510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM
ASSAY ONLY TEMPLATE

A. 510(k) Number:

K170586

B. Purpose for Submission:

To obtain a substantial equivalence determination for the Strep B Carrot Broth One-Step for the qualitative detection of Group B Streptococcus (GBS).

C. Measurand:

Group B Streptococcus (GBS)

D. Type of Test:

Detection of GBS using selective and differential chromogenic medium

E. Applicant:

Hardy Diagnostics

F. Proprietary and Established Names:

Strep B Carrot Broth™ One-Step

G. Regulatory Information:

1. Regulation section:

   21 CFR 866.2360 - Selective culture medium.

2. Classification:

   Class I (non-exempt)

3. Product code:

   PQZ – GBS culture media, selective and differential

4. Panel:

   83 – Microbiology

H. Intended Use:

1. Intended use(s):
   Strep B Carrot Broth™ One-Step is a selective and differential medium which is intended for the detection of Group B *Streptococcus* (GBS) from anovaginal specimen collected from pregnant women. The medium is used as an aid in the qualitative determination of GBS colonization in pregnant women. The color change reaction from white to orange is representative of a positive result for presence of GBS. The medium requires 24 hours of incubation but positive results can be interpreted as early as 16 hours. Due to the properties of Strep B Carrot Broth™ One-Step, non-hemolytic GBS cannot be detected by the medium's color change and require subculture for identification. Any presumptive negative indicated by lack of color change at the end of the incubation period must be subcultured to a non-selective medium (e.g. Tryptic Soy Agar with 5% Sheep Blood) to confirm absence of GBS. Subculture must also be performed to recover isolates for conducting susceptibility testing as recommended for penicillin-allergic women.

2. Indication(s) for use:

   Same as the Intended Use.

3. Special conditions for use statement(s):

   Prescription use only

   Strep B Carrot Broth One-Step with no color change after 24 hours incubation is considered presumptive negative for GBS and should be subcultured to non-selective media followed by biochemical testing to rule-out presence of weakly β-hemolytic or non-hemolytic GBS.

   Storage of vaginal/rectal swabs in the specified specimen transport systems beyond 24 hours at room temperature before inoculating Strep B Carrot Broth One-Step is not recommended.

4. Special instrument requirements:

   Not Applicable

I. Device Description:

Strep B Carrot Broth One-Step is a selective and differential medium used for the detection of *Streptococcus agalactiae* (*S. agalactiae*, (GBS) colonization in pregnant women by testing vaginal/rectal swabs. Color development (light orange, orange, or red-orange color) is a

unique characteristic of β-hemolytic GBS strains resulting from colored pigment production in the presence of substrates such as starch, peptone, serum, and folate pathway inhibitors. Non-hemolytic GBS cannot be detected by color production, but can be recovered from Strep B Carrot Broth One-Step upon subculture to non-selective plates. Growth of microorganisms belonging to other species is either inhibited, or if there is growth, the culture does not produce the expected color reaction.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Todd Hewitt w/CNA (LIM Broth)

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

   K871447

3. Comparison with predicate:

Table 1. Comparison with LIM Broth

Similarities		
Item	Strep B Carrot Broth One-Step (K170586)	LIM Broth (K871447)
Intended Use	Strep B Carrot Broth™ One-Step is a selective and differential medium which is intended for the detection of Group B *Streptococcus* (GBS) from anovaginal specimens collected from pregnant women. The medium is used as an aid in the qualitative determination of GBS colonization in pregnant women. The color change reaction from white to orange is representative of a positive result for presence of GBS. The medium requires 24 hours of incubation but positive results can be interpreted and reported as early as 16 hours. Due to the properties of Strep B Carrot Broth™ One-Step, non-hemolytic GBS cannot be detected by the medium's color change and require subculture for identification. Any presumptive negative indicated by lack of color change at the end of the incubation period must be subcultured to a non-selective medium (e.g., Tryptic Soy Agar with 5% Sheep Blood) to confirm absence of GBS. Subculture must also be performed to recover isolates for conducting susceptibility testing as recommended for penicillin-allergic women.	Product is used in qualitative procedures to isolate Group B Streptococci from clinical specimens containing mixed bacterial flora.
Specimen Type	Vaginal/rectal swabs	Vaginal/rectal swabs
Inoculation	Direct	Direct
Interpretation	Manual/visual, subculture negatives for confirmation and subculture positives as needed for susceptibility testing	Manual/visual, subculture all to recover colonies for complete identification and susceptibility
Culture Media Type	Selective media	Selective media

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

Not Applicable

L. Test Principle:

Strep B Carrot Broth One-Step is a selective, differential medium for the detection of GBS. The ability to detect GBS is based on the presence of selective agents that suppress the growth of organisms other than GBS, and the presence of components necessary for pigment production that allow the detection of GBS colonization based on color development. Vaginal/rectal swabs from antepartum women are inoculated directly into Strep B Carrot Broth One-Step and incubated aerobically at 35°-37°C for 16-24 hours. Positive results can be reported as early as 16 hours. If negative at 16 hours, the broth cultures are re-incubated until 24 hours. The cultures are examined after 24 hours incubation for the development of light orange to orange to orange-red color. After the subculture of negatives to non-selective media, biochemical testing is performed to rule-out the presence of GBS before calling the sample negative.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Reproducibility was demonstrated at three sites using a blinded panel of twelve well-characterized strains, which included 10 hemolytic GBS strains, 1 non-hemolytic GBS strain, and 1 non-GBS strain as the negative control. At each site, panel members were tested in triplicate at 10^3 CFU/ml with Strep B Carrot Broth One-Step each day for five days. Strep B Carrot Broth One-Step tubes were observed for development of light orange to orange color at 24 hours. Testing was done with at least one operator and two readers. All strains produced the expected results with the Strep B Carrot Broth One-Step at 24 hours >95% of the time for each operator (538/540). All non-hemolytic GBS were recovered upon subculture to Tryptic Soy Agar with 5% sheep blood. Isolates were also plated onto Tryptic Soy Agar with 5% sheep blood to ensure viability and purity of cultures.

b. Linearity/assay reportable range:

Not applicable

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

Quality Control (QC) Testing
QC testing was performed at each site to examine color development with Strep B Carrot

Broth One-Step. Five quality control organisms were tested at each study site with Strep B Carrot Broth One-Step for each day of testing. QC testing results provided expected reactions across each testing site (Table 2). The submitted QC data are acceptable.

Table 2: QC Data Summary

Organism	Time of Incubation	Expected Results after 24 hrs at 35-37°C	QC Results (all sites) Observed/Expected
Streptococcus agalactiae ATCC 12386	24 hrs	Growth; bright orange to red color change	99/99
Streptococcus agalactiae clinical strain	24 hrs	Growth; light orange color change	99/99
Streptococcus pyogenes ATCC 19615	24 hrs	Growth; no color change	99/99
Escherichia coli ATCC 25922	24 hrs	Partial to complete inhibition; no color change	99/99
Proteus mirabilis ATCC 12453	24 hrs	Partial to complete inhibition; no color change	99/99

Specimen Stability

Various types of specimen transport swabs were evaluated to determine the acceptable storage conditions required to recover GBS from Strep B Carrot Broth One-Step. Swabs were spiked with GBS and a contrived matrix consisting of organisms commonly found in vaginal flora. Eight different GBS strains were used in this study and spiked into contrived matrix near LoD. Organisms suspenstions in the different transport systems were kept at both room temperature and 2-8°C for 0, 24, 48, 72, 96, and 120 hours before inoculation into Strep B Carrot Broth One-Step. TransPRO swabs with Liquid Amies (flocked swab liquid-based transport system) and four other types of transport systems (Sponge-based Liquid Amies and Liquid Stuart's, and Gel-based Amies Gel and Stuart's Gel) were used in this study. Strep B Carrot Broth One-Step was able to recover 8/8 (100%) of GBS strains and produce orange coloration from swabs in Liquid Amies, Liquid Stuart's, Amies Gel, and Stuart's Gel when stored at 2-8°C for up to 96 hours. 100% of GBS strains also produced the expected orange color reaction from TransPRO Liquid Amies stored at 2-8°C for up to 120 hours. Both color development and recovery of GBS were impacted by specimen storage at room temperature beyond 24 hours. All transport systems tested saw a decline in recovery of GBS after 24 hours storage at room temperature as shown in Table 3 below. A limitation in the package insert has been added regarding storage at room temperature beyond 24 hours with the specified specimen transport swabs.

Table 3. Recovery of GBS in Strep B Carrot Broth One-Step from Specimens Stored at Room Temperature

Matrix[1]	Percent Recovery at Room Temperature (%)				
	24 hrs	48 hrs	72 hrs	96 hrs	120 hrs
Liquid Amies	100	62.5	37.5	N/A[2]	N/A
Liquid Stuart's	100	62.5	37.5	N/A	N/A
Amies Gel	100	87.5	87.5	N/A	N/A
Stuart's Gel	100	87.5	75	N/A	N/A
TransPRO Liquid Amies	100	87.5	75	12.5	0

[1]*Specimens collected in Liquid Amies, Liquid Stuart's, and ESwab Liquid Amies transport systems were evaluated in the clinical studies.*
[2]*N/A-Time point not tested for that swab type*

d. Detection limit:

Recovery Study

A Recovery Study was performed with two GBS strains (ATCC 12386 and ATCC 12403). After preparing six serial dilutions per strain in natural negative matrix and inoculating media, Strep B Carrot Broth One-Step tubes were incubated to determine color development between 12-24 hours at 35°C. Tube color was recorded at 12 hours and every 2 hours until 24 hours incubation had occurred. At 16 hours, the minimum concentration of GBS detected for both strains with Strep B Carrot Broth One-Step was 10^3 CFU/ml. The LoD for the two GBS strains was confirmed by testing Strep B Carrot Broth One-Step with 20 replicates of each strain at the determined LoD concentration (10^3 CFU/ml).

Analytical Reactivity

A study was conducted to demonstrate the sensitivity of Strep B Carrot Broth One-Step in detecting various GBS strains at a concentration of 10^3 CFU/ml. The study included 54 ATCC reference and clinical GBS strains representing six of the nine different serotypes (48 hemolytic, 6 non-hemolytic). Tubes were read at 24 hours of incubation for an orange color reaction, which was indicative of GBS. The inclusivity panel is shown in Table 4 below.

Table 4. GBS Panel for Inclusivity Testing

Strain	Source	Hemolysis	Serotype[1]	Strep B Carrot Broth Observed Color
BAA-611	ATCC	β	V	Orange
12403	ATCC	β	III	Orange
12386	ATCC	β	II	Orange
8017	NCTC	β	III	Orange
1	Clinical	β	V	Orange
2	Clinical	β	II	Orange
KPWP	Clinical	β	III	Orange
P003-001	Clinical	β	Ia	Orange
7	Clinical	β	III	Orange
10	Clinical	β	1a	Orange

11	Clinical	β	V	Orange
13	Clinical	β	VI	Orange
3	Clinical	β	II	Orange
4	Clinical	β	VI	Orange
QOVHI	Clinical	β	Ia	Light Orange
27	Clinical	β	III	Orange
28	Clinical	β	III	Orange
14	Clinical	β	IV	Orange
15	Clinical	β	III	Orange
18	Clinical	β	1b	Orange
19	Clinical	β	1b	Orange
24	Clinical	β	II	Orange
26	Clinical	β	1b	Orange
29	Clinical	β	II	Orange
30	Clinical	β	1b	Orange
MS2	Clinical	β	III	Orange
MS3	Clinical	β	1b	Orange
MS4	Clinical	β	1a	Orange
MS5	Clinical	β	1b	Orange
MS6	Clinical	β	V	Orange
MS7	Clinical	β	1b	Orange
MS8	Clinical	β	1a	Orange
MS9	Clinical	β	1b	Orange
MS10	Clinical	β	1a	Orange
MS11	Clinical	β	NT[1]	Orange
MS12	Clinical	β	III	Orange
French	Clinical	β	1a	Orange
MS13	Clinical	β	NT	Orange
MS14	Clinical	β	1a	Orange
MS15	Clinical	β	1a	Orange
MS17	Clinical	β	1a	Orange
MS18	ATCC	β	1b	Orange
MS19	ATCC	β	NT	Orange
MS26	Clinical	β	1b	Orange
MS27	Clinical	β	III	Orange
MS28	Clinical	β	II	Orange
MS29	Clinical	β	II	Orange
MS30	Clinical	β	1b	Orange
13813	ATCC	Non-hemolytic	II	White
701348	NCIMB	Non-hemolytic	II	White
MS20	ATCC	Non-hemolytic	III	White
MS21	NCTC	Non-hemolytic	III	White
MS22	Clinical	Non-hemolytic	III	White
MS23	Clinical	Non-hemolytic	NT	White

[1] NT= Non-Typable against the nine known serotypes.

In Strep B Carrot Broth One-Step, all 48 β-hemolytic strains produced the expected orange color, and all six non-hemolytic GBS strains showed a negative color reaction. Results also demonstrated that Strep B Carrot Broth One-Step was able to recover all

non-hemolytic GBS strains tested at the LoD (10^3 CFU/ml).

Incubation Study

An Incubation Study was conducted to determine the effect of various incubation times on the performance of Strep B Carrot Broth One-Step when tested with ten GBS strains (hemolytic and non-hemolytic) at 10^3 CFU/ml concentration. The recovery of organisms and development of characteristic color with broth cultures were evaluated every 2 hours from 12-24 hours. At the earliest time point (12 hours), all hemolytic organisms produced some kind of orange color reaction (light orange to orange). All GBS strains, including the non-hemolytic strain tested, were recovered upon subculture of Strep B Carrot Broth One-Step. The earliest incubation time set for positive detection of GBS by color was 16 hours.

e. Analytical specificity:

Cross-Reactivity Study

In order to evaluate the performance of Strep B Carrot Broth One-Step with microorganisms potentially encountered in vaginal/rectal swabs, a Cross-Reactivity Study was completed with 78 non-target organisms (gram negative bacteria, gram positive bacteria, and yeast) at approximately10^8 CFU/ml. Results showed that all 78 organisms from the cross-reactivity panel produced a negative color reaction with Strep B Carrot Broth One-Step. A total of 45 organisms (57.7%) were recoverable when subcultured at the end of 24 hrs incubation. The cross-reactivity panel is shown in Table 5 below.

Table 5. List of non-target organisms tested in Analytical Specificity Study

Organism		
Acinetobacter baumannii	*Enterococcus durans*	*Proteus mirabilis*
Aeromonas hydrophila	*Enterococcus faecalis*	*Providencia alcalifaciens*
Aspergillus brasiliensis	*Enterococcus faecium*	*Pseudomonas aeruginosa*
Bacillus cereus	*Enterococcus flavescens*	*Pseudomonas fluorescens*
Bacillus subtilis	*Enterococcus hirae*	*Saccharomyces cerevisiae*
Bacteroides fragilis	*Enterococcus raffinosus*	*Salmonella enterica (typhii)*
Bifidobacterium breve	*Enterococcus saccharolyticus*	*Salmonella enterica arizonae*
Campylobacter coli	*Escherichia coli*	*Serratia marcescens*
Campylobacter jejuni	*Gardnerella vaginalis*	*Shigella boydii*
Candida albicans	*Geotrichum candidum*	*Shigella flexneri*
Candida glabrata	*Hafnia alvei*	*Shigella sonnei*
Candida parapsilosis	*Klebsiella oxytoca*	*Staphyloccocus aureus*
Candida tropicalis	*Klebsiella pneumoniae*	*Staphylococcus epidermidis*
Citrobacter brakkii	*Lactobacillus acidophilus*	*Staphylococcus saprophyticus*
Citrobacter freundii	*Lactobacillus gasseri*	*Stenotroph. maltophilia*
Citrobacter koseri	*Lactobacillus leichmannii*	*Streptoccocus mutans*
Clostridium difficile	*Lactococcus lactis*	*Streptococcus anginosus*

Organism		
Clostridium novyi	*Legionella pneumophila*	*Streptococcus bovis*
Clostridium perfringens	*Listeria monocytogenes*	*Streptococcus dysgalactiae*
Clostridium sporogenes	*Micrococcus luteus*	*Streptococcus mitis*
Corynebacterium jekeium	*Moraxella cartarrhalis*	*Streptococcus pneumoniae*
Enterobacter aerogenes	*Morganella morganii*	*Streptococcus pyogenes*
Enterobacter cloacae	*Neisseria gonorrhoeae*	*Streptococcus salivarius*
Enterococcus casseliflavus	*Pediococcus acidilacti*	*Streptococcus uberis*
Enterococcus cecorum	*Peptostreptococcus anaerobius*	*Vibrio parahaemolyticus*
Enterococcus dispar	*Plesiomonas shigelloides*	*Yersinia enterocolitica*

Microbial Interference Study

A Microbial Interference Study was conducted to demonstrate that high levels of non-target organism will not suppress color development and recover of GBS. All organisms that were recovered upon subculture from Strep B Carrot Broth One-Step in the Analytical Specificity Study were used in the Microbial Interference Study. Additionally, *L. acidophilus* (ATCC 4356) and *E. coli* (ATCC 25922) were included in this study. Non-target organisms at a concentration of 10^8 CFU/ml were mixed with one hemolytic and one non-hemolytic GBS strain at the LoD. If the target organism was not recovered, the concentration of the non-target organism was lowered 10-fold until the target organism was recovered.

At 24 hrs, both GBS strains (*S. agalactiae,* ATCC 12386 and *S. agalactiae,* ATCC 13813) gave the expected results in the presence of 10^8 CFU/ml of all non-target strains in the Microbial Interference Study, except in the presence of *Enterococcus faecalis* (ATCC 29212). In the presence of *E. faecalis*, proper color development with the β-hemolytic GBS strain (ATCC 12386) was observed at 10^5 CFU/ml or lower. For the non-hemolytic GBS strain (ATCC 13813) tested, it was recovered upon subculture when the concentration of *E. faecalis* was 10^6 CFU/ml or lower. The potential for high concentrations of *E. faecalis* to inhibit the detection and recovery of GBS is noted as a Limitation in the device labeling.

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not Applicable. Compared to Standard Reference Method

b. Matrix comparison:

Not Applicable

3. Clinical studies:

a. Clinical Sensitivity:

Strep B Carrot Broth One-Step was evaluated at four clinical sites. A total of 884 vaginal/rectal swabs from pregnant women were prospectively collected. Due to protocol deviations (enrollment criteria not met), 108 specimens were excluded from the study leaving 776 swab specimens to be inoculated and incubated in Strep B Carrot Broth Kit. An additional 5 samples were excluded due to improper storage (time of set-up) before enrichment. In total, 771 compliant specimens were included in the final performance calculations.

A 30 µl aliquot of the clinical specimen in transport media was used to inoculate Strep B Carrot Broth One-Step, and the culture was incubated at 35-37°C for 24 hours. The samples included in the evaluation of performance consisted of 771 specimens obtained in three different types of transport swabs/media—Liquid Stuart's Sponge (n=284), Liquid Amies Sponge (n=111), and Liquid Amies ESwab (n=376). For the Reference Culture Method, vaginal/rectal specimens were tested by inoculating LIM Broth with 30 µl of specimen from the transport swab system and incubating for 24 hours at 35-37°C. Turbid LIM Broth cultures were subcultured to Tryptic Soy Agar with 5% Sheep Blood, and all colonies with characteristic appearance suggestive of GBS were screened to confirm the presence of GBS (both hemolytic and non-hemolytic strains) using established laboratory methods: gram stain, catalase, latex agglutination.

Color development after enrichment in Strep B Carrot Broth One-Step was observed after 24 hours. The Strep B Carrot enriched broth culture (regardless of color development) was also subcultured to Tryptic Soy Agar with 5% Sheep Blood using a 10 µl loop, and the agar plate was incubated for 24 hours at 35-37°C in a CO_2 enriched environment. All colony types were submitted for identification. Results of Strep B Carrot Broth One-Step at 24 hours incubation were compared to the Reference Culture Method. The color change from white to orange with Strep B Carrot Broth One-Step was representative of a positive result for the presence of GBS. Tables 7-9 below show the clinical performance data for Strep B Carrot Broth One-Step vs the Reference Culture Method (all sites). Performance (sensitivity and specificity) of Strep B Carrot Broth One-Step was calculated based on color development and the recovery of GBS from the medium and compared to the recovery of β-hemolytic GBS and total GBS strains by the Reference Culture Method.

All isolates with discrepant results were frozen in CryoSavers with Brucella Broth and returned to Hardy Diagnostics for testing. The identity of each isolate was confirmed (β-hemolytic GBS, non-hemolytic GBS, or non-GBS isolate). Once the identity was confirmed, positive organisms (β-hemolytic GBS or non-hemolytic

GBS) were tested at LoD (10^3 CFU/ml) in donated negative-vaginal rectal matrix for their recovery from the LIM Culture Reference Method, color development in Strep B Carrot Broth One-Step, and recovery from the Strep B Carrot Broth One-Step + Subculture method.

Table 7. Comparison between Strep B Carrot Broth One-Step + Subculture (Recovery of all GBS) vs Reference Culture Method (all GBS)

Strep B Carrot Broth One-Step Plus Subculture (24 hrs)	**Reference Culture Method**		
	Positive	Negative	Total
Positive	161	11	172
Negative	2	597	599
Total	163	608	771
Sensitivity: 98.8% (161/163), 95% CI (95.6%-99.7%) Specificity: 98.2% (597/608), 95% CI (96.8%-99.0%)			

Table 8. Comparison between Strep B Carrot Broth One-Step (color) vs Reference Culture Method (all GBS)

Strep B Carrot Broth One-Step Plus Subculture (24 hrs)	**Reference Culture Method**		
	Positive	Negative	Total
Positive	143	8[1]	151
Negative	20[2]	600	620
Total	163	608	771
Sensitivity: 87.7% (143/163), 95% CI (81.8%-91.9%) Specificity: 98.7% (600/608), 95% CI (97.4%-99.3%)			

[1] *There were 8 False Positives observed. All isolates were re-tested and confirmed at Hardy Diagnostics using the discrepant analysis protocol described above. Of these, six isolates were originally negative by LIM reference method, showed a positive color reaction in Strep B Carrot Broth One-Step, and were confirmed to be β-hemolytic when subcultured on Blood Agar. One was not able to be confirmed because no GBS isolate was frozen and the remaining specimen had β-hemolytic colonies present on the blood agar plates; however, Proteus swarmed the plates, preventing the technician from isolating the β-hemolytic colonies for identification.*

[2] *There were 20 False Negatives observed. All isolates were re-tested and confirmed at Hardy Diagnostics using the discrepant analysis protocol described above. Fourteen of the β Group B Streptococci isolates recovered from LIM, but originally gave a negative Strep B Carrot Brot One-Step color reaction, were confirmed as β Group B Streptococci and subsequently confirmed to have a positive Strep B Carrot Broth One-Step color reaction at LoD. Two isolates were identified as very weak β Group B Streptococci and did not produce the expected color reaction in Strep B Carrot Broth One-Step. Four isolates were confirmed as non-hemolytic Group B Streptococci with a negative color reaction in Strep B Carrot Broth One-Step.*

Table 9. Comparison between Strep B Carrot Broth One-Step (color) vs Reference Culture Method (only β-hemolytic GBS)[1]

Strep B Carrot Broth One-Step Plus Subculture (24 hrs)	Reference Culture Method		
	Positive	Negative	Total
Positive	141	10	151
Negative	15	605	620
Total	156	615	771
Sensitivity: 90.4% (141/156), 95% CI (84.7%-94.1%) Specificity: 98.4% (605/615), 95% CI (97.0%-99.1%)			

[1]*Considering that non-hemolytic GBS cannot be detected by the medium's color change and require subculture for identification, there were 5 specimens that were found to be non-hemolytic. If these specimens are included as negatives, then the overall sensitivity and specificity values observed when comparing the recovery of β-hemolytic GBS by the LIM Reference Method to the Strep B Carrot Broth One-Step color development can also be evaluated.*

b. Clinical specificity:

See above

c. Other clinical supportive data (when a. and b. are not applicable):

Not Applicable

4. Clinical cut-off:

Not Applicable

5. Expected values/Reference range:

The overall prevalence of GBS (both hemolytic and non-hemolytic strains) by the Reference Culture Method was 21.1% (163/771).

N. Proposed Labeling:

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

O. Conclusion:

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