

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
ASSAY ONLY TEMPLATE**

**A. 510(k) Number:**

K112125

**B. Purpose for Submission:**

To determine substantial equivalence for the *illumigene*<sup>®</sup> Group B Streptococcus (GBS) DNA Amplification Assay used for the qualitative detection of *Streptococcus agalactiae*.

**C. Measurand:**

Segment of the *Streptococcus agalactiae* genome

**D. Type of Test:**

Qualitative in vitro diagnostic using Loop-mediated isothermal DNA amplification (LAMP) technology

**E. Applicant:**

Meridian Bioscience, Inc.

**F. Proprietary and Established Names:**

*illumigene*<sup>®</sup> Group B Streptococcus (GBS) DNA Amplification Assay  
*illumigene*<sup>®</sup> Group B *Streptococcus* (GBS) External Control Kit

**G. Regulatory Information:**

<b>Product Code</b>	<b>Classification</b>	<b>Regulation Section</b>	<b>Panel</b>
NJR, Nucleic acid amplification assay system, <i>Streptococcus</i> spp., serological reagents	Class I	21 CFR § 866.3740	Microbiology (83)

## H. Intended Use:

### g. Intended use:

The *illumigene*<sup>®</sup> Group B *Streptococcus* (GBS) assay, performed on the *illumipro-10*, is a qualitative *in vitro* diagnostic for the detection of *Streptococcus agalactiae* in enriched cultures obtained from vaginal/rectal swab specimens from antepartum women. Enriched cultures are obtained by 18-24 hour incubation of vaginal/rectal swab specimens in selective broth medium, either Lim Broth or TransVag Broth.

The *illumigene*<sup>®</sup> GBS assay utilizes loop-mediated isothermal DNA amplification (LAMP) technology to detect *Streptococcus agalactiae* by targeting a segment of the *Streptococcus agalactiae* genome. Results from the *illumigene*<sup>®</sup> GBS assay can be used as an aid in establishing the GBS colonization status of antepartum women. This assay does not diagnose or monitor treatment for GBS infections. The *illumigene*<sup>®</sup> GBS assay does not provide susceptibility results. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women.

The *illumigene*<sup>®</sup> Group B *Streptococcus* is intended for use in hospital, reference or state laboratory settings. The device is not intended for point-of-care use.

### 2. Indications for use:

The *illumigene*<sup>®</sup> Group B *Streptococcus* (GBS) assay, performed on the *illumipro-10*, is a qualitative *in vitro* diagnostic for the detection of *Streptococcus agalactiae* in enriched cultures obtained from vaginal/rectal swab specimens from antepartum women. Enriched cultures are obtained by 18-24 hour incubation of vaginal/rectal swab specimens in selective broth medium, either Lim Broth or TransVag Broth.

The *illumigene*<sup>®</sup> GBS assay utilizes loop-mediated isothermal DNA amplification (LAMP) technology to detect *Streptococcus agalactiae* by targeting a segment of the *Streptococcus agalactiae* genome. Results from the *illumigene*<sup>®</sup> GBS assay can be used as an aid in establishing the GBS colonization status of antepartum women. This assay does not diagnose or monitor treatment for GBS infections. The *illumigene*<sup>®</sup> GBS assay does not provide susceptibility results. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women.

The *illumigene*<sup>®</sup> Group B *Streptococcus* is intended for use in hospital, reference or state laboratory settings. The device is not intended for point-of-care use.

3. Special conditions for use statement(s):

- For Prescription Use Only
- The device is not intended for point-of-care use

4. Special instrument requirements:

*illumipro-10*<sup>TM</sup> Automated Isothermal Amplification and Detection System

**I. Device Description:**

The *illumigene*<sup>®</sup> Molecular Diagnostic Test System is comprised of the *illumigene*<sup>®</sup> Group B Streptococcus (GBS) DNA Amplification Test Kit, the *illumigene*<sup>®</sup> Group B Streptococcus (GBS) External Control Kit and the *illumipro-10*<sup>TM</sup> Automated Isothermal Amplification and Detection System. The *illumigene*<sup>®</sup> Group B Streptococcus (GBS) DNA amplification assay utilizes loop-mediated isothermal amplification (LAMP) technology to detect the presence of *Streptococcus agalactiae* in enriched cultures obtained from vaginal/rectal swab specimens taken from antepartum women. Each *illumigene*<sup>®</sup> GBS assay is completed using *illumigene*<sup>®</sup> Control Reagent, *illumigene*<sup>®</sup> Reaction Buffer, an *illumigene*<sup>®</sup> GBS Test Device and an *illumigene*<sup>®</sup> Heat Treatment Tube. Samples are diluted with the *illumigene*<sup>®</sup> control heat-treatment in the *illumigene*<sup>®</sup> Heat Treatment Tube and DNA amplification occurs in the *illumigene*<sup>®</sup> GBS Test Device.

The *illumipro-10*<sup>TM</sup> heats each *illumigene*<sup>®</sup> GBS Test Device containing prepared samples and Control Reagent, facilitating amplification of target DNA. When *S. agalactiae* is present in the enriched culture sample, a conserved sequence of the *S. agalactiae* is amplified and magnesium pyrophosphate is formed. Magnesium pyrophosphate forms a precipitate in the reaction mixture. The *illumipro-10*<sup>TM</sup> detects the change in light transmission through the reaction mixture created by the precipitating magnesium pyrophosphate. Sample results are reported as Positive or Negative based on the detected change in light transmission.

The *illumigene*<sup>®</sup> Group B Streptococcus (GBS) External Control Kit consists of a Positive Control Reagent and a Negative Control Reagent. External Control reagents are provided to aid the user in detection of reagent deterioration, adverse environmental or test conditions, or variance in operator performance that may lead to test errors. The *illumigene*<sup>®</sup> Group B Streptococcus External Control Kit is required for routine Quality Control.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Cepheid<sup>®</sup> Smart GBS, Model SCGBS-100N-50

2. Predicate 510(k) numbers:

K062948

3. Comparison with predicates:

<b>Similarities</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
	<b>K112125</b>	<b>K062948</b>
<b>Intended Use</b>	Qualitative	Same
<b>Test Principle</b>	DNA Amplification Assay	Same
<b>Specimen Types</b>	Vaginal/Rectal Swab Specimen Enriched in Lim Broth	Same
<b>Amplification</b>	Self contained and automated	Same
<b>Detection</b>	Self contained and automated	Same
<b>Calibration</b>	Not required	Same

<b>Differences</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
	<b>K112125</b>	<b>K062948</b>
<b>Specimen Types</b>	Vaginal/Rectal Swab Specimen Enriched in TransVag Broth	Vaginal/Rectal Swab Specimen
<b>Reading Time</b>	60 minutes	75 minutes
<b>DNA Amplification Technology</b>	Loop-Mediated Isothermal Amplification (LAMP)	Real-Time Polymerase Chain Reaction (PCR)
<b>Target Sequences Detected</b>	213 base pair (bp) sequence residing in the 593-805 bp region of <i>S. agalactiae</i> genome Segment 3	Unique region of the <i>S. agalactiae</i> chromosome
<b>Reagents</b>	<i>illumigene</i> ® Control Reagent <i>illumigene</i> ® Reaction Buffer <i>illumigene</i> ® GBS Test Device <i>illumigene</i> ® Heat Treatment Tubes	Sample Preparation Reagent Treatment Reagent Lysis Reagent Master Mix Positive Control Negative Control

<b>Differences</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
	<b>K112125</b>	<b>K062948</b>
<b>Instrumentation</b>	<i>Illumipro-10™</i> Automated Isothermal Amplification and Detection System	SmartCycler® Dx System
<b>Reading Method</b>	Visible Light Transmission	Fluorescence
<b>Performance:</b>		
• <b>Sensitivity</b>	<b>97.4%</b> [95% CI: 91.9% - 99.0%]	<b>98.7%</b> [95% CI: 92.8% - 100.0%]
• <b>Specificity</b>	<b>92.3%</b> [95% CI: 90.0% - 94.1%]	<b>90.4%</b> [95% CI: 85.8% - 93.9%]

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

Clinical and Laboratory Standards Institute. 2008. User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline— Second Edition (EP12-A2)

Clinical and Laboratory Standards Institute. 2005. User Verification of Performance for Precision and Trueness; Approved Guideline—Second Edition (EP15-A2)

Clinical and Laboratory Standards Institute. 2005. Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition (EP7-A2)

**L. Test Principle:**

The *illumigene*® Group B Streptococcus (GBS) Assay is based on loop-mediated isothermal amplification technology (LAMP). Loop-mediated amplification is accomplished by the use of specially designed primers that provide specific and continuous isothermal DNA amplification. Magnesium-pyrophosphate is produced as a by-product of LAMP amplification. The magnesium-pyrophosphate forms a white precipitate in the reaction solution, giving the reaction solution a turbid appearance. The presence of turbidity signifies a positive reaction while the absence of turbidity represents a negative reaction.

## M. Performance Characteristics:

### 1. Analytical performance:

#### a. *Precision/Reproducibility:*

For Meridian's reproducibility studies, blind coded panels of 10 samples were supplied to three independent laboratories. Samples were randomly sorted within each panel to mask sample identities. The panels included contrived samples manufactured near the assay limit of detection (i.e., low positive samples), n = 3 and high negative samples, n = 3. The panels also included contrived positive (n = 3) samples and natural negative samples (n = 1). Testing was performed by different operators at each site on the same day (intra-assay variability) for five days (inter-assay variability). Three lots of illumigene GBS and five *illumipro-10*<sup>TM</sup> instruments were used in this study. The results are given in the table below:

	Site 1		Site 2		Site 3		Total	
Sample Type	Percent agreement		Percent agreement		Percent agreement		Percent agreement	
Negative	10/10	100%	10/10	100%	10/10	100%	30/30	100%
High Negative	30/30	100%	30/30	100%	30/30	100%	90/90	100%
Low Positive	30/30	100%	30/30	100%	30/30	100%	90/90	100%
Positive	30/30	100%	30/30	100%	30/30	100%	90/90	100%

Reproducibility studies are acceptable.

#### b. *Linearity/assay reportable range:*

Not applicable as this assay is qualitative

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

##### *Stability:*

Sample storage and hold time studies were performed to characterize *illumigene*<sup>®</sup> Group B Streptococcus assay ranges. Validation studies performed at Meridian indicated that Lim broth represented the worst-case matrix; therefore all samples except two were prepared from enriched Lim medium. The latter two samples (one high negative and one LoD positive sample) were prepared from TransVag broth. Results demonstrated that undiluted samples can be held at 19-27<sup>0</sup> C for up to 6 hours or at 2-8<sup>0</sup> C for up to 7 days after culture enrichment and prior to testing. Samples diluted with *illumigene*<sup>®</sup> Control Reagent can be held at room temperature

for up to 15 minutes prior to heat-treatment. Heat-treated samples can be held at room temperature for up to 45 minutes prior to further processing.

Sample freeze/thaw studies were also performed. Samples were enriched 18-24 hours in enrichment broth and frozen prior to initiation of testing, then exposed to multiple freeze/thaw cycles. Results demonstrated that freeze/thaw of samples should *not* be done.

Final testing demonstrated that Lim Broth in combination with Dacron/polyester, flocked nylon, and foam swab types perform acceptably with the *illumigene*<sup>®</sup> GBS assay. The Amies Clear swab type has been identified in the Limitations section of the Package Insert as an incompatible swab type with the *illumigene*<sup>®</sup> GBS assay.

d. *Detection limit:*

Sensitivity studies were designed to determine the analytical limit of detection of *S. agalactiae* diluted in Lim broth. Six common strains of *S. agalactiae*, representing six different serotypes, were evaluated using the *illumigene*<sup>®</sup> GBS assay. Each strain was spiked into negative Lim broth and then diluted serially. A minimum of twenty replicates of each dilution were individually processed and tested to establish LoD. Testing was performed using three production lots of *illumigene*<sup>®</sup> GBS and six *illumipro-10*<sup>™</sup> instruments. External Positive and Negative Controls were tested each day throughout the study.

The LoD of the assay ranged from 60 CFU/Test to 1280 CFU/Test. The table below shows the lowest concentration for each serotype that produced positive results for 95% of the replicates tested.

<b>Serotype</b>	<b><i>Streptococcus agalactiae</i> Strain Description</b>	<b>CFU/Test</b>
1a	NCTC 11248	60
1b	ATCC 12401	80
1c	NCTC 11253	640
II	II/2	320
III	ATCC 12403	160
V	ATCC BAA	611

Additional *S. agalactiae* strains were tested and produced positive reactions at 1280 CFU/test with *illumigene*<sup>®</sup> GBS. Strains and serotypes were tested as follows: Serotype IV: NCTC 11930; Serotype VIa: NCTC 08188; Serotype VII: VII/2; Serotype VIII: VIII/2; Serotype X: NCTC 11249; Unknown Serotype: ATCC 13813 and ATCC12386.

LoD studies are acceptable.

e. *Analytical specificity:*

Interference Testing:

Selected substances that might be expected to be present in vaginal/rectal swab samples taken from antepartum women were added to a negative Lim broth sample and two contrived positive Lim broth samples. The negative sample was prepared by pooling confirmed negative Lim Broth samples while the contrived positive samples were prepared by spiking a pooled, confirmed negative Lim sample with either *Streptococcus agalactiae*, strain 11248 Serotype Ia (123 CFU/test) or *Streptococcus agalactiae*, strain 12401 Serotype Ib (80 CFU/test). Potentially interfering substances were added to Lim broth samples at final concentrations of 2.5% v/v or greater when the substances could be pipetted. Substances that could not be pipetted were coated onto cotton swabs, immersed in the negative/positive Lim broth samples and tested. Dilution Controls were prepared by adding a phosphate buffered saline solution in place of the potentially cross-reactive organisms. Each inoculated sample was tested in triplicate.

Results demonstrated that the following substances, at the specified saturated solvent/diluents concentrations, do not interfere with *illumigene*<sup>®</sup> Group B Streptococcus test results: Amniotic fluid (10% v/v), Human DNA (100 ng/Test), Urine (30% v/v), Whole Blood (2.5% v/v), Meconium, Stool, Hemorrhoid cream (30.65 mg/100mg), Miconazole (fungicide), Mucin (0.5-1.5%), Spermicidal gel (nonoxynol 9) (4mg/100mg). Lubricating gel produced False Negative Results in 1 of 11 replicates tested. Body Powder produced False Negative Results in 1 of 10 replicates tested. Whole Blood at concentrations greater than 2.5% v/v interferes with the *illumigene*<sup>®</sup> GBS assay.

Interference studies are acceptable.

Cross-reactivity Study:

Microorganisms that could potentially cross-react, expected to be present in vaginal/rectal swab specimens were added to negative and contrived positive Lim Broth samples. The negative sample was prepared by pooling confirmed negative Lim Broth samples. The contrived positive sample was prepared by spiking a confirmed negative matrix with *Streptococcus agalactiae*, strain 12401, at 122 CFU/test, near the limit of detection for this strain. Potentially cross-reactive microorganisms were added at concentrations of  $1.2 \times 10^8$  CFU/mL (bacteria and fungi) and virus at a minimum of  $1 \times 10^5$  TCID<sub>50</sub>/mL. Dilution controls for each sample were prepared by adding sterile saline solution in place of the potentially cross-reactive microorganisms. Each sample was tested in triplicate. Cross-reactivity with *Enterococcus dispar* was observed in one of seven replicates tested.

Results demonstrated that the following microorganisms at the indicated concentrations do not interfere with the *illumigene*<sup>®</sup> GBS assay:

*Aeromonas hydrophila*, *Alcaligenes faecalis*, *Bacillus cereus*, *Bacillus subtilis*, *Bacteroides fragilis*, *Campylobacter coli*, *Campylobacter fetus*, *Campylobacter jejuni*, *Candida albicans*, *Candida glabrata*, *Candida krusei*, *Candida parapsilosis*, *Candida tropicalis*, *Citrobacter freundii*, *Clostridium bifermentans*, *Clostridium butyricum*, *Clostridium difficile*, *Clostridium histolyticum*, *Clostridium novyi*, *Clostridium perfringens*, *Clostridium septicum*, *Clostridium sordellii*, *Clostridium sporogenes*, *Clostridium tetani*, *Corynebacterium genitalium*, *Corynebacterium urealyticum*, *Corynebacterium xerosis*, *Enterobacter aerogenes*, *Enterobacter cloacae*, *Enterococcus avium*, *Enterococcus durans*, *Enterococcus faecalis*, *Enterococcus faecium*, *Escherichia coli*, *Escherichia coli* 0157:H7, *Escherichia fergusonii*, *Escherichia hermannii*, *Gardnerella vaginalis*, *Haemophilus ducreyi*, *Helicobacter pylori*, *Klebsiella pneumoniae*, *Lactobacillus acidophilus*, *Lactobacillus brevis*, *Lactobacillus casei*, *Lactobacillus delbruekii subspecies lactis*, *Lactobacillus jensenii*, *Lactococcus lactis*, *Legionella pneumophila*, *Listeria monocytogenes*, *Moraxella osloensis*, *Morganella morganii*, *Neisseria gonorrhoeae*, *Peptostreptococcus anaerobius*, *Plesiomonas shigelloides*, *Porphyromonas asaccharolytica*, *Prevotella melaninogenica*, *Propionibacterium acnes*, *Proteus mirabilis*, *Proteus vulgaris*, *Pseudomonas aeruginosa*, *Pseudomonas fluorescens*, *Salmonella Group B*, *Salmonella Group C*, *Salmonella Group D*, *Salmonella Group E*, *Serratia liquefaciens*, *Serratia marcescens*, *Shigella boydii*, *Shigella flexneri*, *Shigella sonnei*, *Staphylococcus aureus*, *Staphylococcus aureus* (Cowan), *Staphylococcus epidermidis*, *Staphylococcus saprophyticus*, *Streptococcus anginosus*, *Streptococcus bovis*, *Streptococcus dysgalactiae equisimilis*, *Streptococcus intermedius*, *Streptococcus mitis*, *Streptococcus oralis*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Streptococcus salivarius*, *Streptococcus sanguinis*, *Vibrio parahaemolyticus*, *Yersinia enterocolitica*, Adenovirus 40, Adenovirus 41, BK virus, Coxsackievirus, Echovirus, Epstein Barr virus, Herpes Simplex Virus-1, Herpes Simplex Virus-2, Rotavirus. *Mycoplasma genitalium*, *Mycoplasma hominis* and *Ureaplasma urealyticum* were tested at final concentrations ranging between  $1.6 \times 10^6$  and  $9.9 \times 10^6$  CFU/mL with no reaction with the *illumigene*<sup>®</sup> GBS assay.

Cross reactivity studies are acceptable.

2. Comparison studies:

a. *Method Comparison with Predicate:*

Not applicable

b. *Matrix comparison:*

Not applicable

3. Clinical Studies:

a. *Clinical Sensitivity:*

Clinical trials for the *illumigene*<sup>®</sup> Group B Streptococcus (GBS) assay, including the *illumipro*<sup>™</sup>-10 Automated Isothermal amplification and detection system, were conducted. Performance characteristics of the *illumigene*<sup>®</sup> GBS assay were determined by comparison to GBS bacterial culture. Four independent clinical test sites located in the Midwestern and Southern regions of the United States evaluated a total of 826 qualified patient samples. Samples were obtained according to established guidelines for the collection of clinical specimens for culture of Group B Streptococcus and enriched for 18-24 hours in either Lim Broth or TransVag Broth prior to *illumigene*<sup>®</sup> testing. Four hundred and three (48.8%) specimens were enriched with Lim Broth and 423 (51.2%) specimens were enriched with TransVag Broth prior to testing. The age groups of patients tested ranged from 15 years of age to 44 years of age, with age unknown for three (0.4%) of the patient population. No differences in test performance were observed based on enrichment medium or patient age. Overall assay Sensitivity is reported as 97.4% [95% CI: 91.9% - 99.0%] where Specificity is 92.3% [95% CI: 90.0% - 94.1%].

The table below shows overall assay performance, including evaluation by enrichment medium.

Sample Type	Positive Samples			Negative Samples		
	<i>Illumigene</i> <sup>®</sup> /culture	% Sensitivity	95% CI	<i>Illumigene</i> <sup>®</sup> /culture	% Specificity	95% CI
<b>Total</b>	<b>150/154</b>	<b>97.4</b>	<b>91.9-99.0</b>	610/661	<b>92.3</b>	<b>90.0-94.1</b>
<b>LIM</b>	82/84	97.6	91.7-99.3	296/313	94.0	90.8-96.1
<b>TransVag</b>	68/70	97.1	90.2	314/346	90.8	87.2-93.4

The following table summarizes assay performance by Clinical site:

Site Identification	Enrichment Broth	Positive Samples			Negative Samples		
		<i>Illumigene</i> <sup>®</sup> /culture	% Sensitivity	95% CI	<i>Illumigene</i> <sup>®</sup> /culture	% Specificity	95% CI
Site 1	TransVag	32/33	97.0	84.7-99.5	197/199	99.0	96.4-99.7
Site 2	TransVag	36/37	97.3	86.2-99.5	117/147	79.6	72.4-85.3
Site 3	LIM	38/39	97.4	86.8-99.5	162/168	96.4	92.4-98.4
Site 4	LIM	44/45	97.8	88.4-99.6	134/147	97.8	92.4-98.4

Invalid results were obtained for 11/826 samples tested or 1.3%. Two of the 11 samples remained invalid after repeat testing of the original sample. Specimens that generated discrepant results were further evaluated by independent testing laboratories using FDA cleared molecular assays. Sixteen of nineteen Lim Broth False Positive results were positive by an alternate molecular method. All thirty-two TransVag Broth False Positive results were positive by an alternate molecular method. In addition to discrepant sample analysis, a selection of concordant samples was tested with non-*illumigene*<sup>®</sup> molecular methodologies. Concordant result testing showed a combined correlation between molecular methods of 97.7%. Results from discrepant analysis were *not* used to calculate Sensitivity and Specificity.

Clinical studies are acceptable.

b. *Clinical Specificity*

See Section 3a

c. *Other Clinical Supportive data*

Not applicable

4. Clinical cut-off:

Not Applicable

5. Expected Values/Reference Range:

Approximately 10-30% of antepartum women are colonized with Group B *Streptococcus* in the vagina or rectum. The overall incidence of GBS colonization in antepartum women tested during this study was 24.3% (201 of 826). Incidence of GBS colonization for enrichment performed using Lim Broth was found to be 25.1% (101 of 403); while incidence for specimens enriched by TransVag Broth was found to be 23.6% (100 of 423).

## N. Instrument Name

*illumipro-10*<sup>TM</sup>

## O. System Descriptions:

System Description was reviewed in previous submission, K100818 and K110012. No systems or software changes were made.

### 1. Modes of Operation:

The *illumipro*<sup>TM</sup>-10 heats each *illumigene*<sup>®</sup> GBS Test Device containing prepared samples and Control Reagent, facilitating amplification of target DNA. When *S. agalactiae* is present in the enriched culture sample, a conserved sequence of the *S. agalactiae* is amplified and magnesium pyrophosphate is formed. Magnesium pyrophosphate forms a precipitate in the reaction mixture. The *illumipro*<sup>TM</sup>-10 detects the change in light transmission through the reaction mixture created by the precipitating magnesium pyrophosphate. Sample results are reported as Positive or Negative based on the detected change in light transmission.

### 2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes  or No

### 3. Specimen Identification:

The *illumipro-10*<sup>TM</sup> utilizes software to automate incubation and detection of *illumigene* Molecular Diagnostic in vitro diagnostic test reactions. The *illumipro-10*<sup>TM</sup> reports sample results as INVALID, POSITIVE or NEGATIVE

### 4. Specimen Sampling and Handling:

Specimens are prepared manually. Incubation and detection are automated using the *illumipro-10*<sup>TM</sup>

### 5. Calibration:

Calibration of the *illumipro-10* is not required.

### 6. Quality Control:

The *illumigene*<sup>®</sup> Group B *Streptococcus* (GBS) External Control Kit consists of a Positive Control Reagent and a Negative Control Reagent. External Control reagents are provided to aid the user in detection of reagent deterioration, adverse

environmental or test conditions, or variance in operator performance that may lead to test errors. The *illumigene*<sup>®</sup> Group B Streptococcus External Control Kit is required for routine Quality Control.

**P. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

**Q . Conclusion :**

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