on one end and a fluorophore on the other end. Upon annealing to target or PRC amplicons, the fluorescence signal increases due to physical separation of the fluorophore from the quencher. Solana measures and interprets the fluorescent signal for each Reaction Tube, using on-board method-specific algorithms. Solana then reports the test results for each Reaction Tube to the user on its display screen, and optionally prints out the results via a printer.

510(k) Summary

Materials Provided:

- 48 Tests per Kit

Component	Quantity	Storage
Strep Complete Lysis Buffer	48 tubes/kit 0.5 mL	2°C to 8°C
Strep Dilution Buffer	48 tubes/kit 0.5 mL	2°C to 8°C
GAS Reaction Tubes	48 tubes/kit	2°C to 8°C
Strep C/G Reaction Tubes	48 tubes/kit	2°C to 8°C

Materials required but not provided:

- External controls for Group A Streptococcus (e.g. Quidel Molecular A + G Streptococci Control Set #M111, which contains positive and negative controls, serves as an external processing and extraction control)
- Sterile DNase-free filter-blocked or positive displacement micropipettor tips
- Micropipettor
- Stopwatch or timer
- Scissors or a blade
- Heat block capable of 95° C ± 2° C temperature
- Solana workflow tray and transfer rack
- Solana Instrument
- Thermometer

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Lyra® Direct Strep

2. Predicate 510(k) number(s):
   K133883

3. Comparison with predicate:

Similarities		
Item	**Solana® Strep Complete Assay**	**Lyra™ Direct Strep Assay (k133883)**
Intended Use	The Solana® Strep Complete Assay is a rapid *in vitro* diagnostic test, using	The Lyra Direct Strep Assay is a Real-Time PCR *in vitro* diagnostic test for

510(k) Summary

Similarities		
Item	**Solana® Strep Complete Assay**	**Lyra™ Direct Strep Assay (k133883)**
	isothermal amplification technology (helicase-dependent amplification, HDA), for the qualitative detection and differentiation of *Streptococcus pyogenes* (Group A β-hemolytic Streptococcus) and *Streptococcus dysgalactiae* (pyogenic Group C and G β-hemolytic Streptococcus) nucleic acids isolated from throat swab specimens obtained from patients with signs and symptoms of pharyngitis, such as sore throat. The Solana® Strep Complete Assay is intended for use only with the Solana® instrument.	the qualitative detection and differentiation of Group A β-hemolytic *Streptococcus* (*Streptococcus pyogenes*) and pyogenic Group C and G β-hemolytic *Streptococcus* nucleic acids isolated from throat swab specimens obtained from patients with signs and symptoms of pharyngitis, such as sore throat. The assay does not differentiate between pyogenic Groups C and G β-hemolytic *Streptococcus*. All negative test results should be confirmed by bacterial culture, because negative results do not preclude Group A, C or G Strep infection and should not be used as the sole basis for treatment. The assay is intended for use in hospital, reference, or state laboratory settings. The device is not intended for point-of-care use.

510(k) Summary

Similarities		
Item	**Solana® Strep Complete Assay**	**Lyra™ Direct Strep Assay (k133883)**
Sample Types	Throat swab specimens	Same
Sample Heat Lysis	Manual	Same
Detection Technique	Automatically detects fluorescence after dissociation of fluorophore from quencher during amplification	Same

Differences		
Item	**Solana® Strep Complete Assay**	**Lyra™ Direct Strep Assay (k133883)**
DNA Amplification Technology	Helicase-dependent amplification (HDA); self-contained	Real time polymerase chain reaction
Instrument	Solana™	ABI 7500 Fast DX Thermocycler
Target Sequence Detected	78 base pair (bp) sequence *S. pyogenes* genome, resident in the DNase B (*sdaB*) gene 67 base pair (bp) sequence Protein G gene of *S. dysgalactiae* (pyogenic Group C and G β-hemolytic Streptococcus)	GAS – 99bp product in the putative competence (*comX*1.1) gene Pyo GCS/GGS – 188bp product in the tagatose-6-phosphate kinase (*lacC*) gene

510(k) Summary

Differences		
Item	**Solana® Strep Complete Assay**	**Lyra™ Direct Strep Assay (k133883)**
Testing Time	25 minutes	60 -70 minutes
Clinical Sensitivity	GAS* Sensitivity: 98.8%[95% CI: 97.3% to 99.4%] Pyo GCS/GGS* *S. dysgalactiae* Sensitivity: 100%[95% CI: 95.3% - 100%]	GAS* Sensitivity: 96.5%[95% CI: 91.3% - 98.6%] Pyo GCS/GGS* Sensitivity: 95.7%[95% CI: 88.1% - 98.5%]
Clinical Specificity	GAS* Specificity: 98.9%[95% CI: 98.3% to 99.2%] Pyo GCS/GGS* *S. dysgalactiae* Specificity: 99.5%[95% CI: 99.1% - 99.7%]	GAS* Specificity: 98.0%[95% CI: 97.0% - 98.6%] Pyo GCS/GGS* Specificity: 98.3%[95% CI: 97.4% - 98.9%]

*GAS = Group A Streptococcus; Pyo GCS/GGS = Pyogenic Group C/G Streptococcus

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

Not applicable

L. Test Principle:

Patient specimen on a throat swab is transferred to a Lysis Tube and subjected to heat-treatment at 95°±2°C for 5 minutes. The heat-treated sample is added to a Dilution Tube, and then transferred to two Reaction Tubes, GAS Reaction Tube and Strep C/G Reaction Tube. GAS Reaction Tube contains white lyophilized HDA reagents, dNTPs, primers and probes specific for the amplification and detection of *S. pyogenes* target sequence, while C/G Reaction Tube contains blue lyophilized HDA reagents, dNTPs, primers and probes specific for the amplification and detection of *S. dysgalactiae* target sequence. Once rehydrated with the diluted sample, the Reaction Tubes are placed in a Solana Instrument for amplification and detection of the target sequences. In Solana, the target sequences are

amplified by specific primers and detected by a specific fluorescence probe included in each Reaction Tube. Two competitive process controls (PRCs) are included in the Lysis Tube to monitor sample processing, inhibitory substances in clinical samples, reagent failure or device failure for each target. PRCs are amplified by the target-specific primers and detected by a PRC specific fluorescence probe.

The target and PRC probes are labeled with a quencher on one end and a fluorophore on the other end. Upon annealing to target or PRC amplicons, the fluorescence signal increases due to physical separation of the fluorophore from the quencher. Solana measures and interprets the fluorescent signal for each Reaction Tube, using on-board method-specific algorithms. Solana then report the test results for each Reaction Tube to the user on its display screen, and optionally prints out the results via a printer.

M. Performance Characteristics:

1. Analytical performance:

   a. Precision/Reproducibility:

   Reproducibility

   In order to confirm the reproducibility of the Solana Strep Complete Assay a blinded and randomized study panel containing both *Streptococcus pyogenes* and *Streptococcus dysgalactiae* negative and positive samples (3x, 1x, 0.3x LOD) were tested at three (3) test sites (one in-house laboratory and two (2) clinical sites) with three (3) instruments. Each site tested a reproducibility panel and Assay Controls for five (5) days in triplicate. Testing was done by two operators at each site. Each operator ran the panel once a day using one lot of Solana Strep Complete Assay. A total of five hundred forty (540) specimens were tested (including controls). The Solana Strep Complete Assay generated reproducible results in this study.

510(k) Summary

***Streptococcus pyogenes* Category**	**SITE**						**Overall Percent Positive**		**95% Confidence Interval**
	Site #1		**Site #2**		**Site #3**				
	Detected: #positive /# tested	*% Positive*	*Detected: #positive /# tested*	*% Positive*	*Detected: #positive /# tested*	*% Positive*			
GAS High Negative	13/30	43%	10/30	33%	13/30	43%	36/90	40%	27% to 47%
GAS Low Positive	30/30	100%	30/30	100%	30/30	100%	90/90	100%	96% to 100%
GAS Moderate Positive	30/30	100%	30/30	100%	30/30	100%	90/90	100%	96% to 100%
GAS Negative	0/30	0%	0/30	0%	0/30	0%	0/90	0%	0% to 4%
GAS Positive Control	30/30	100%	30/30	100%	30/30	100%	90/90	100%	96% to 100%
GAS Negative Control	0/30	100%	0/30	0%	0/30	100%	0/90	0%	0% to 4%

***Streptococcus dysgalactiae* Category**	**SITE**						**Overall Percent Positive**		**95% Confidence Interval**
	Site #1		**Site #2**		**Site #3**				
	Detected: #positive /# tested	*% Positive*	*Detected: #positive /# tested*	*% Positive*	*Detected: #positive /# tested*	*% Positive*			
C/G High Negative	10/30	33%	6/30	20%	5/30	17%	21/90	23%	16% to 33%
C/G Low Positive	30/30	100%	30/30	100%	30/30	100%	90/90	100%	96% to 100%
C/G Moderate Positive	30/30	100%	30/30	100%	30/30	100%	90/90	100%	96% to 100%
C/G Negative	0/30	0%	0/30	0%	0/30	0%	0/90	0%	0% to 4%
C/G Positive Control	30/30	100%	30/30	100%	30/30	100%	90/90	100%	96% to 100%
C/G Negative Control	0/30	100%	0/30	0%	0/30	100%	0/90	0%	0% to 4%

The results suggest that there are no significant differences between different users using different instruments at 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.

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Specimen Stability:

A study was performed to determine the stability of samples collected in a number of routinely used swab systems: nylon flocked swabs in Amies media, Rayon swab in Amies media, polyester swab in Amies media, Rayon swab in Stuart media, polyester swab in Stuart media, and Rayon in Amies gel.

Freshly grown stocks of *Streptococcus pyogenes* and *Streptococcus dysgalactiae,* of known titer, were used to spike the swabs listed above. The spiked samples were stored at 25°C ± 2°C for 2 days and then at 2° to 8°C for up to 6 more days prior to being tested in the Solana® Strep Complete Assay. A separate study was performed where the spiked samples were stored at ≤-15°C or ≤-70°C for a minimum of 32 days before testing.

Based on this study, specimens collected using various collection/transport systems listed above can be stored at 25°C ± 2°C for 2 days and then at 2 to 8°C for up to 6 more days before testing or at ≤-15°C or ≤-70°C for up to 32 days before testing.

Controls:

External Controls (Quidel Molecular A + G Streptococci Control Set #M111, which contains positive and negative controls, serves as an external processing and extraction control) were run on the Solana® Strep Complete Assay each day of testing.

The assay controls are described as follows:

a. The *process control* is used to monitor sample processing, to detect HDA inhibitory specimens and to confirm the integrity of assay reagents and Solana instrument functionality. The process control is included in the Lysis Buffer 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 specimen and processed as described in the Assay Procedure. The external positive control is intended to monitor substantial reagent and instrument failure.

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

d. Detection limit:

The analytical sensitivity (limit of detection or LOD) of the Solana® Strep Complete Assay was determined using quantified (CFU/mL) cultures of two (2) *Streptococcus pyogenes* and two (2) *Streptococcus dysgalactiae* strains by serially dilution. Analytical sensitivity (LOD) is defined as the lowest concentration at which 95% of all replicates tested positive.

The LOD for the two (2) *Streptococcus pyogenes* strains tested were $1.5x10^4$ CFU/mL (ATCC #19615) and $8.5x10^4$ CFU/mL (ATCC #12344). The LOD for the two (2) *Streptococcus dysgalactiae* strains were $5.7x10^5$ CFU/mL (ATCC #12394) and $7.1x10^5$ CFU/mL (ATCC #10009).

Based on this data the reported LOD for *Streptococcus pyogenes* and *Streptococcus dysgalactiae* using the Solana® Strep Complete Assay is $8.5x10^4$ CFU/mL and $7.1x10^5$ CFU/mL, respectively.

e. Analytical specificity:

Cross Reactivity:

An *in silico* BLAST analysis of primers used in the Solana® Strep Complete Assay against sixty-one (61) potential interfering organisms (see below) did not show evidence of cross-reactivity.

Arcanobacterium sp.	Human adenovirus F	*Lactobacillus* sp.[1]
Bacillus sp.	Human adenovirus G	*Legionella pneumophila*
Bacteroides sp.[2]	Human coronavirus 229E	Measles virus
Bordetella sp.	Human coronavirus HKU1	Human Metapneumovirus

[1] Includes *L. acidophilus*
[2] Includes *B. ovatus*

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Branhamella sp.	Human coronavirus NL63	*Moraxella* sp.
Burkholderia sp.	Human enterovirus A	Mumps virus
Campylobacter sp.[3]	Human enterovirus B	*Mycoplasma pneumoniae*
Candida sp.	Human enterovirus C	*Neisseria* sp.
Corynebacterium sp.	Human enterovirus D	*Peptostreptococcus* sp.
Cytomegalovirus	Human herpesvirus 1	*Proteus* sp.
Enterobacterio phage MS2	Human herpesvirus 2	*Pseudomonas* sp.
Enterococcus sp.	Human herpesvirus 4	Respiratory syncytial virus Type B
Escherichia coli	Human parainfluenza virus 1	*Saccharomyces cerevisiae*
Fusobacterium sp.	Human parainfluenza virus 2	*Serratia* sp.
Haemophilus sp.	Human parainfluenza virus 3	*Staphylococcus* sp.
Human adenovirus A	Human parainfluenza virus 4a and 4b	*Treponema* sp.
Human adenovirus B	Influenza virus A	*Veillonella* sp.
Human adenovirus C	Influenza virus B	*Yersinia* sp.
Human adenovirus D	Influenza virus C	*Prevotella oralis*[4]
Human adenovirus E	*Klebsiella* sp.	*Parvimonas micra*[5]
Veillonella parvula		

A study was performed to evaluate the performance of the Solana® Strep Complete Assay in the presence of forty-five (45) microorganisms commonly found in throat specimens. Each potentially interfering microorganism was tested in the presence of 2 x LOD *Streptococcus pyogenes* and *Streptococcus dysgalactiae* (2 strains each) in the presence of clinically relevant levels of viruses (10^5pfu/ml) and bacteria (10^6cfu/mL) or higher. All strain combinations were spiked on to swabs. The strains included in the cross-reactivity study are shown in the table below.

Acinetobacter lwoffii	*Staphylococcus epidermidis* MRSE
Arcanobacterium haemolyticum	*Stenotrophomonas maltophilia*
Bacillus cereus	*Streptococcus agalactiae*
Bordetella pertussis	*Streptococcus anginosus*

[3] Includes *C. rectus*
[4] In NCBI, *Bacteroides oralis* is *Prevotella oralis*.
[5] In NCBI, *Peptostreptococcus micros* is *Parvimonas micra*.

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Burkholderia cepacia	*Streptococcus bovis*
Corynebacterium diphtheria	*Streptococcus canis*
Enterococcus faecalis	*Streptococcus gordonii (Virdans type)*
Escherichia coli	*Streptococcus intermedius*
Fusobacterium necrophorum	*Streptococcus mitis*
Haemophilus influenza type A	*Streptococcus mutans*
Klebsiella pneumonia	*Streptococcus oralis*
Lactobacillus acidophilus	*Streptococcus pneumoniae*
Lactococcus lactis	*Streptococcus salivarius*
Legionella jordanis	*Streptococcus sanguinis*
Legionella micdadei	*Streptococcus suis*
Legionella pneumophila	*Candida albicans*
Moraxella cartarrhalis	Adenovirus Type 1
Neisseria gonorrhoeae	Adenovirus Type 11 (Slobitski)
Neisseria subflava	Influenza A
Peptostreptococcus micros (aka Parvimonas micra)	Influenza B
Pseudomonas aeruginosa	Parainfluenza Type 4B (VR-1377)
Serratia marcescens	Rhinovirus Type 15 (1734)
Staphylococcus aureus MRSA	

Of the 45 microorganisms tested that might be found in throat specimens, *Klebsiella pneumoniae, Serratia marcescens* and *Enterococcus faecalis* each cross-reacted once out of six times tested (triplicate testing was repeated for each cross-reactive strain) with the Solana® Strep Complete Assay.

Interference:

A study was conducted using two strains of *Streptococcus pyogenes* (ATCC 19615 and 12344) and *Streptococcus dysgalactiae* strains (ATCC 12394 and ATCC 10009) tested near LOD to evaluate the Solana® Strep Complete Assay for potential interference using a panel consisting of twenty-eight (28) common biological and chemical substances found in throat samples. Substances were introduced into the swabs at concentrations which were medically relevant. Each of the strains was tested for each substance. None of the substances tested were found to interfere with the Solana® Strep Complete Assay.

510(k) Summary

Substance Name	Test Concentration	Interference? (Y/N)
Children's Dimetapp DM Cold & Cough Elixir	25% v/v	No
Chloraseptic Max: Sore Throat Relief	10% v/v	No
BreathSavers 3 Hour Mint-Spearmint	10% w/v	No
Cepacol Sore Throat: Cherry Flavor	5% w/v	No
Robitussin Cough & Cold-CF Max	10% v/v	No
Ricola Mountain Herb Throat Drops-Sugar Free	15% w/v	No
Human Saliva	10% v/v	No
Robitussin Nighttime Cold, & Flu	10% v/v	No
Crest Pro-Health Night Mint	25% v/v	No
CVS Tussin CF	15% v/v	No
Chloraseptic Throat Cherry lozenge	10% w/v	No
Halls Cherry Mentholyptus	15% w/v	No
Tic Tac Freshmints	10% w/v	No
Zicam® Oral Mist	0.625% v/v	No
Sucrets Complete-Vapor Cherry	5% w/v	No
Acetaminophen	19.5 mg/mL	No
Aspirin	12.3 mg/mL	No
Ibuprofen	15.6 mg/mL	No
Benadryl	2.7 mg/mL	No
Crest® Complete Toothpaste	5% w/v	No
Contac® Cold + Flu Caplets Night	10% w/v	No
Children's Wal-Tap Elixir Cold & Allergy (Dimetap Children's Cold and Allergy)	25% v/v	No
Children's Wal-Tap DM Elixir Cold & Cough	25% v/v	No
Robitussin Nighttime Cough, Cold, & Flu (peak cold)	10% v/v	No
Halls Mentholyptus (not cherry flavor)	15% w/v	No
Listerine Cool Mint Antiseptic	15% v/v	No
Whole Blood	5% v/v	No
Mucin (Bovine Submaxillary Gland, type I-S)	5.0 mg/mL	No

510(k) Summary

Analytical Reactivity (Inclusivity):

The inclusivity of the Solana® Strep Complete Assay was further evaluated by functional testing of organisms in addition to those strains used in the LOD study. Seven (7) strains of *Streptococcus pyogenes* (GAS) and twenty five (25) *Streptococcus dysgalactiae* (C/G) strains were tested at concentrations at a LOD of $8.5x10^4$ CFU/mL and $7.1x10^5$ CFU/mL, respectively.

Bacterial species	Bacterial Strain	Concentration CFU/mL	Strain Detected (Yes/No)
Streptococcus pyogenes	ATCC 12384	$8.5x10^4$	Yes
Streptococcus pyogenes	NCIMB 13285	$8.5x10^4$	Yes
Streptococcus pyogenes	CCUG 33061	$8.5x10^4$	Yes
Streptococcus pyogenes	CCUG 33409	$8.5x10^4$	Yes
Streptococcus pyogenes	CCUG 39158	$8.5x10^4$	Yes
Streptococcus pyogenes	ATCC 49399	$8.5x10^4$	Yes
Streptococcus pyogenes	CCUG 53553	$8.5x10^4$	Yes
S. dysgalactiae subspecies equisimilis group G	ATCC 6644	$7.1x10^5$	Yes
S. dysgalactiae subspecies equisimilis group C	ATCC 9542	$7.1x10^5$	Yes
S. dysgalactiae subspecies equisimilis group C	ATCC 12388	$7.1x10^5$	Yes
S. dysgalactiae subspecies equisimilis group C	ATCC 35666	$7.1x10^5$	Yes
S. dysgalactiae subspecies equisimilis group G	CCUG 502	$7.1x10^5$	Yes
S. dysgalactiae subspecies equisimilis group C	CCUG 1483	$7.1x10^5$	Yes
S. dysgalactiae subspecies equisimilis group C	CCUG 6713	$7.1x10^5$	Yes
S. dysgalactiae subspecies equisimilis group G	CCUG 15679	$7.1x10^5$	Yes
S. dysgalactiae subspecies equisimilis group G	CCUG 15680	$7.1x10^5$	Yes
S. dysgalactiae subspecies equisimilis group G	CCUG 21557	$7.1x10^5$	Yes
S. dysgalactiae subspecies equisimilis group G	CCUG 24070	$7.1x10^5$	Yes
S. dysgalactiae subspecies equisimilis group G	CCUG 26147	$7.1x10^5$	Yes
S. dysgalactiae subspecies equisimilis group G	CCUG 27477	$7.1x10^5$	Yes
S. dysgalactiae subspecies equisimilis group C	CCUG 27479	$7.1x10^5$	Yes
S. dysgalactiae subspecies equisimilis group C	CCUG 27480	$7.1x10^5$	Yes
S. dysgalactiae subspecies equisimilis group G	CCUG 27482	$7.1x10^5$	Yes
S. dysgalactiae subspecies equisimilis group G	CCUG 27483	$7.1x10^5$	Yes
S. dysgalactiae subspecies dysgalactiae group C	CCUG 27658	$7.1x10^5$	Yes
S. dysgalactiae subspecies dysgalactiae group C	CCUG 27659	$7.1x10^5$	Yes
S. dysgalactiae subspecies dysgalactiae group C	CCUG 27664	$7.1x10^5$	Yes
S. dysgalactiae subspecies dysgalactiae group C	CCUG 28115	$7.1x10^5$	Yes
S. dysgalactiae subspecies dysgalactiae group C	CCUG 28116	$7.1x10^5$	Yes
S. dysgalactiae subspecies equisimilis group C	CCUG 28238	$7.1x10^5$	Yes
S. dysgalactiae subspecies equisimilis group G	CCUG 33802	$7.1x10^5$	Yes
S. dysgalactiae subspecies dysgalactiae group C	CCUG 48477	$7.1x10^5$	Yes

f. Assay cut-off:

Not applicable.

510(k) Summary

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

A comparison study was conducted between negative clinical matrix and the contrived negative matrices used in the analytical studies in order to validate their use. The matrix comparison study results are shown in the table below.

		Contrived Negative Matrix		Pooled Negative Clinical Matrix	
		Detected	% Pos	Detected	% Pos
Streptococcus pyogenes ATCC 19615	1 x LOD	20/20	100%	20/20	100%
Streptococcus dysgalactiae ATCC 12394	1 x LOD	20/20	100%	20/20	100%

These studies demonstrate that the contrived negative matrices do not alter the performance of the device in the context of these analytical studies.

3. Clinical studies:

a. Clinical Sensitivity:

Performance characteristics of the Solana Strep Complete Assay were established during a prospective study during the winter through summer of 2016 (February to July). Two thousand six hundred eighty-eight (2688) fresh throat swab specimens were included in this study at four (4) external and one (1) internal laboratories across the United States using the same swab that was plated for the culture. A single specimen was collected per patient. Samples were collected on Polyester or Rayon Swab with liquid Amie's, Polyester Swab or Rayon swab with liquid Stuart's or nylon swab with liquid Amies.

510(k) Summary

A composite result of directly cultured patients' throat swabs combined with the culture. Cultured isolates were typed by latex agglutination. β-hemolytic isolates that were typed as Group C or G were subcultured and the species were determined using an FDA-cleared MALDI TOF assay. Swab transport fluid was also tested using another FDA cleared nucleic acid amplification test (NAAT) and cultured at a central reference laboratory. Results from culture and NAAT were used to calculate assay sensitivity and specificity. Each site cultured the swabs prior to performing the Solana Strep Complete Assay. The swab specimens were processed and tested with Solana Strep Complete Assay. The leftover swab transport media was shipped to the central location for an additional culture and NAAT testing.

A specimen was recorded as positive for either *Streptococcus pyogenes* or *Streptococcus dysgalactiae* if either the culture or the FDA-cleared NAAT was positive, respectively.

Two thousand six hundred eighty-eight (2688) fresh throat swab specimens were tested using the algorithm described above (dual culture, FDA-cleared NAAT and Solana Strep Complete Assay). Two (2) specimens were repeatedly invalid when tested with the Solana® Strep Complete Assay (0.07%). These specimens have been removed from additional analysis. The table below details the combined results for *Streptococcus pyogenes* for the remaining two thousand six hundred eighty-six (2686).

Combined Clinical Sites' Results for *Streptococcus pyogenes*			
	Combined Culture and NAAT Result		
Solana Strep Complete Assay	Positive	Negative	Total
Positive	475	25	500
Negative	6	2180	2186
Total	481	2205	2686
			95% CI
Sensitivity	475/481	98.8%	97.3% to 99.4%
Specificity	2180/2205	98.9%	98.3% to 99.2%
Site 1- *Streptococcus pyogenes* Results			
	Combined Culture and NAAT Result		
Solana® Strep Complete Assay	Positive	Negative	Total
Positive	90	4	94
Negative	2	679	681
Total	92	683	775
			95% CI
Sensitivity	90/92	97.8%	92.4% to 99.4%

510(k) Summary

Specificity	679/683	99.4%	98.5% to 99.8%
Site 2 - *Streptococcus pyogenes* Results			
	Combined Culture and NAAT Result		
Solana® Strep Complete Assay	Positive	Negative	Total
Positive	84	6	90
Negative	1	510	511
Total	85	516	601
			95% CI
Sensitivity	84/85	98.8%	93.6% to 99.8%
Specificity	510/516	98.8%	97.5% to 99.5%
Site 3- *Streptococcus pyogenes* Results			
	Combined Culture and NAAT Result		
Solana® Strep Complete Assay	Positive	Negative	Total
Positive	100	3	103
Negative	3	492	495
Total	103	495	598
			95% CI
Sensitivity	100/103	97.1	91.8% to 99.0%
Specificity	492/495	99.4%	98.2% to 99.8%
Site 4- *Streptococcus pyogenes* Results			
	Combined Culture and NAAT Result		
Solana® Strep Complete Assay	Positive	Negative	Total
Positive	83	12	95
Negative	0	254	254
Total	83	266	349
			95% CI
Sensitivity	83/83	100%	95.6% to 100%
Specificity	254/266	95.5%	92.3% to 97.4%
Site 5- *Streptococcus pyogenes* Results			
	Combined Culture and NAAT Result		
Solana® Strep Complete Assay	Positive	Negative	Total
Positive	118	0	118
Negative	0	245	245
Total	118	245	363
			95% CI
Sensitivity	118/118	100%	96.8% to 100%
Specificity	245/245	100%	98.5% to 100%

Two thousand six hundred eighty-eight (2688) fresh throat swab specimens were tested using the algorithm described above (dual culture, FDA-cleared NAAT and Solana Strep

510(k) Summary

Complete Assay). Two (2) specimens were repeatedly invalid when tested with the Solana® Strep Complete Assay (0.07%). The table below details the combined results for *Streptococcus dysgalactiae* for the remaining two thousand six hundred eighty-six (2686).

Combined Clinical Sites' Results for *Streptococcus dysgalactiae*			
	Combined Culture and NAAT Result		
Solana® Strep Complete Assay	Positive	Negative	Total
Positive	78	14	92
Negative	0	2594	2594
Total	78	2608	2686
			95% CI
Sensitivity	78/78	100%	95.3% to 100%
Specificity	2594/2608	99.5%	99.1% to 99.7%
Site 1 - *Streptococcus dysgalactiae* Results			
	Combined Culture and NAAT Result		
Solana® Strep Complete Assay	Positive	Negative	Total
Positive	32	4	36
Negative	0	739	739
Total	32	743	775
			95% CI
Sensitivity	32/32	100%	89.3% to 100%
Specificity	739/743	99.5	98.6% to 99.8%
Site 2 - *Streptococcus dysgalactiae* Results			
	Combined Culture and NAAT Result		
Solana® Strep Complete Assay	Positive	Negative	Total
Positive	16	5	21
Negative	0	580	580
Total	16	585	601
			95% CI
Sensitivity	16/16	100%	80.6% to 100%
Specificity	580/585	99.1%	98.0% to 99.6%
Site 3- *Streptococcus dysgalactiae* Results			
	Combined Culture and NAAT Result		
Solana® Strep Complete Assay	Positive	Negative	Total
Positive	26	4	30
Negative	0	568	568
Total	26	572	598
			95% CI

510(k) Summary

Sensitivity	26/26	100%	87.1% to 100%
Specificity	568/572	99.3%	98.2% to 99.7%
Site 4- *Streptococcus dysgalactiae* Results			
	Combined Culture and NAAT Result		
Solana® Strep Complete Assay	Positive	Negative	Total
Positive	2	0	2
Negative	0	347	347
Total	2	347	349
			95% CI
Sensitivity	2/2	100%	34.2% to 100%
Specificity	347/347	100%	98.9% to 100%
Site 5- *Streptococcus dysgalactiae* Results			
	Combined Culture and NAAT Result		
Solana® Strep Complete Assay	Positive	Negative	Total
Positive	2	1	3
Negative	0	360	360
Total	2	361	363
			95% CI
Sensitivity	2/2	100%	34.2% to 100%
Specificity	360/361	99.7%	98.4% to 100%

All pyogenic Group C and Group G streptococcal species found during this assay were Group C and G *S. dysgalactiae.*

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

5. Expected values:

The prevalence of *Streptococcus pyogenes* (Group A β-hemolytic Streptococcus) and *Streptococcus dysgalactiae* (pyogenic Group C and G β-hemolytic Streptococcus) with the Solana Strep Complete Assay has been calculated based on the age of the patient.

510(k) Summary

Two (2) specimens were invalid when tested with the Solana® Strep Complete Assay (0.07%) (in both the initial and repeat test no process control was detected) and have been removed from the Expected Values table. The table below presents the data for the remaining two thousand six hundred eighty-six (2686) specimens.

The overall incidence of *Streptococcus pyogenes* or *Streptococcus dysgalactiae* in patients tested during this study based on culture results alone was 16.0% (431/2686) for *Streptococcus pyogenes* and 2.4%(65/2686) for *Streptococcus dysgalactiae*. The overall incidence of *Streptococcus pyogenes* or *Streptococcus dysgalactiae* in patients tested during this study based on a combination of culture results and another FDA-cleared NAAT assay was 17.9% (481/2686) for *Streptococcus pyogenes* and 2.9% (78/2686) for *Streptococcus dysgalactiae*.

Combined Study Prevalence (2686)						
Age	*Streptococcus pyogenes*			*Streptococcus dysgalactiae*		
	Total #	Total Positive	Prevalence	Total #	Total Positive	Prevalence
≤ 2 years	158	11	7.0%	158	3	1.9%
3 to 12 years	1189	336	28.3%	1189	12	1.0%
13 to 21 years	556	50	9.0%	556	38	6.8%
≥ 22 years	783	103	13.2%	783	39	5.0%
Overall	2686	481	17.9%	2686	78	2.9%

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:

The Solana instrument heats each reaction tube to 64°C. If present, the target sequence is amplified by *S. pyogenes* and/or *S. dysgalactiae* specific primers and detected by *S. pyogenes* and/or *S. dysgalactiae* specific fluorescence probes included in the Reaction Tube. Each probe has a florescent dye of specific wavelength. The target probes are labeled with a quencher on one end and a fluorophore on the other end. In addition, the target probes carry a ribonucleic acid. Upon annealing to the respective 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 is sufficient and it satisfies the requirements of 21 CFR Part 809.10, 21 CFR 801.109, and the special controls.