November 7, 2018

DiaSorin Molecular LLC
Sharon Young
Principal Regulatory Affairs Specialist
11331 Valley View Street
Cypress, California 90630

Re: K182467
Trade/Device Name: Simplexa GBS Direct, Simplexa GBS Positive Control Pack
Regulation Number: 21 CFR 866.3740
Regulation Name: *Streptococcus* spp. Serological Reagents
Regulatory Class: Class I
Product Code: NJR, OOI
Dated: September 5, 2018
Received: September 10, 2018

Dear Sharon Young:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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

Sincerely,

Steven R. Gitterman -S for

Uwe Scherf, 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)*
K182467

Device Name
Simplexa™ GBS Direct
Simplexa™ GBS Positive Control Pack

Indications for Use *(Describe)*

Simplexa™ GBS Direct

The DiaSorin Molecular Simplexa™ GBS Direct assay is a real-time polymerase chain reaction (PCR) assay intended for use on the LIAISON® MDX instrument for the in vitro qualitative detection of Group B Streptococcus (GBS) nucleic acid from 18 to 24 hour Lim broth enrichments of vaginal/rectal specimen swabs obtained from antepartum women. Assay results can be used as an aid in determining the colonization status of antepartum women, but are not intended to diagnose or monitor treatment of a GBS infection.

The Simplexa™ GBS Direct assay does not provide susceptibility results. Culture isolates are needed to perform susceptibility testing as recommended for penicillin-allergic women.

Simplexa™ GBS Positive Control Pack

The Simplexa™ GBS Positive Control Pack is intended to be used as a control with the Simplexa™ GBS Direct kit. This control is not intended for use with other assays or systems.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Applicant	DiaSorin Molecular LLC. 11331 Valley View Street Cypress, California 90630 USA
Establishment Registration No.	2023365
Contact Person	Sharon Young Principal Regulatory Affairs Specialist tel 562.240.6680 fax 562.240.6529 Sharon.Young@DiaSorin.com
Summary Date	October 25 2018
Proprietary Name	Simplexa™ GBS Direct and Simplexa™ GBS Positive Control Pack
Generic Name	Nucleic Acid Amplifications System, Group B Streptococcus, Direct Specimen Testing
Classification	Class I
Predicate Devices	GenePOC GBS LB Assay K170557

Intended Use

Simplexa™ GBS Direct
The DiaSorin Molecular Simplexa™ GBS Direct assay is a real-time polymerase chain reaction (PCR) assay intended for use on the LIAISON® MDX instrument for the in vitro qualitative detection of Group B Streptococcus (GBS) nucleic acid from 18 to 24 hour Lim broth enrichments of vaginal/rectal specimen swabs obtained from antepartum women. Assay results can be used as an aid in determining the colonization status of antepartum women, but are not intended to diagnose or monitor treatment of a GBS infection.

The Simplexa™ GBS Direct assay does not provide susceptibility results. Culture isolates are needed to perform susceptibility testing as recommended for penicillin-allergic women.

Simplexa™ GBS Positive Control Pack
The Simplexa™ GBS Positive Control Pack is intended to be used as a control with the Simplexa™ GBS Direct kit. This control is not intended for use with other assays or systems.

Device Description

The Simplexa™ GBS Direct assay system is a real-time PCR system that enables the direct amplification and qualitative detection of Group B Strep bacterial DNA from vaginal swabs enriched in Lim Broth for eighteen to twenty-four (18 to 24) hours that have not undergone a nucleic acid extraction. The system consists of the Simplexa™ GBS Direct assay, the LIAISON® MDX (with LIAISON® MDX Studio Software), the Direct Amplification Disc (DAD) and associated accessories.

In the Simplexa™ GBS Direct assay, primers and fluorescent probes are used together to amplify Group B *Streptococcus* bacterial DNA and the Internal Control (DNA IC). The assay targets a conserved region of the *cfb* gene to identify Group B *Streptococcus* in the specimen. The DNA IC is used to detect PCR failure and/or inhibition.

Kit Description

Component Name	REF	EC SYMBOL ON LABEL		Abbreviated Name	Cap Color	Number of Vials	Reactions per Vial/Kit	Volume per Vial
Simplexa™ GBS Direct Reaction Mix	MOL3551	REAG	C	RM	Orange	24	1/24	50 µL

Component Description

<table>
<tr><th>Kit Component</th><th>Contents</th></tr>
<tr><td>Simplexa™ GBS Direct Reaction Mix (RM)</td><td>
DNA polymerase, buffers, dNTPs, Internal Control DNA Template, dye-labeled fluorescent primers and probes specific for detection of Group B Strep and for the DNA Internal Control
<table>
<tr><th>Target</th><th>Probe Fluorophore (Dye)</th><th>Excitation</th><th>Emission</th><th>Targeted Gene</th></tr>
<tr><td>GBS</td><td>CFR610</td><td>590</td><td>610</td><td>cfb</td></tr>
<tr><td>Internal Control DNA (IC)</td><td>Q670</td><td>644</td><td>670</td><td>NA</td></tr>
</table>
</td></tr>
<tr><td>Simplexa™ GBS Direct Barcode Card</td><td>Assay specific parameters, lot number, expiration date.</td></tr>
</table>

MATERIALS SUPPLIED SEPARATELY
Direct Amplification Disc Kit (REF MOL1455) Direct Amplification Discs for use on the LIAISON® MDX

Predicate Device Information

Similarities		
Comparison to Predicate Device	**Predicate Device: GenePOC GBS LB Assay K170557**	**Candidate Device: Simplexa™ GBS Direct and Simplexa™ GBS Positive Control Pack**
Product Code	NJR and OOI 21 CFR 866.3740 – Streptococcal spp. serological reagents 21 CFR 862.2570 – Instrumentation for clinical multiplex test systems	Same
Organism Detected	Group B *Streptococcus*	Same
Measurand	Target DNA sequence in cfb gene of Streptococcus agalactiae (Group B Streptococcus, GBS)	Conserved region of the cfb gene of Streptococcus agalactiae (Group B Streptococcus, GBS)
Intended Use	The GenePOC GBS LB assay performed on the revogene instrument is a qualitative in vitro diagnostic test designed to detect Group B Streptococcus (GBS) DNA from 18-24 hour LIM broth enrichments of vaginal/rectal specimen swabs	The DiaSorin Molecular Simplexa™ GBS Direct assay is a real-time polymerase chain reaction (PCR) assay intended for use on the LIAISON® MDX instrument for the in vitro qualitative detection of Group B Streptococcus (GBS) nucleic acid from 18 to 24 hour Lim broth

Similarities		
Comparison to Predicate Device	**Predicate Device: GenePOC GBS LB Assay K170557**	**Candidate Device: Simplexa™ GBS Direct and Simplexa™ GBS Positive Control Pack**
	obtained from pregnant women. The GenePOC GBS LB assay utilizes automated sample processing and real-time polymerase chain reaction (PCR) to detect a cfb gene sequence specific to the Streptococcus agalactiae genome. The GenePOC GBS LB assay is indicated for the identification of antepartum GBS colonization and does not provide susceptibility results. It is not intended to diagnose or monitor treatment of GBS infection. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women.	enrichments of vaginal/rectal specimen swabs obtained from antepartum women. Assay results can be used as an aid in determining the colonization status of antepartum women, but are not intended to diagnose or monitor treatment of a GBS infection. The Simplexa™ GBS Direct assay does not provide susceptibility results. Culture isolates are needed to perform susceptibility testing as recommended for penicillin-allergic women. Simplexa™ GBS Positive Control Pack The Simplexa™ GBS Positive Control Pack is intended to be used as a control with the Simplexa™ GBS Direct kit. This control is not intended for use with other assays or systems.
Automated System (Sample to Answer)	Yes	Yes

Differences		
Comparison to Predicate Device	**GenePOC GBS LB Assay K170557**	**Simplexa™ GBS Direct and Simplexa™ GBS Positive Control Pack**
Instrumentation	Revogene instrument	LIAISON® MDX
Single Use	Yes Cartridge (PIE) can be used once.	No. Consumable disc can be used until all eight (8) wedges have been used.

CLINICAL PERFORMANCE

The performance of the Simplexa™ GBS Direct assay was evaluated in a prospective study that was conducted with residual de-identified Lim broth enrichment cultures of vaginal/rectal swabs obtained from pregnant women at thirty-five to thirty-seven (35-37) weeks of gestation. The specimens were collected and enriched according to established CDC guidelines. Lim Broth cultures were incubated for eighteen to twenty-four (18-24) hours at 35-37 °C. Four hundred and thirty-two (432) samples that met the prescribed inclusion criteria were used to evaluate the performance of the Simplexa™ GBS Direct assay in comparison to those obtained with a GBS culture reference method. All samples were tested fresh upon completion of the enrichment process. Aliquots were made from each freshly enriched Lim Broth sample; the first aliquot was held at 2-8 °C and tested on the Simplexa™ GBS Direct at the collection site, and the second aliquot was kept at 2-8 °C and sent on cold packs to a central laboratory for GBS culture.

For the GBS culture reference method, enriched Lim Broth samples were sub-cultured to selective and non-selective blood agar for twenty-four (24) hours. If GBS was not observed, the plates were re-incubated for an additional twenty-four (24) hours and deemed negative if GBS was not identified. Colonies with an appearance that was suggestive of GBS were further processed to confirm the presence of GBS using general laboratory methods, which included: gram stain, catalase testing, and latex agglutination.

The testing of samples with Lim broth incubation periods per CDC guidelines included eighty-four (84) total runs with thirty-one (31) control pairs, all of which produced the expected positive/negative results. The invalid rate of the clinical prospective study samples with Lim broth incubation periods per CDC guidelines was 0.0%, zero out of four hundred and thirty-two (0/432). The results of the study are shown in Table 1.

Table 1. Clinical Agreement Summary Results - Prospective Clinical Agreement Results Simplexa™ GBS Direct vs. Culture

Simplexa™ GBS Direct Results	Culture Comparator Method		
	Detected	Not Detected	Total
Detected	97	13[b]	110
Not Detected	3[a]	319	322
Total	100	332	432
	Sensitivity 97.0%(97/100) 95% CI: 91.5% to 99.0%	**Specificity** 96.1%(319/332) 95% CI: 93.4% to 97.7%	

[a] 3/3 samples with discrepant results were negative when tested with an alternate FDA cleared NAAT.
[b] 11/13 samples with discrepant results were positive when tested with an alternate FDA cleared NAAT.

REPRODUCIBILITY

Three (3) investigative sites assessed the device's inter-site, inter-day and inter/intra-assay reproducibility. Each of the laboratories tested Simplexa™ GBS Direct Positive Control, No Template Control (Lim Broth), and four (4) contrived samples in negative matrix. Two (2) strains of GBS were used in the study, BAA-22 and BAA-1138. The four (4) contrived samples consisted of a low positive (LP) at approximately 1.5 x LoD and a medium positive (MP) at approximately 3.5 x LoD for each GBS strain. The assays were performed in triplicate on five (5) different days. Each site had two (2) operators who each assayed the entire sample panel and Positive Control once per day, for a total of two (2) sets of data per day on a total of six (6) LIAISON® MDX instruments. The combined results for all sites are presented in Tables 2 and 3.

Table 2. Simplexa™ GBS Direct Reproducibility (FAM)

GBS (FAM)	Site 1			Site 2			Site 4			Total % Agreement with Expected Results	95% CI
	% Agreement with Expected Results	Avg Ct	Total %CV	% Agreement with Expected Results	Avg Ct	Total %CV	% Agreement with Expected Results	Avg Ct	Total %CV		
BAA-22 – LP	100.0% (30/30)	33.2	1.2	100.0% (30/30)	33.7	1.7	100.0% (30/30)	32.1	0.9	100.0% (90/90)	95.9% to 100.0%
BAA-22 – MP	100.0% (30/30)	32.6	1.1	100.0% (30/30)	31.6	1.3	100.0% (30/30)	31.9	1.1	100.0% (90/90)	95.9% to 100.0%
BAA-1138 – LP	100.0% (30/30)	34.1	1.6	93.3% (28/30)	34.6	3.1	100.0% (30/30)	33.1	2.3	97.8% (88/90)	92.3% to 99.4%
BAA-1138 – MP	100.0% (30/30)	32.7	1.2	100.0% (30/30)	33.1	1.4	100.0% (30/30)	31.9	1.5	100.0% (90/90)	95.9% to 100.0%
PC	100.0% (30/30)	30.2	0.6	100.0% (30/30)	28.7	0.7	100.0% (30/30)	29.1	0.7	100.0% (90/90)	95.9% to 100.0%
NTC	100.0% (30/30)	NA	NA	100.0% (30/30)	NA	NA	100.0% (30/30)	NA	NA	100.0% (90/90)	95.9% to 100.0%
Total Agreement	**100.0% (180/180) 95% CI: 97.9% to 100.0%**			**98.9% (178/180) 95% CI: 96.0% to 99.7%**			**100.0% (180/180) 95% CI: 97.9% to 100.0%**			**99.6% (538/540) 95% CI: 98.7% to 99.9%**	

Table 3. Simplexa™ GBS Direct Internal Control Reproducibility (Q670)

Sample DNA IC (Q670)	Site 1			Site 2			Site 4			Total % Agreement with Expected Results	95% CI
	% Agreement with Expected Results	Avg Ct	Total %CV	% Agreement with Expected Results	Avg Ct	Total %CV	% Agreement with Expected Results	Avg Ct	Total %CV		
BAA-22 – LP	100.0% (30/30)	31.1	0.9	100.0% (30/30)	31.1	0.7	100.0% (30/30)	29.8	0.6	100.0% (90/90)	95.9% to 100.0%
BAA-22 – MP	100.0% (30/30)	31.0	0.4	100.0% (30/30)	30.3	0.6	100.0% (30/30)	30.6	0.7	100.0% (90/90)	95.9% to 100.0%
BAA-1138 – LP	100.0% (30/30)	31.0	0.8	100.0% (30/30)	31.1	0.4	100.0% (30/30)	29.9	1.6	100.0% (90/90)	95.9% to 100.0%
BAA-1138 – MP	100.0% (30/30)	31.0	0.7	100.0% (30/30)	31.1	0.5	100.0% (30/30)	29.8	0.7	100.0% (90/90)	95.9% to 100.0%
PC	100.0% (30/30)	30.9	0.7	100.0% (30/30)	30.2	0.4	100.0% (30/30)	30.4	0.6	100.0% (90/90)	95.9% to 100.0%
NTC	100.0% (30/30)	31.0	0.5	100.0% (30/30)	31.1	0.5	100.0% (30/30)	30.0	0.9	100.0% (90/90)	95.9% to 100.0%
Total Agreement	**100.0% (180/180) 95% CI: 97.9% to 100.0%**			**100.0% (180/180) 95% CI: 97.9% to 100.0%**			**100.0% (180/180) 95% CI: 97.9% to 100.0%**			**100.0% (540/540) 95% CI: 99.3% to 100.0%**	

ANALYTICAL SENSITIVITY/LIMIT OF DETECTION

The Limit of Detection (LoD) was determined for the Simplexa™ GBS Direct assay using quantified stocks of two (2) GBS strains (BAA-22 and BAA-1138) serially diluted into negative eighteen to twenty-four (18 to 24) hour Lim broth enrichments of vaginal/rectal specimen swabs obtained from antepartum women. The LoD was determined to be the lowest concentration that could be detected positive ≥ 95% of the time. The results are shown in Table 4.

Table 4. Simplexa™ GBS Direct Summary of Limit of Detection (LoD)

GBS strain	LoD Concentration (CFU/mL)
ATCC BAA-22 (serotype III)	80,000
ATCC BAA-1138 (serotype Ia)	30,000

ANALYTICAL REACTIVITY/CROSS REACTIVITY

Analytical Reactivity

The Simplexa™ GBS Direct assay was evaluated for analytical reactivity to an additional eighteen (18) GBS strains spiked at 2 x LoD into eighteen to twenty-four (18 to 24) Lim broth enrichments of vaginal/rectal specimen swabs obtained from antepartum women. The results are shown in Table 5. All eighteen (18) strains were detected.

Table 5. Simplexa™ GBS Direct Analytical Reactivity

No.	Group B *Streptococcus* Strain	Serotype	Concentration CFU/mL (2 x LoD)	Simplexa™ GBS Direct %Detection # Detected / # Tested
1	ATCC BAA-1177	Ia	110,000	100% (3/3)
2	ATCC 51487	Ib	110,000	100% (3/3)
3	ATCC 27591	Ic	110,000	100% (3/3)
4	ATCC 12973	II	110,000	100% (3/3)
5	ATCC BAA-2675	II	110,000	100% (3/3)
6	ATCC BAA-1176	III	110,000	100% (3/3)
7	ATCC BAA-2674	III	110,000	100% (3/3)
8	ATCC 12403	III	110,000	100% (3/3)
9	ATCC 49446	IV	110,000	100% (3/3)
10	ATCC BAA-2673	IV	110,000	100% (3/3)
11	ATCC BAA-2672	V	110,000	100% (3/3)
12	ATCC BAA-611	V	110,000	100% (3/3)
13	ATCC BAA-2671	VI	110,000	100% (3/3)
14	ATCC BAA-2670	VII	110,000	100% (3/3)
15	ATCC BAA-2669	VIII	110,000	100% (3/3)

No.	Group B *Streptococcus* Strain	Serotype	Concentration CFU/mL (2 x LoD)	Simplexa™ GBS Direct %Detection # Detected / # Tested
16	ATCC BAA-2668	IX 1	110,000	100% (3/3)
17	ATCC 13813	Non-Hemolytic	110,000	100% (3/3)
18	ATCC BAA-2666	Non-Hemolytic	110,000	100% (3/3)

Cross Reactivity (Analytical Specificity)

The Simplexa™ GBS Direct assay's analytical specificity was evaluated by testing the ability of the assay to exclusively identify GBS without any cross-reactivity to organisms that are closely related, or cause similar clinical symptoms or may be present in eighteen to twenty-four (18 to 24) hour Lim broth enrichments of vaginal/rectal specimen swabs obtained from antepartum women. Seventy-four (74) potential cross-reacting organisms were spiked into GBS negative enriched Lim broth and tested in triplicate. Four (4) organisms with low concentration stocks were additionally tested *in silico*. No cross reactivity was observed demonstrating the specificity of the Simplexa™ GBS Direct assay. The results are presented in Table 7.

Table 7. Simplexa™ GBS Direct Cross Reactivity (Analytical Specificity)

No.	Cross Reactant	Tested Concentration	Expected Negative Results % Detection (# Detected/ # Tested)
1	*Acinetobacter baumannii*	1 x 10^6 CFU/mL	0% (0/3)
2	*Actinomyces israelii*	1 x 10^6 CFU/mL	0% (0/3)
3	*Aerococcus viridans*	1 x 10^6 CFU/mL	0% (0/3)
4	*Aeromonas hydrophila*	1 x 10^6 CFU/mL	0% (0/3)
5	*Atopobium vaginae*	1 x 10^6 CFU/mL	0% (0/3)
6	*Bacillus cereus*	1 x 10^6 CFU/mL	0% (0/3)
7	*Bacteroides fragilis*	1 x 10^6 CFU/mL	0% (0/3)
8	*Bifidobacterium adolescentis*	1 x 10^6 CFU/mL	0% (0/3)
9	*Bifidobacterium breve*	1 x 10^6 CFU/mL	0% (0/3)
10	*Blastocystis hominis*	1 x 10^6 cells/mL	0% (0/3)
11	*Brevibacterium linens*	1 x 10^6 CFU/mL	0% (0/3)
12	*Campylobacter jejuni*	1 x 10^6 CFU/mL	0% (0/3)
13	*Candida albicans*	1 x 10^6 CFU/mL	0% (0/3)
14	*Candida glabrata*	1 x 10^6 CFU/mL	0% (0/3)
15	*Candida parapsilosis*	1 x 10^6 CFU/mL	0% (0/3)
16	*Candida tropicalis*	1 x 10^6 CFU/mL	0% (0/3)
17	*Chlamydia trachomatis*	1 x 10^6 IFU/mL	0% (0/3)
18	*Chromobacterium violaceum*	1 x 10^6 CFU/mL	0% (0/3)
19	*Clostridium difficile*	1 x 10^6 CFU/mL	0% (0/3)
20	*Clostridium perfringens*	1 x 10^6 CFU/mL	0% (0/3)

No.	Cross Reactant	Tested Concentration	Expected Negative Results % Detection (# Detected/ # Tested)
21	*Corynebacterium genitalium*	1 x 10^6 CFU/mL	0% (0/3)
22	*Cryptococcus neoformans*	1 x 10^6 CFU/mL	0% (0/3)
23	*Enterobacter cloacae*	1 x 10^6 CFU/mL	0% (0/3)
24	*Enterococcus avium*	1 x 10^6 CFU/mL	0% (0/3)
25	*Enterococcus faecalis*	1 x 10^6 CFU/mL	0% (0/3)
26	*Enterococcus faecium*	1 x 10^6 CFU/mL	0% (0/3)
27	*Escherichia coli*	1 x 10^6 CFU/mL	0% (0/3)
28	*Fusobacterium nucleatum*	1 x 10^6 CFU/mL	0% (0/3)
29	*Gardnerella vaginalis**	NA	NA
30	*Giardia lamblia*	1 x 10^6 cells/mL	0% (0/3)
31	HSV-1	1 x 10^5 $TCID_{50}$/mL	0% (0/3)
32	HSV-2	1 x 10^5 $TCID_{50}$/mL	0% (0/3)
33	HIV-1	5 x 10^4 $TCID_{50}$/mL *	0% (0/3)
34	HPV Genotype 18	1 x 10^5 IU/mL	0% (0/3)
35	White Blood Cells (Human genomic DNA)	1 x 10^6 cells/mL	0% (0/3)
36	Human rotavirus	1 x 10^4 $TCID_{50}$/mL *	0% (0/3)
37	*Klebsiella oxytoca*	1 x 10^6 CFU/mL	0% (0/3)
38	*Klebsiella pneumoniae*	1 x 10^6 CFU/mL	0% (0/3)
39	*Lactobacillus acidophilus*	1 x 10^6 CFU/mL	0% (0/3)
40	*Lactobacillus crispatus*	1 x 10^6 CFU/mL	0% (0/3)
41	*Lactobacillus delbrueckii subsp. lactis*	1 x 10^6 CFU/mL	0% (0/3)
42	*Lactobacillus iners*	1 x 10^6 CFU/mL	0% (0/3)
43	*Lactobacillus jensensii*	1 x 10^6 CFU/mL	0% (0/3)
44	*Mobiluncus curtisii*	1 x10^6CFU/mL	0% (0/3)
45	*Mobiluncus mulieris*	1 x 10^6 CFU/mL	0% (0/3)
46	*Mycoplasma genitalium*	5 x 10^5 CCU/mL*	0% (0/5)**
47	*Mycoplasma hominis*	1 x 10^6 CCU/mL	0% (0/3)
48	Norovirus Genogroup GI*	NA	NA
49	Norovirus Genogroup GII*	NA	NA
50	*Neisseria gonorrhoeae*	1 x 10^6 CFU/mL	0% (0/3)
51	*Peptostreptococcus anaerobius*	1 x 10^6 CFU/mL	0% (0/3)
52	*Porphyromonas asaccharolytica*	1 x 10^6 CFU/mL	0% (0/3)
53	*Prevotella melaninogenica*	1 x 10^6 CFU/mL	0% (0/3)

No.	Cross Reactant	Tested Concentration	Expected Negative Results % Detection (# Detected/ # Tested)
54	*Propionibacterium acnes*	1 x 10^6 CFU/mL	0% (0/3)
55	*Proteus mirabilis*	1 x 10^6 CFU/mL	0% (0/3)
56	*Pseudomonas aeruginosa*	1 x 10^6 CFU/mL	0% (0/3)
57	*Salmonella enterica* subsp enterica	1 x 10^6 CFU/mL	0% (0/3)
58	*Serratia marcescens*	1 x 10^6 CFU/mL	0% (0/3)
59	*Shigella sonnei*	1 x 10^6 CFU/mL	0% (0/3)
60	*Staphylococcus aureus*	1 x 10^6 CFU/mL	0% (0/3)
61	*Staphylococcus epidermidis*	1 x 10^6 CFU/mL	0% (0/3)
62	*Staphylococcus saprophyticus*	1 x 10^6 CFU/mL	0% (0/3)
63	*Streptococcus anginosus*	1 x 10^6 CFU/mL	0% (0/3)
64	*Streptococcus bovis*	1 x 10^6 CFU/mL	0% (0/3)
65	*Streptococcus dysgalactiae*	1 x 10^6 CFU/mL	0% (0/3)
66	*Streptococcus intermedius*	1 x 10^6 CFU/mL	0% (0/3)
67	*Streptococcus mitis*	1 x 10^6 CFU/mL	0% (0/3)
68	*Streptococcus oralis*	1 x 10^6 CFU/mL	0% (0/3)
69	*Streptococcus pneumoniae*	1 x 10^6 CFU/mL	0% (0/3)
70	*Streptococcus pyogenes*	1 x 10^6 CFU/mL	0% (0/3)
71	*Streptococcus salivarius*	1 x 10^6 CFU/mL	0% (0/3)
72	*Streptococcus sanguinis*	1 x 10^6 CFU/mL	0% (0/3)
73	*Streptococcus suis*	1 x 10^6 CFU/mL	0% (0/3)
74	*Streptococcus uberis*	1 x 10^6 CFU/mL	0% (0/3)
75	*Trichomonas vaginalis**	NA	NA
76	*Ureaplasma urealyticum*	1 x 10^6 CCU/mL	0% (0/3)
77	VZV	1 x 10^5 copies/mL	0% (0/3)
78	*Yersinia enterocolitica*	1 x 10^6 CFU/mL	0% (0/3)

* Tested *in silico* and no potential for cross-reaction with the Simplexa™ GBS Direct primers and probe observed.
** Tested in quintuplicate due to assay set up error.
NA = not available

INTERFERENCE

The performance of the Simplexa™ GBS Direct assay was evaluated with twenty-six (26) potentially interfering endogenous and exogenous substances that may be present in eighteen to twenty-four (18 to 24) hour Lim broth enrichments of vaginal/rectal specimen swabs obtained from antepartum women. All samples were prepared by spiking each potentially interfering substance into a baseline consisting of either the ATCC BAA-1138 or ATCC BAA-22 strain of GBS at a concentration of 2 x LoD in eighteen to twenty-four (18 to 24) hour Lim broth enrichments of vaginal/rectal specimen swabs obtained from antepartum women. Each interferent was spiked into the baseline sample and tested at the concentrations listed in Table 8. The results are presented in Table 8. No interference was observed at the concentrations indicated in Table 8.

Table 8. Simplexa™ GBS Direct Interference

	Potentially Interfering Substance	Active Ingredient	Interferent Concentration
1	Amniotic Fluid	NA	10% v/v
2	Antacids (Gaviscon)	Aluminum Hydroxide / Magnesium Hydroxide	5 % v/v*
3	Antacids/Gastritis Medication	Calcium Carbonate	10 mg/mL
4	Anti-Diarrheal Medication (Imodium)	Loperamide Hydrochloride	10% v/v
5	Anti-Diarrheal Medication (Pepto Bismol)	Bismuth Subsalicylate	10% v/v
6	Anti-Fungal /Anti-Itch Vaginal	Nystatin	10 mg/mL**
7	Anti-Hemorrhoid Creams/Ointments	Hydrocortisone	10 mg/mL
8	Anti-Hemorrhoid Creams/Ointments	Phenylephrine HCl	10 mg/mL
9	Antimicrobials	Clotrimazole	10% w/v
10	Fecal Fat	Palmitic Acid	5 mg/mL*
11	Gastritis Medications (Nexium)	Esomeprazole Magnesium	0.31 mg/mL*
12	Laxatives	Sennosides	5 mg/mL*
13	Meconium	NA	0.31% w/v *
14	Mesalazine enema	Mesalazine	5 mg/mL*
15	Mineral Oil enema	Mineral Oil	10% v/v
16	Moist Towelettes	Benzalkonium Chloride	10% v/v
17	Moist Towelettes	Ethanol	10% v/v
18	Mucus	Immunoglobulin, Lysozyme, Polymers	10% v/v
19	Non-Steroidal Anti-Inflammatory Medications	Naproxen Sodium	3 mg/mL*
20	Radiology Oral Compounds	Barium Sulfate	5 mg/mL*
21	Seminal Fluid	NA	5% v/v*

	Potentially Interfering Substance	Active Ingredient	Interferent Concentration
22	Spermicidal Lubricant	Nonoxynol-9	10 mg/mL
23	Stool	NA	0.31% w/v*
24	Topical Products	Baby Powder	10 mg/mL
25	Topical Products	KY Jelly	10% w/v*
26	Whole Blood	Glucose, Hormones, Enzymes, Ions, Iron, etc.	10% v/v

* False negative and/or Invalid results were obtained at higher concentrations
** On initial testing 1 sample produced an EC505 error due to insufficient information to determine whether amplification occurred; the retest result was acceptable

INHIBITION BY OTHER MICROORGANISMS

The Simplexa™ GBS Direct assay was evaluated by testing the ability to identify GBS when other potentially inhibitory organisms were present at high concentrations. The panel of seventy-four (74) potentially inhibitory organisms were individually spiked into a pool with a low concentration of GBS BAA-22 or BAA-1138 strains at approximately 2 x LoD in Lim broth enrichments eighteen to twenty-four (18 to 24) hour of vaginal/rectal specimen swabs obtained from antepartum women. No false negative results were observed with GBS BAA-22 in the presence of any of the potentially interfering organisms or viruses. However, with GBS BAA-1138, at least one false negative result was obtained in the presence of each of the following species: *Bacillus cereus*, *Candida parapsilosis, Clostridium perfringens*, *Peptostreptococcus anaerobius*, *Staphylococcus saprophyticus*, *Streptococcus pyogenes* and *Ureaplasma urealyticum* (Table 9). Additional *in silico* analysis demonstrated no potential for cross-reaction or interference with the Simplexa™ GBS Direct primers and probe by Norovirus genogroups I and II or *Trichomonas vaginalis*.

Table 9. Simplexa™ GBS Direct Microbial Inhibition

No.	Organism	GBS Strain	Tested Concentration	% Detection (# Detected/ # Tested)
1	*Acinetobacter baumannii*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
2	*Actinomyces israelii*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
3	*Aerococcus viridans*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
4	*Aeromonas hydrophila*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)

No.	Organism	GBS Strain	Tested Concentration	% Detection (# Detected/ # Tested)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
5	*Atopobium vaginae*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
6	*Bacillus cereus*	BAA-1138	1 x 10^6 CFU/mL	88.9 %(8/9)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
7	*Bacteroides fragilis*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
8	*Bifidobacterium adolescentis*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
9	*Bifidobacterium breve*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
10	*Blastocystis hominis*	BAA-1138	1 x 10^6 cells/mL	100% (3/3)
		BAA-22	1 x 10^6 cells/mL	100% (3/3)
11	*Brevibacterium linens*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
12	*Campylobacter jejuni*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
13	*Candida albicans*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
14	*Candida glabrata*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
15	*Candida parapsilosis*	BAA-1138	1 x 10^6 CFU/mL	77.8% (7/9)

No.	Organism	GBS Strain	Tested Concentration	% Detection (# Detected/ # Tested)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
16	*Candida tropicalis*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
17	*Chlamydia trachomatis*	BAA-1138	1 x 10^6 IFU/mL	100% (3/3)
		BAA-22	1 x 10^6 IFU/mL	100% (3/3)
18	*Chromobacterium violaceum*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
19	*Clostridium difficile*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
20	*Clostridium perfringens*	BAA-1138	1 x 10^6 CFU/mL	88.9 %(8/9)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
21	*Corynebacterium genitalium*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
22	*Cryptococcus neoformans*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
23	*Enterobacter cloacae*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
24	*Enterococcus avium*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
25	*Enterococcus faecalis*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
26	*Enterococcus faecium*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)

No.	Organism	GBS Strain	Tested Concentration	% Detection (# Detected/ # Tested)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
27	*Escherichia coli*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
28	*Fusobacterium nucleatum*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
29	*Giardia lamblia*	BAA-1138	1 x 10^6 cells/mL	100% (3/3)
		BAA-22	1 x 10^6 cells/mL	100% (3/3)
30	HIV-1	BAA-1138	5 x 10^4 $TCID_{50}$/mL	100% (3/3)
		BAA-22	5 x 10^4 $TCID_{50}$/mL	100% (3/3)
31	HPV Genotype 18	BAA-1138	1 x 10^5 IU/mL	100% (3/3)
		BAA-22	1 x 10^5 IU/mL	100% (3/3)
32	HSV-1	BAA-1138	1 x 10^5 $TCID_{50}$/mL	100% (3/3)
		BAA-22	1 x 10^5 $TCID_{50}$/mL	100% (3/3)
33	HSV-2	BAA-1138	1 x 10^5 $TCID_{50}$/mL	100% (3/3)
		BAA-22	1 x 10^5 $TCID_{50}$/mL	100% (3/3)
34	Human DNA (White Blood Cells)	BAA-1138	1 x 10^6 WBC/mL	100% (3/3)
		BAA-22	1 x 10^6 WBC/mL	100% (3/3)
35	Human rotavirus	BAA-1138	1 x 10^4 $TCID_{50}$/mL	100% (3/3)
		BAA-22	1 x 10^4 $TCID_{50}$/mL	100% (3/3)
36	*Klebsiella oxytoca*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)

No.	Organism	GBS Strain	Tested Concentration	% Detection (# Detected/ # Tested)
37	*Klebsiella pneumoniae*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
38	*Lactobacillus acidophilus*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
39	*Lactobacillus crispatus*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
40	*Lactobacillus delbrueckii subsp. lactis*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
41	*Lactobacillus iners*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
42	*Lactobacillus jensensii*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
43	*Mobiluncus curtisii*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
44	*Mobiluncus mulieris*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
45	*Mycoplasma genitalium*	BAA-1138	5 x 10^5 CCU/mL	100% (3/3)
		BAA-22	5 x 10^5 CCU/mL	100% (3/3)
46	*Mycoplasma hominis*	BAA-1138	1 x 10^6 CCU/mL	100% (3/3)
		BAA-22	1 x 10^6 CCU/mL	100% (3/3)
47	*Neisseria gonorrhoeae*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)

No.	Organism	GBS Strain	Tested Concentration	% Detection (# Detected/ # Tested)
48	Norovirus genogroup I*	NA	NA	NA
49	Norovirus genogroup II*	NA	NA	NA
50	*Peptostreptococcus anaerobius*	BAA-1138	1 x 10^6 CFU/mL	88.9 %(8/9)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
51	*Porphyromonas asaccharolytica*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
52	*Prevotella melaninogenica*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
53	*Propionibacterium acnes*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
54	*Proteus mirabilis*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
55	*Pseudomonas aeruginosa*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
56	*Salmonella enterica* subsp *enterica*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
57	*Serratia marcescens*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
58	*Shigella sonnei*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
59	*Staphylococcus aureus*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)

No.	Organism	GBS Strain	Tested Concentration	% Detection (# Detected/ # Tested)
60	*Staphylococcus epidermidis*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
61	*Staphylococcus saprophyticus*	BAA-1138	1 x 10^6 CFU/mL	77.8% (7/9)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
62	*Streptococcus anginosus*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
63	*Streptococcus bovis*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
64	*Streptococcus dysgalactiae*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
65	*Streptococcus intermedius*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
66	*Streptococcus mitis*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
67	*Streptococcus oralis*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
68	*Streptococcus pneumoniae*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
69	*Streptococcus pyogenes*	BAA-1138	1 x 10^6 CFU/mL	88.9 %(8/9)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
70	*Streptococcus salivarius***	BAA-1138	1 x 10^6 CFU/mL	100% (6/6)
		BAA-22	1 x 10^6 CFU/mL	100% (6/6)

No.	Organism	GBS Strain	Tested Concentration	% Detection (# Detected/ # Tested)
71	*Streptococcus sanguinis*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
72	*Streptococcus suis*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
73	*Streptococcus uberis*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)
74	*Trichomonas vaginalis**	NA	NA	NA
75	*Ureaplasma urealyticum*	BAA-1138	1 x 10^6 CCU/mL	77.8% (7/9)
		BAA-22	1 x 10^6 CCU/mL	100% (3/3)
76	VZV	BAA-1138	1 x 10^5 copies/mL	100% (3/3)
		BAA-22	1 x 10^5 copies/mL	100% (3/3)
77	*Yersinia enterocolitica*	BAA-1138	1 x 10^6 CFU/mL	100% (3/3)
		BAA-22	1 x 10^6 CFU/mL	100% (3/3)

* Tested *in silico* and no potential for cross-reaction or interference with the Simplexa™ GBS Direct primers and probe observed
****** *Streptococcus salivarius* was inadvertently tested twice.
NA = not available

CARRY-OVER CONTAMINATION

Amplification carry-over for the Simplexa™ assays has been assessed. The study was performed by testing alternating high positive and negative samples on each disc. No evidence of carry-over contamination was observed.

EXPECTED VALUES

The prevalence of GBS as determined by the Simplexa™ GBS Direct assay in a multi-site clinical study with prospectively collected specimens is shown in Table 10.

Table 10. Expected Values per Site

Site ID	Total	Simplexa™ GBS Direct Positive	GBS Prevalence
01	168	49	29.2%
05	208	44	21.2%
06	56	17	30.4%
All	432	110	25.5%

The expected values for GBS per site varied between 21.2% and 30.4%. The overall prevalence for all sites was 25.5% one hundred and ten of four hundred and thirty-two (110/432) by the Simplexa™ GBS Direct assay and 23.1% one hundred of four hundred and thirty-two (100/432) as determined by a culture reference method.

CONCLUSION

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