December 21, 2017

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

Re: K173250
Trade/Device Name: Solana GBS Assay
Regulation Number: 21 CFR 866.3740
Regulation Name: *Streptococcus* spp. serological reagents
Regulatory Class: Class I
Product Code: NJR
Dated: October 5, 2017
Received: October 10, 2017

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k173250

Device Name
Solana® GBS Assay

Indications for Use *(Describe)*
The Solana® GBS assay is a qualitative in vitro diagnostic test for detection of Group B Streptococcus in either LIM or Carrot enrichment broth cultures of vaginal/rectal swabs from antepartum women following 18 to 24 hours of incubation. The Solana® GBS Assay utilizes helicase-dependent amplification (HDA) of the Thiolase (atoB) gene sequence. The Solana® GBS Assay is intended for use only with the Solana® Instrument.

The Solana® GBS Assay does not provide susceptibility results. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women.

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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Ron.Lollar@quidel.com

Date of preparation of 510(k) summary:

December 04, 2017

A. 510(k) Number:

K173250

B. Purpose for Submission:

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

C. Measurand:

Thiolase (atoB) gene

D. Type of Test:

Helicase-Dependent Amplification (HDA)

510(k) Summary

E. Applicant:

Quidel Corporation

F. Proprietary and Established Names:

Solana® GBS Assay

G. Regulatory Information:

Table 1. **Regulatory Information**

Product Code	**Classification**	**Regulation Section**	**Panel**
NJR	Class I	21 CFR 866.3740 *Streptococcus* spp. serological reagents	Microbiology (83)

H. Intended Use:

1. Intended Use(s):

   The Solana® GBS assay is a qualitative in vitro diagnostic test for detection of Group B Streptococcus in either LIM or Carrot enrichment broth cultures of vaginal/rectal swabs from antepartum women following 18 to 24 hours of incubation.

   The Solana® GBS Assay utilizes helicase-dependent amplification (HDA) of the Thiolase (atoB) gene sequence. The Solana® GBS Assay is intended for use only with the Solana® Instrument.

   The Solana® GBS Assay does not provide susceptibility results. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women.

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 GBS Assay amplifies and detects GBS DNA isolated from enrichment broth cultures of vaginal/rectal swabs from antepartum women following 18 to 24 hours of incubation.

The assay consists of two (2) major steps: 1) specimen preparation, and 2) amplification and detection of target sequence specific to GBS using isothermal Helicase-Dependent Amplification (HDA) in the presence of target-specific fluorescence probe.

Patient specimen 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 and mixed. 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 specific target sequences. In Solana, the GBS target sequence is amplified by GBS specific primers and detected by a GBS specific fluorescence probe included in the Reaction Tube. A competitive process control (PRC) is included in the Process Tube to monitor sample processing, for the presence of inhibitory substances in clinical samples, reagent or device failure. The PRC target is amplified by 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 (FAM or ROX, respectively) on the other end. In addition, the target and PRC probes carry a ribonucleic acid. Upon annealing to GBS 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 will then report the test results to the user on its display screen, and it can print out the results using the attached printer.

510(k) Summary

Materials Provided:

Solana® GBS Assay Kit: M311
48 Tests per kit

Table 2. **Kit Components**

Component	**Quantity**	**Storage**
Process Buffer	48 tubes/kit 1.0 mL	2°C to 8°C
Reaction Tubes	48 tubes/kit	2°C to 8°C

Materials required but not provided:

- External controls for GBS (e.g. Quidel Molecular GBS Control Set, which contains positive and negative controls, serves as an external processing and extraction 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
- Enrichment broth culture (e.g. Lim, Carrot)

J. Substantial Equivalence Information:

1. Predicate device name(s):

   AmpliVue® GBS Assay

2. Predicate 510(k) number(s):
   K133503

510(k) Summary

3. Comparison with predicate:

Table 3. **Similarities**		
Item	**Solana® GBS Assay**	**AmpliVue® GBS Assay (k133503)**
Intended Use	The Solana® GBS assay is a qualitative in vitro diagnostic test for detection of Group B Streptococcus in either LIM or Carrot enrichment broth cultures of vaginal/rectal swabs from antepartum women following 18 to 24 hours of incubation. The Solana® GBS Assay utilizes helicase-dependent amplification (HDA) of the Thiolase (atoB) gene sequence. The Solana® GBS Assay is intended for use only with the Solana® Instrument. The Solana® GBS Assay does not provide susceptibility results. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women.	The AmpliVue® GBS Assay is a qualitative in vitro diagnostic test for the rapid detection of Group B Streptococcus from vaginal/rectal swabs from antepartum women following 18 to 24 hours of incubation in an LIM enrichment broth culture. The AmpliVue® GBS Assay utilizes helicase-dependent amplification (HDA) of the Thiolase (atoB) gene sequence and a self-contained disposable amplification detection device that allows for manual evaluation of assay results. Results can be used as an aid in determining the colonization status of antepartum women. The AmpliVue® GBS Assay does not provide susceptibility results. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women. The AmpliVue® GBS Assay is intended for use in hospital, reference or state laboratory settings. The device is not intended for point-of-care use.
Sample Types	Enriched broth cultures of Vaginal/Rectal swab specimens	Same
Extraction	Manual	Same
DNA Amplification Technology	Helicase-dependent amplification (HDA)	Same

510(k) Summary

Table 3. **Similarities**		
Item	**Solana® GBS Assay**	**AmpliVue® GBS Assay (k133503)**
Target Sequence Detected	Thiolase (atoB) gene	Same

Table 4. **Differences**		
Item	**Solana® GBS Assay**	**AmpliVue® GBS Assay (k133503)**
Sample Type Enrichment Culture	LIM Broth, Carrot Broth	Lim Broth
Detection Technique	Automated	Manual
Instrument	Solana	None
Testing Time	38 to 42 minutes	75 to 90 minutes
Clinical Sensitivity	100% (95%CI: 98.0 – 100%)	99.5% (95% CI: 96.9-100%)
Clinical Specificity	95.9% (95%CI: 94.0 to 97.3%)	92.7% (95% CI: 90.5-94.3%)

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

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

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

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

L. Test Principle:

The Solana GBS Assay amplifies and detects GBS DNA isolated from enrichment broth cultures of vaginal/rectal swabs from antepartum women following 18 to 24 hours of incubation.

510(k) Summary

The assay consists of two (2) major steps: 1) specimen preparation, and 2) amplification and detection of target sequence specific to GBS using isothermal Helicase-Dependent Amplification (HDA) in the presence of target-specific fluorescence probe.

Patient specimen 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 and mixed. 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 specific target sequences. In Solana, the GBS target sequence is amplified by GBS specific primers and detected by GBS specific fluorescence probe included in the Reaction Tube. A competitive process control (PRC) is included in the Process Tube to monitor sample processing, for the presence of inhibitory substances in clinical samples, reagent or device failure. The PRC target is amplified by 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 (FAM or ROX, respectively) on the other end. In addition, the target and PRC probes carry a ribonucleic acid. Upon annealing to GBS 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 will then report the test results to the user on its display screen, and it can print out the results using the attached printer.

M. Performance Characteristics:

1. Analytical performance:

a. Precision/Reproducibility:

A four-sample panel consisting of three levels of contrived positive samples and a negative contrived sample were tested in this study. *Streptococcus agalactiae* strains SS617 or SS618 were diluted in negative Lim broth enriched vaginal/rectal matrix to 3x LOD ($2.4x10^6$ CFU/mL and $2.1x10^6$ CFU/mL respectively) for moderate positive, 1x LOD ($8.0x10^5$ CFU/mL and $7.1x10^5$ CFU/mL respectively) for low positive and diluted to C20 to C80 for high negative / low positive ($8.0x10^3$ CFU/mL and $7.1x10^3$ CFU/mL respectively). Negative matrix without spiked organism was used for the negative sample. The Solana GBS Assay was used per the instructions for use.

Panels and controls were tested at each site by two operators per instrument for five days, each sample tested in three (3) replicates, for a total of 90 results per level (2 operators x 5 days x 3 sites x 3 replicates).

510(k) Summary

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*			
GBS strain SS617 High Negative [1] ($8.0x10^3$ CFU/mL)	11/16	68.8	9/16	56.3	8/16	50.0	28/48	58.3	44.3 to 71.2
GBS strain SS617 Low Positive ($8.0x10^5$ CFU/mL)	16/16	100	16/16	100	16/16	100	48/48	100	92.6 to 100
GBS strain SS617 Moderate Positive ($2.4x10^6$ CFU/mL)	16/16	100	16/16	100	16/16	100	48/48	100	92.6 to 100
GBS strain SS618 High Negative ($2.63x10^4$ CFU/mL)	2/14	14.3	6/14	42.9	4/14	28.6	12/42	28.6	17.2 to 43.6
GBS strain SS618 Low Positive ($7.1x10^3$ CFU/mL)	14/14	100	14/14	100	14/14	100	42/42	100	91.6 to 100
GBS strain SS617 Moderate Positive ($2.1x10^6$ CFU/mL)	14/14	100	14/14	100	14/14	100	42/42	100	91.6 to 100
Negative Sample	0/30	100	0/30	100	0/30	100	0/90	100	95.9 to 100
GBS Positive Control	30/30	100	30/30	100	30/30	100	90/90	100	95.9 to 100
GBS Negative Control	0/30	100	0/30	100	0/30	100	0/90	100	95.9 to 100

[1] The Expected Result for High Negative samples was Negative

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

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:

The stability of vaginal/rectal swab culture matrix prior to addition to Process Buffer was evaluated. Testing was performed with Lim and Carrot broth vaginal/rectal swab culture matrix using one (1) strain of GBS cells at near the LOD target level (strain BAA-611, 1.18 x10^6 CFU/mL). Enrichment cultures were shown to be stable for up to 48 hours at 20°C to 25°C or 7 days at 2°C to 8°C prior to processing.

Controls:

- 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.

External Controls (Quidel Molecular GBS Control Set), were run on the Solana® GBS Assay each day of testing during the analytical and clinical studies. These controls are described as follows:

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

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

- It is recommended that the reactivity of each new lot and each new shipment of the Solana GBS 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 GBS 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 GBS assay was determined using genomic GBS DNA and quantified (CFU/mL) cultures of six *Streptococcus agalactiae* strains (ATCC BAA-611, SS617, SS618, SS619, ATCC 12403, and SS700) serially diluted in a negative LIM Broth enriched vaginal/rectal matrix.

The LOD of the Solana GBS assay was furthered confirmed using frozen GBS cells in Negative Carrot Broth enriched vaginal/rectal matrix.

Table 6. LOD Results

Target Type		Strain Name	Determined LOD		
			Copies/Assay	CFU/mL	CFU/Assay
GBS Genomic DNA			16.67		
GBS Cells	Freshly Grown	ATCC BAA-611		$5.9x10^5$	$1.4x10^3$
		SS617		$8.0x10^5$	$1.9x10^3$
		SS618		$7.1x10^5$	$1.7x10^3$
		SS619		$7.6x10^5$	$1.8x10^3$
		ATCC 12403		$2.6x10^6$	$6.3x10^3$
		SS700		$4.9x10^5$	$1.2x10^3$
	Frozen	ATCC 12403		$2.6x10^6$	$6.3x10^3$
	Carrot Broth	ATCC 12403		$2.6x10^6$	$6.3x10^3$

e. Analytical specificity:

Cross Reactivity:

A study was performed to determine if ninety-seven (97) microorganisms or viruses (eighty-two (82) bacteria, three yeast (3), eleven (11) viruses and a parasite (1)) potentially found in vaginal/rectal samples cross-react with the Solana® GBS Assay. The same ninety-seven (97) microorganisms were used to determine if they interfered with one GBS strain (ATCC 12403) at 2x LOD ($5.2x10^6$ CFU/mL) in the Solana® GBS Assay The potentially cross-reactive or interfering microorganisms were tested at or above clinically relevant levels (bacteria ≥ 1×10^6 CFU/mL, viruses the ≥ $1 \times 10^5 TCID_{50}$/mL).

Human genomic DNA was also evaluated for cross-reactivity and interference.

Table 7. Bacteria

Aeromonas hydrophila (2 strains)	*Enterococcus faecalis*	*Salmonella enterica enterica Serovar Typhimurium*
Abiotrophia defectiva	*Enterococcus faecium*	*Salmonella enterica indica*

510(k) Summary

Table 7. Bacteria		
Acinetobacter baumanii	*Escherischia coli*	*Serratia liquefaciens*
Alcaligenes faecalis faecalis	*Escherischia fergusonii*	*Serratia marcescens*
Bacillus cereus	*Gardnerella vaginalis*	*Shigella boydii*
Bacillus subtilis (2 strains)	Group C Strep	*Shigella flexneri*
Bacteroides fragilis (2 strains)	*Helicobacter pylori*	*Shigella sonnei*
Bifidobacterium adolescentis (2 strains)	*Klebsiella oxytoca*	*Staphyloccocus aureus*
Campylobacter fetus	*Klebsiella pneumoniae*	*Staphylococcus epidermidis*
Campylobacter hyointestinalis	*Lactobacillus acidophilus*	*Stenotrophomonas maltophilia*
Campylobacter jejuni (2 strains)	*Legionella pneumophila*	*Streptoccocus mutans*
Chlamydia trachomatis [1]	*Listeria monocytogenes*	*Streptoccocus pyogenes*
Citrobacter freundii	*Mobiluncus mulieris*	*Streptococcus bovis*
Clostridium bifermentans	*Moraxella cartarrhalis*	*Streptococcus dysgalactiae*
Clostridium butyricum	*Morganella morganii*	*Streptococcus gordonii*
Clostridium difficile	*Neisseria gonorrhoeae*	*Streptococcus intermedius*
Clostridium haemolyticum	*Peptostreptococcus anaerobius*	*Streptococcus mitis*
Clostridium novyi	*Pleisiomonas shigelloides*	*Streptococcus oralis*
Clostridium orbiscindens	*Porphyromonas asaccharolytica*	*Streptococcus pneumoniae*
Clostridium perfringens	*Prevotella melaninogenica*	*Streptococcus salivarius*
Clostridium septicum	*Proteus mirabilus*	*Streptococcus suis*
Clostridium sordellii	*Providencia alcalifaciens*	*Streptococcus uberis*
Clostridium sporogenes	*Pseudomonas aeruginosa*	*Ureaplasma urealyticum*
Edwardsiella tarda	*Pseudomonas fluorescens*	*Vibrio parahaemolyticus*
Enterobacter aerogenes	*Salmonella choleraesius (typhimurium)*	*Yersinia enterocolitica*
Enterobacter cloacae	*Salmonella enterica arizonae*	

[1] Tested at 10^6 Inclusion Forming Units/mL

Table 8. Yeast		
Candida albicans	*Candida glabrata*	*Candida parapsilosis*

510(k) Summary

Table 9. Viruses		
Adenovirus	Enterovirus	Norovirus
CMV	HPV-16 [1]	Rotavirus
Coxsackie virus	HSV1 (Macintyre)	VZV
Echovirus	HSV2 (G)	

[1] Tested using a transformed cell line at 1 x 10^5 copies/mL

Table 10. Parasite
Trichomonas vaginalis [1]

[1] Tested at 10^6 trichomonads/mL

None of the organisms or viruses tested above cross-reacted or interfered with the performance of the Solana GBS Assay.

Human genomic DNA did not cross-react or interfere with the performance of the Solana GBS Assay.

Interference:

The performance of Solana GBS Assay was evaluated with thirty-four (34) potentially interfering substances that may be present in vaginal/rectal specimens. The substances were tested in GBS negative Lim broth enriched vaginal/rectal matrix in the presence or absence of GBS cells (strain ATCC 12403) at 2x LOD ($5.2x10^6$ CFU/mL) in the Solana GBS Assay.

Table 11. Interfering Substances			
Substance Name	**Test Concentration in Contrived Sample**	**Substance Name**	**Test Concentration in Contrived Sample**
Cortizone 10 (Hydrocortisone)	0.1% Swab Amount/µL	Hemoglobin	64 µg/mL
Desitin (Zinc Oxide)	0.1% Swab Amount/µL	Prilosec (Esomeprazole Magnesium Hydrate)	10 µg/mL
Urine	2% (v/v)	Fecal Fat-Stearic Acid	520 µg/mL

Table 11. Interfering Substances			
Substance Name	**Test Concentration in Contrived Sample**	**Substance Name**	**Test Concentration in Contrived Sample**
Preparation H (Phenylephrine)	0.04% (w/v)	Tagamet (Cimetidine)	10 µg/mL
Tums (Calcium Carbonate)	10 µg/mL	Miconazole Nitrate Salt	0.04% (w/v)
Mylanta (AI(OH)3, MG(OH)3)	2 µg/ml	Nystatin	200 USP U/ml
Fleet Mineral Oil Enema	0.2% (v/v)	Fecal Sugar-Dextrose	20 µg/mL
Gynol II Vaginal Contraceptive (Nonoxynol-9)	0.1% Swab Amount/µL	Human Serum Albumin	200 µg/mL
Imodium AD (Loperamide HCl)	20 µg/ml	Triclosan	0.002% w/v
Pepto Bismol (Bismuth subsalicylate)	17 µg/ml	Hemorrhoidal cream (Target Brand Cream)	0.1% Swab Amount/µL
Tucks personal cleaning pads (Witch hazel)	2% (v/v)	KY Jelly	0.1% Swab Amount/µL
Benzalkonium Chloride Towelettes	0.0024% (v/v)	Petroleum Jelly	0.1% Swab Amount/µL
Ethanol	0.2% (v/v)	Body Powder	0.1% Swab Amount/µL
Whole Blood	2% (v/v)	Meconium	0.1% Swab Amount/µL
Fecal Fat- Palmitic acid	26 µg/mL	Baby Powder	0.1% Swab Amount/µL
Mucin	60 µg/mL	Amniotic Fluid	2% (v/v)
Barium Sulfate	100 µg/mL	Stool	0.1% Swab Amount/µL

No false positive results or interference was seen with any of the thirty-four (34) potentially interfering substances that were tested.

Analytical Reactivity (Inclusivity):

The reactivity of the Solana GBS Assay was evaluated against an additional fourteen (14) strains of *Streptococcus agalactiae* with different serotypes or that were not typed, in

addition to GBS strains BAA-611, SS617, SS618, SS619, ATCC 12403, and SS700 used in the LOD study. The testing was performed at 1X LOD (2.6×10^6 CFU/mL) level of the assay. All additional fourteen (14) strains were detected in the Solana GBS Assay. The serotypes of these GBS strains are listed in the table below:

Table 12. GBS Strains at 1x LOD ($2.6x10^6$ CFU/mL)

GBS Strain	**Serotype**
ATCC 12973	II
CCUG 28551	IV
CCUG 29785	VI
CNCTC 6609	VII
BAA-2669	VIII
BAA-2668	IX
ATCC 49449	X
ATCC 27956	Not typed
ATCC 7077	Not typed
ATCC 4768	Not typed
ATCC 12927	Not typed
ATCC 9925	Not typed
ATCC 55194	Not typed
ATCC 55191	Not typed

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:

510(k) Summary

Performance characteristics of the Solana GBS Assay were established during a prospective study conducted from July 2017 to September 2017. Seven hundred fifty-three (753) specimens used for this study were collected from antepartum women between 35 to 37 weeks gestation at four distinct geographical sites across the United States. The age range for these women was between 15 to 44 years old. Specimens were inoculated into either LIM or Carrot broth (403 and 350 specimens, respectively) and incubated for 18 to 24 hours at 35°C. Post-incubation specimens were tested by both the Solana GBS Assay and bacterial culture. One (1) specimen (0.2%) was invalid in the Solana GBS Assay when initially tested and upon repeat testing. This specimen has been removed from additional analysis. Table 13 below is for the remaining seven hundred fifty-two (752) specimens.

Table 13. **Sensitivity/Specificity of the Solana GBS Assay for GBS Compared to Bacterial Culture**

Broth Type	N	TP	FP	TN	FN	Sensitivity (95% CI)	Specificity (95% CI)
LIM	402	88	13	301	0	100 (95.8 to 100)	95.9 (93.0 to 97.6)
Carrot	350	97	10	243	0	100 (96.2 to 100)	96.0 (92.9 to 97.8)
Combined	752	185	23*	544	0	100 (98.0 to 100)	95.9 (94.0 to 97.3)

* Nineteen (19) of twenty-three (23) Solana GBS Assay Positive/Bacterial Culture Negative specimens were positive by an additional FDA-cleared molecular test.

Prevalence based on culture = 24.6% (185/752)
Prevalence based on Solana® GBS Assay = 27.7% (208/752)

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:

Clinical performance of the Solana GBS assay with Lim and Carrot enrichment broths was established during a prospective study conducted from July 2017 to September 2017. Seven hundred fifty-three (753) specimens collected from antepartum women between 35 to 37 weeks' gestation at four distinct geographical sites across the United States, were tested. One (1) specimen (0.2%) was invalid in the Solana GBS Assay when initially tested and upon repeat testing. This specimen has been removed from additional analysis. The age range for these women was between 15 to 44 years old. The percentage of positive cases as determined by the Solana GBS assay during the study was 27.7% (208/752).

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

Instrument: Solana® Instrument

O. System Descriptions:

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 and 21 CFR 801.109.

Q. Conclusion:

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