DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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QUIDEL CORPORATION July 1st, 2015
RONALD H. LOLLAR
SENIOR DIRECTOR, CLINICAL AND REGULATORY AFFAIRS
2005 EAST STATE STREET, SUITE 100
ATHENS, OH 45701

Re: K150868
Trade/Device Name: Solana™ Gas Assay, Solana™ Instrument
Regulation Number: 21 CFR 866.2680
Regulation Name: *Streptococcus spp.* nucleic acid-based assay
Regulatory Class: II
Product Code: PGX
Dated: March 31, 2015
Received: April 1, 2015

Dear Mr. Lollar:

This letter corrects our substantially equivalent letter of June 23, 2015.

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,

Sally A. Hojvat -S

Sally A. Hojvat, 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)*
k150868

Device Name
Solana™ GAS Assay, Solana™ Instrument

Indications for Use *(Describe)*
The Solana™ GAS Assay is a rapid in vitro diagnostic test for the qualitative detection of Group A β-hemolytic Streptococcus (Streptococcus pyogenes) nucleic acids isolated from throat swab specimens obtained from patients with signs and symptoms of pharyngitis, such as sore throat. The Solana™ GAS Assay is intended for use only with 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:

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Date of preparation of 510(k) summary:

March 31, 2015

A. 510(k) Number:

K150868

B. Purpose for Submission:

To obtain substantial equivalence for the Solana™ GAS Assay when performed on the Solana™ instrument

C. Measurand:

DNase B (*sdaB*) sequence of *Streptococcus pyogenes* (Group A Streptococcus)

D. Type of Test:

Helicase-dependent amplification (HDA)

510(k) Summary

E. Applicant:

Quidel Corporation

F. Proprietary and Established Names:

Solana™ GAS Assay
Solana™ instrument

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™ GAS Assay is a rapid *in vitro* diagnostic test for the qualitative detection of Group A β-hemolytic Streptococcus (*Streptococcus pyogenes*) nucleic acids isolated from throat swab specimens obtained from patients with signs and symptoms of pharyngitis, such as sore throat. The Solana™ GAS 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

4. Special instrument requirements:

   Solana™ instrument

I. Device Description:

The Solana™ GAS Assay amplifies and detects GAS 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 GAS 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 a Reaction Tube. The Reaction Tube contains lyophilized HDA reagents, dNTPs, primers and probes. Once rehydrated with the diluted sample, the Reaction Tube is placed in Solana for amplification and detection of GAS-specific target sequence. In Solana, the target sequence is amplified by GAS specific primers and detected by a GAS specific fluorescence probe included in the Reaction Tube. A competitive process control (PRC) is included in the Lysis Tube to monitor sample processing, inhibitory substances in clinical samples, reagent failure or device failure. The PRC target is amplified by GAS 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. In addition, the target and PRC probes carry a ribonucleic acid. Upon annealing to GAS 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 instrument will then report the test results to the user on its display screen, and it can print out the results via a printer.

Materials Provided:

- 48 Tests per Kit

Component	Quantity	Storage
Dilution Buffer	48 tubes/kit 0. 5 mL	2° to 8°C
Lysis Buffer	48 tubes/kit 0. 5 mL	2° to 8°C
Reaction Tubes	48 tubes/kit	2° 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
- Micro tube tray
- Heat block capable of 95° C ± 2° C temperature
- 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™ GAS Assay**	**Lyra™ Direct Strep Assay (k133883)**
Intended Use	The Solana™ GAS Assay is a rapid *in vitro* diagnostic test for the qualitative detection of Group A β-hemolytic Streptococcus (*Streptococcus pyogenes*) nucleic acids isolated from throat swab specimens obtained from patients with signs and symptoms of pharyngitis, such as sore throat. The Solana™ GAS	The Lyra Direct Strep Assay is a Real-Time PCR *in vitro* diagnostic test for the qualitative detection and differentiation of Group A β-hemolytic *Streptococcus* (*Streptococcus pyogenes*) and pyogenic Group C and G β-hemolytic

510(k) Summary

Similarities		
Item	**Solana™ GAS Assay**	**Lyra™ Direct Strep Assay (k133883)**
	Assay is intended for use only with the Solana™ instrument.	*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™ GAS 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
Testing Time	45 minutes	60 -70 minutes

Differences		
Item	**Solana™ GAS 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	GAS* – 99bp product in the putative competence (*comX*1.1) gene Pyo GCS/GGS* – 188bp product in the tagatose-6-phosphate kinase (*lacC*) gene
Clinical Sensitivity	98.2% (95% CI: 95.5-99.3%)	GAS Sensitivity: 96.5%[95% CI: 91.3% -

Differences		
Item	**Solana™ GAS Assay**	**Lyra™ Direct Strep Assay (k133883)**
		98.6%] Pyo GCS/GGS Sensitivity: 95.7%[95% CI: 88.1% - 98.5%]
Clinical Specificity	97.1% (95% CI: 95.7-98.0%)	GAS Specificity: 98.0%[95% CI: 97.0% - 98.6%] Pyo GCS/GGS Specificity: 98.3%[95% CI: 97.4% - 98.9%]

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°C for 5 minutes. The heat-treated sample is added to a Dilution Tube, and then transferred to a Reaction Tube. The Reaction Tube contains lyophilized HDA reagents, dNTPs, primers and probes. Once rehydrated with the diluted sample, the Reaction Tube is placed in Solana for amplification and detection of GAS-specific target sequence. In Solana, the target sequence is amplified by GAS specific primers and detected by a GAS specific fluorescence probe included in the Reaction Tube. A competitive process control (PRC) is included in the Lysis Tube to monitor sample processing, inhibitory substances in clinical samples, reagent failure or device failure. The PRC target is amplified by GAS 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. In addition, the target and PRC probes carry a ribonucleic acid. Upon annealing to GAS 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 instrument will then report the test results to the user on its display screen, and it can print out the results via a printer.

510(k) Summary

M. Performance Characteristics:

1. Analytical performance:

a. Precision/Reproducibility:

Reproducibility

In order to confirm the reproducibility of the Solana™ GAS Assay, a blinded and randomized study panel containing *Streptococcus pyogenes* negative and positive samples were tested at three test sites (one in-house laboratory and two clinical sites) with three (3) instruments. Each site tested a reproducibility panel and Assay Controls for five 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™ GAS Assay. A total of 540 specimens were tested (including controls). The Solana™ GAS Assay generated the following reproducible results in this study.

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	24/30	80%	20/30	67%	14/30	47%	58/90	64%	54-74%
GAS Low Positive	30/30	100%	30/30	100%	30/30	100%	90/90	100%	96%-100%
GAS Moderate Positive	30/30	100%	30/30	100%	30/30	100%	90/90	100%	96%-100%
GAS Negative	0/30	0%	0/30	0%	0/30	0%	0/90	0%	0%-4%
GAS Positive Control	30/30	100%	30/30	100%	30/30	100%	90/90	100%	96%100%
GAS Negative Control	0/30	100%	0/30	0%	0/30	100%	0/90	0%	0%-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):

510(k) Summary

Traceability:

Not applicable. This assay is qualitative.

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.

A freshly grown stock of GAS bacteria of known titer was 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 8 more days prior to being tested in the Solana™ GAS 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 8 more days before testing or at ≤-15°C or ≤-70°C for up to 32 days before testing.

Controls:

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™ GAS 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 and to confirm the integrity of assay reagents and cassette detection. 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 swab specimen and processed as described in the Assay Procedure. The external positive control is intended to monitor substantial reagent and cassette 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 swab 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 GAS DNA or amplicon.

d. Detection limit:

The analytical sensitivity (limit of detection or LoD) of the Solana™ GAS Assay was determined using quantified (CFU/mL) cultures of two *Streptococcus pyogenes* strains by serial dilution. The LoD is defined as the lowest concentration at which 95% of all replicates tested positive.

The GAS bacterial strains were freshly grown. The cell density of these bacterial suspensions was estimated using the OD_{600} reading. After a cell suspension with OD_{600} of 0.1 (0.5 McFarland units) were established, the bacteria were serially diluted in to densities ranging from 3x to 0.3x LoD levels based on preliminary studies.

Each test dilution was run as 20 replicates in the Solana™ assay and plated on 20 TSA + 5% blood plates. The study was performed in 5 experiments of 14 assays per strain. For each experiment, 4 replicates of each of the three bacterial dilutions were performed, along with a positive and a negative run control. All five experiments of the LoD study for each strain were completed within 8 hours. The stocks of cells were stored on ice or at 4 °C when not in use.

The highest dilution where at least 19 of 20 replicates show detection of GAS (95% positivity) was assigned the Limit of Detection of the strain. The CFU/mL was calculated based on the average bacterial plate count of the dilution.

The LoD for the 2 *Streptococcus pyogenes* strains tested were 2.44 $x10^4$ CFU/mL (ATCC #19615) and 6.81 $x10^4$ CFU/mL (ATCC #12344). Based on this data the reported LoD for the Solana™ GAS Assay is 6.81 $x10^4$ CFU/mL.

510(k) Summary

e. Analytical specificity:

Cross Reactivity:

An *in silico* BLAST analysis of primers used in the Solana™ GAS 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
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		

[1] Includes *L. acidophilus*
[2] Includes *B. ovatus*
[3] Includes *C. rectus*
[4] In NCBI, *Bacteroides oralis* is *Prevotella oralis.*
[5] In NCBI, *Peptostreptococcus micros* is *Parvimonas micra*.

510(k) Summary

A study was performed to evaluate the performance of the Solana™ GAS Assay in the presence of forty-six (46) other microorganisms commonly found in throat specimens. Each potentially interfering microorganism was tested in the presence of 2 x LoD Group A *Streptococcus* (2 strains) 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*
Burkholderia cepacia	*Streptococcus bovis*
Corynebacterium diphtheria	*Streptococcus canis*
Enterococcus faecalis	*Streptococcus dysgalactiae subsp equisimilis*
Escherichia coli	*Streptococcus gordonii (Virdans type)*
Fusobacterium necrophorum	*Streptococcus intermedius*
Haemophilus influenza type A	*Streptococcus mitis*
Klebsiella pneumonia	*Streptococcus mutans*
Lactobacillus acidophilus	*Streptococcus oralis*
Lactococcus lactis	*Streptococcus pneumoniae*
Legionella jordanis	*Streptococcus salivarius*
Legionella micdadei	*Streptococcus sanguinis*
Legionella pneumophila	*Streptococcus suis*
Moraxella cartarrhalis	*Candida albicans*
Neisseria gonorrhoeae	Adenovirus Type 1
Neisseria subflava	Adenovirus Type 11 (Slobitski)
Peptostreptococcus micros (aka Parvimonas micra)	Influenza A
Pseudomonas aeruginosa	Influenza B
Serratia marcescens	Parainfluenza Type 4B (VR-1377)
Staphylococcus aureus MRSA	Rhinovirus Type 15 (1734)

None of the organisms or viruses tested above cross-reacts with the performance of the Solana™ GAS Assay.

510(k) Summary

Interference:

A study was conducted using two strains of *Streptococcus pyogenes* (ATCC 19615 and 12344) tested near LoD to evaluate the Solana™ GAS 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 assay dilution tubes 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™ GAS Assay.

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

510(k) Summary

Substance Name	Test Concentration	Interference? (Y/N)
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

Analytical Reactivity (Inclusivity):

The reactivity of the Solana™ GAS Assay was evaluated against an additional seven (7) strains of Streptococcus pyogenes (GAS) at concentrations near the limit of detection (LoD) of the assay.

Each strain was tested as three replicates in the Solana™ GAS Assay. The study was performed in multiple experiments. For each experiment, three replicates of up to three strains were performed, along with a positive and a negative run control. All seven strains were detected by the Solana™ GAS Assay.

Bacterial Strain	Concentration CFU/mL	Strain Detected (Yes/No)
ATCC 12384	6.81×10^4	Yes
NCIMB 13285	6.81×10^4	Yes
CCUG 33061	6.81×10^4	Yes
CCUG 33409	6.81×10^4	Yes
CCUG 39158	6.81×10^4	Yes
ATCC 49399	6.81×10^4	Yes
CCUG 53553	6.81×10^4	Yes

f. Assay cut-off:

Not applicable.

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%

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 GAS Assay were established during a prospective study conducted December 2014 to February 2015. One thousand eighty-two (1082) fresh throat swab specimens from female and male patients were collected at four distinct geographical sites across the United States. A single specimen was collected per patient. Samples were collected on Polyester, Nylon or Rayon Swab with liquid Amies or Polyester Swab or Rayon with liquid Stuart's. The swabs were inoculated by conventional streak-stab culture technique onto a trypticase soy agar plate containing 5% horse red blood cells. Testing with the Solana device was performed at the four external laboratories using the same swab that was plated for the culture. All residual specimen transport media from the samples was shipped daily (with cold packs) to a central location. The transport media was cultured using the same testing protocol as that employed by the clinical sites.

One thousand eighty-two (1082) fresh throat specimens were cultured for Group A β-hemolytic Streptococcus and tested with the Solana GAS Assay. The specimens were cultured at the testing sites and the transport media was cultured at a central location. The specimen was considered positive if either the swab or the transport media was positive for β-hemolytic Streptococcus (Composite Culture) and typed as Lancefield group A by latex agglutination. The table below details the overall performance using composite culture results as a reference.

510(k) Summary

Performance Results of Solana GAS Assay for Group A β-hemolytic Streptococcus			
Overall Performance (All Sites)			
	Composite Culture		
Solana GAS Assay	Positive	Negative	Total
Positive	220	24*	244
Negative	4**	833	837
Total	224	857	1081
			95% CI
Sensitivity	220/224	98.2%	95.5% to 99.3%
Specificity	833/857	97.2%	95.9% to 98.1%
* Of the twenty-four (24) discordant specimens, sixteen (16) of these specimens were positive for GAS when tested with an additional FDA-cleared molecular device, eight (8) were negative. ** Of the four (4) discordant specimen, three (3) were negative when tested with an additional FDA-cleared molecular device.			
Site 1 Performance			
	Composite Culture		
Solana® GAS Assay	Positive	Negative	Total
Positive	60	5	65
Negative	1	333	334
Total	61	338	399
			95% CI
Sensitivity	60/61	98.4%	91.3% to 99.7%
Specificity	333/338	98.5%	96.6 % to 99.4%
Site 2 Performance			
	Composite Culture		
Solana® GAS Assay	Positive	Negative	Total
Positive	69	9	78
Negative	1	134	135
Total	70	143	213
			95% CI
Sensitivity	69/70	98.6%	92.3% to 99.7%
Specificity	134/143	93.7%	88.5 % to 96.7%
Site 3 Performance			
	Composite Culture		
Solana® GAS Assay	Positive	Negative	Total
Positive	29	6	35
Negative	0	186	186
Total	29	192	221
			95% CI
Sensitivity	29/29	100%	88.3% to 100%
Specificity	186/192	96.9%	93.4 % to 98.6%

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

5. Expected values:

The overall prevalence of Group A β-hemolytic Streptococcus in patients tested during this study was 20.7% (224/1081) based on composite bacterial culture and 22.6% (244/1081) based on the Solana™ GAS Assay. All clinical specimens collected during this study were collected between December 2014 and February 2015.

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 GAS specific primers and detected by a GAS specific fluorescence probe included in the Reaction Tube. 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 GAS 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.