

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

A. 510(k) Number:

K151866

B. Purpose for Submission:

To obtain a substantial equivalence determination for a premarket notification for the BD BACTEC Peds Plus /F Culture Vial (plastic)

C. Measurand:

Aerobic microorganisms from blood (bacteria and yeast)

D. Type of Test:

Liquid culture medium for recovery of microorganisms from blood using fluorescent technology to detect the increased CO₂ produced by the growth of microorganisms

E. Applicant:

Becton, Dickinson and Company

F. Proprietary and Established Names:

BD BACTEC Peds Plus/F Culture Vials (plastic)

G. Regulatory Information:

1. Regulation section:

21 CFR 866.2560 Microbial Growth Monitor

2. Classification:

Class I

3. Product code:

MDB System, Blood Culturing

4. Panel:

H. Intended Use:

1. Intended use(s):

BD BACTEC Peds Plus /F culture vials (enriched Soybean-Casein Digest broth with CO₂) are for aerobic blood cultures. Principal use is with the BD BACTEC fluorescent series instruments for the qualitative culture and recovery of aerobic microorganisms (mainly bacteria and yeast) from pediatric and non-pediatric blood specimens which are generally less than 5 mL in volume.

2. Indication(s) for use:

Same as Intended Use.

3. Special conditions for use statement(s):

Prescription Use

- Some organisms may be dependent on having a minimum amount of blood in the medium for optimal growth. Fastidious organisms, such as certain *Haemophilus* species, require growth factors from the blood specimen, such as NAD, or factor V. Optimal growth of these organisms is dependent on having greater than 0.5 mL blood in the specimen. If the blood specimen volume is very small (0.5mL or less) an appropriate supplement may be required for recovery of these organisms.
- Studies have demonstrated that the resins present in this medium do not adequately neutralize meropenem preparations. Based on the neutralization study with *Candida albicans* and Fluconazole, the media showed some degree of neutralization; however the results were inconclusive. The adequacy of antifungal neutralization by resins in the BD BACTEC Peds Plus/F vial (plastic) is unknown.
- The default 5-day (120 hours) protocol was utilized for all analytical testing with the BACTEC Peds Plus/F culture media and protocol lengths of >5 days have not been evaluated.

4. Special instrument requirements:

BACTEC fluorescent series instruments BACTEC FX, BACTEC FX40, BACTEC 9240 and BACTEC 9050 and were evaluated using software versions listed below:

Instrument	Software Version
BACTEC FX	V4.60
BACTEC 9240	V4.95
BACTEC 9050	V2.01
BACTEC FX 40	V2.00A and V2.49G*

* V2.49G was the working build and released as version V2.50

I. Device Description

The blood sample to be tested is inoculated into one or more vials which are inserted into the BACTEC fluorescent series instrument for incubation and periodic reading. Each vial contains a chemical sensor which can detect increases in CO₂ produced by the growth of microorganisms. The sensor is monitored by the instrument every ten minutes for an increase in its fluorescence, which is proportional to the amount of CO₂ present. A positive reading indicates the presumptive presence of viable microorganisms in the vial. Detection is limited to microorganisms that will grow in a particular type of culture medium.

J. Substantial Equivalence Information:

1. Predicate device name(s):

BACTEC Peds Plus/F Culture Vials Soybean-Casein Digest Broth with Resins

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

K954927

3. Comparison with predicate:

Table 1: Comparison with Predicate Device

Similarities		
Item	Device BD BACTEC Peds Plus/F Culture Vials (plastic)	Predicate BACTEC Peds Plus/F Culture Vials (glass) K954927
Intended Use	This device is for qualitative aerobic culture and recovery of microorganisms from human blood, to be used with the BD BACTEC fluorescent series instruments	Same
Sample Type	Human blood	Same
Sample Volume	0.5- 5.0 mL of blood (recommended 1.0- 3.0 mL)	0.5 - 5.0 mL of blood (optimum 1.0 - 3.0 mL)
Growth Medium Volume	40 mL enriched soybean-casein digest broth	Same
Instrument	BD BACTEC fluorescent series	Same
Detection Technology	Continuous monitoring; measurement of CO ₂ increase; resins for absorption of antimicrobials; rocking agitation	Same

Similarities		
Item	Device BD BACTEC Peds Plus/F Culture Vials (plastic)	Predicate BACTEC Peds Plus/F Culture Vials (glass) K954927
	parameters	
Incubation	35°C (± 1.5°C) up to 120 hours	Same

Differences		
Vial Material	Plastic	Glass
Vial Weight	Lighter than glass	-
Vial Height	5.0 inches	5.6 inches
Sensor Adhesion Promoter	Yes	None
Vial Sensor	2.6 gram per vial, specific for the plastic vial geometry	1.75 gram per vial
Sensor Components	BCP (indicator)- 6.5 mg/vial Red dye- 4.0 mg/vial	BCP (indicator)- 1.8 mg/vial Red dye- 1.9 mg/vial

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

Not Applicable

L. Test Principle:

The BD BACTEC Peds Plus /F medium is an enriched soybean- casein digest broth, with each vial containing 40 mL of broth. Sodium polyanetholesulfonate (SPS) is added to the medium as an anticoagulant that inhibits bacteriocidal activities in the blood. The concentration of SPS has been adjusted to accommodate the low blood volumes of 0.5- 5.0 mL per vial.

Each BD BACTEC Peds Plus/F culture vial contains a chemical sensor in a silicon rubber base that can detect increases in CO₂ produced by the growth of microorganisms. Low volume (0.5- 5 mL) of blood is inoculated into the BD BACTEC Peds Plus/F blood culture vial, which is inserted into the BD BACTEC Fluorescent Series instrument for incubation, agitation and periodic measurement. When microorganisms are present in the blood sample, they metabolize nutrients in the culture medium, releasing CO₂ into the medium. A dye in the sensor reacts with the CO₂, modulating the amount of light that is absorbed by the fluorescent material in the sensor. The instrument's photo detectors monitor the sensor every 10 minutes and measure the level of fluorescence, which is proportional to the amount of CO₂ present in the vial. Positivity of a vial is determined by algorithms resident in the instrument rack's microprocessor. The algorithms use the rate of CO₂ production as well as the absolute increase in CO₂ to interpret the data.

Culture vials flagged as presumptively positive are removed from the instrument for

subculture and Gram stain in order to identify the microorganisms for further evaluation and proposed patient treatment. Culture vials that are not flagged as positive remain in the instrument until the test protocol has been completed and negative vials are discarded at the end of protocol (120 hours).

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The BACTEC Peds Plus/F (plastic) vial was evaluated across three lots in the Time To Detection (TTD) and the Percent Recovery studies. Different lots of key raw materials were used to manufacture each lot of culture media.

The results stratified by lot (combining blood volumes, inoculum levels, organisms, and instruments) are shown in Table 2.

Table 2: Positive Percent Recovery and Time To Detection by Lots

Plastic lot	Total #	Positive Percent Recovery	Median TTD (hrs)
1	448	89.06%	20.025
2	448	91.74%	20.445
3	448	90.4%	20.325

The analysis was acceptable and there was no statistically significant difference across the lots in the precision study.

b. *Linearity/assay reportable range:*

Not applicable

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

Quality Control

An internal validation study across three lots with inoculum at 10-100 CFU per vial was conducted using the organisms listed below. *Haemophilus influenzae*, *Neisseria meningitidis*, *Candida albicans*, *Pseudomonas aeruginosa*, *Streptococcus pneumoniae*, and *Alcaligenes faecalis* were evaluated by testing 18 vials for each; *Streptococcus pyogenes* and *Escherichia coli* were evaluated by testing 21 vials each; *Staphylococcus aureus* was evaluated by testing six vials. All organisms were detected ≤ 72 hours, with mean ranges between 7.5 (*Streptococcus pyogenes*) to 37.7 hours (*Neisseria meningitidis*).

<i>Streptococcus pyogenes</i>	ATCC 19615
<i>Escherichia coli</i>	ATCC 25922
<i>Streptococcus pneumoniae</i> *	ATCC 6305
<i>Pseudomonas aeruginosa</i>	ATCC 27853
<i>Candida albicans</i>	ATCC18804
<i>Neisseria meningitidis</i>	ATCC 13090
<i>Alcaligenes faecalis</i>	ATCC 8750
<i>Haemophilus influenzae</i>	ATCC 19418
<i>Staphylococcus aureus</i>	ATCC 25923

*CLSI recommended strain

d. *Detection limit:*

The microbial detection limit study was conducted to assess the capability of the culture media to detect low numbers of organisms (expected target level of 0-1 and 1-10 CFU/vial) when present in blood. The study included 15 organisms (12 bacteria and 3 yeast strains) tested at two blood volumes, each at challenging target inoculum levels of 0-1 and 1-10 CFU/vial across three lots with BACTEC FX and BACTEC 9240:

15 org x 2 blood vol x 2 inoculum levels x 3 lots x 2 instrument types = 360

For statistical analysis, 95% two-sided bootstrap confidence intervals for differences were used. The results were stratified by organism and are shown in Table 3.

Table 3: Microbial Detection Limit difference by organism

Organism Name	Number of Samples	Percent recovery for modified vial (Plastic)	Percent recovery for predicate vial (Glass)	Difference in Percent Recovery between Plastic and Glass	95% CI lower bound	95% CI upper bound
<i>Candida albicans</i>	24	75	75	0	-23.1	23.1
<i>Candida glabrata</i>	24	83.33	79.17	4.17	-20.28	28.61
<i>Cryptococcus neoformans</i>	24	75	83.33	-8.33	-28.06	11.39
<i>Enterococcus faecalis</i>	24	66.67	66.07	0	-20	20
<i>Escherichia coli</i>	24	70.83	75	-4.17	-28.61	20.28
<i>Haemophilus influenzae</i>	24	75	79.17	-4.17	-28.61	20.28
<i>Haemophilus parainfluenzae</i> biotype I	24	41.67	45.83	-4.17	-22.35	14.02
<i>Micrococcus luteus</i>	24	50	45.83	4.17	-22.87	31.2
<i>Neisseria</i>	24	87.5	75	12.5	-8.52	33.52

Organism Name	Number of Samples	Percent recovery for modified vial (Plastic)	Percent recovery for predicate vial (Glass)	Difference in Percent Recovery between Plastic and Glass	95% CI lower bound	95% CI upper bound
<i>gonorrhoeae</i>						
<i>Neisseria meningitidis</i>	24	79.17	79.17	0	-25.83	25.53
<i>Pseudomonas aeruginosa</i>	24	100	70.83	29.17	7.62	50.71
<i>Staphylococcus aureus</i>	24	83.33	58.33	25	1.19	48.81
<i>Staphylococcus epidermidis</i>	24	54.17	58.33	-4.17	-28.61	20.28
<i>Streptococcus pneumoniae</i>	24	45.83	20.83	25	-1.46	51.46
<i>Streptococcus sanguinis</i>	24	66.67	79.17	-12.5	-36.48	11.48

At the low target inoculum level of 1-10 CFU/vial, there were:

- Three *Haemophilus parainfluenzae* recovery failures with four CFUs on the subculture plate in both modified plastic and predicate glass vials
- One *Neisseria meningitidis* recovery failure with five CFUs on the subculture plate in the modified plastic vial.

Both organisms are included in the limitation section of the Package Insert. Recommendation for each is included. For *N. meningitidis*, there were no recovery failures with the higher volume of 5 mL of blood. For *H. parainfluenzae*, see “False Negatives” section below for details.

Data was also evaluated at target inoculum level of 0-1 and 1-10 CFU/vial across two blood volumes (0.5 and 5.0mL) in the Time to Detection (TTD) study as shown in Table 4.

Table 4: Time To Detection at target 0-1, 1-10 CFU across 0.5 and 5.0 mL blood

Target Inoculum level	Blood Volume	Median TTD (Plastic)	Median TTD (Glass)	Median TTD difference (Plastic - Glass)
0-1 CFU	0.5mL	26.4	27.60	-0.165
	5mL	32.65	33.69	-0.995
1-10 CFU	0.5mL	28.52	30.67	-0.5
	5mL	24.81	25.03	-0.33

In summary, both data sets demonstrated that the modified plastic device performed equivalently when compared to the predicate glass device.

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

Performance of the BD BACTEC Peds Plus/F (plastic) blood culture vials was evaluated in seeded internal analytical studies to demonstrate comparable performance to the predicate device, the BD BACTEC Peds Plus/F (glass) blood culture vials. Comparison results were acceptable. The comparisons were made using the following parameters: Time to detection, percent recovery, false negative rate, false positive rate and antimicrobial neutralization capability. For statistical analysis, 95% two-sided bootstrap confidence intervals for differences were used.

a. *Method comparison with predicate device:*

Instrument Time to Detection (TTD) study

The TTD analysis was evaluated in the combined Percent recovery and the Microbial Detection Limit studies using the BD BACTEC FX and 9240 instruments at three inoculum levels, across two blood volumes (0.5 mL and 5.0 mL) over three media lots. The Percent Recovery study represented the standard inoculum of 10 to 100 CFU per vial and the Microbial Detection Limit study represented the challenge inoculum levels of 0 to 1 and 1 to 10 CFU per vial. The performance is demonstrated in Table 5.

Table 5: Summary of TTD study

		Median of TTD for Plastic (95% CI)	Median of TTD for Glass (95% CI)	Median of TTD difference for Plastic – Glass (95% CI)
Inoculum Levels	0 to 1	30.908 (23.645, 46.965)	31.28 (23.81, 42.025)	-0.75 (-1.75, 0.085)
	1 to 10	26.733 (23.205, 30.255)	27.84 (23.655, 31.785)	-0.415 (-0.75, 0)
	10 to 100	24.135 (21.31, 27.47)	24.425 (21.435, 27.09)	-0.08 (-0.33, 0.25)
Blood Volume	0.5mL	27.34 (23.65, 31.075)	27.862 (24.34, 31.395)	-0.25 (-0.585, 0.25)
	5mL	25.165 (22.255, 27.85)	25.105 (22.18, 28.31)	-0.33 (-0.5, -0.08)
Media Lots	Lot 1	26.265 (22.31, 31.01)	27.415 (23.045, 31.59)	-0.415 (-0.92, -0.075)
	Lot 2	25.935 (22.29, 30.1)	25.52 (21.925, 29.605)	-0.08 (-0.415, 0.335)
	Lot 3	25.6 (22.375, 29.65)	26.315 (22.78, 30.02)	-0.335 (-0.745, 0.08)

For all inoculum levels data combined, it was observed that the estimated median for the modified plastic vial and the predicate glass vial was 17.5 hours and 18.11 hours respectively; the median TTD difference was -0.25 hours, with 95% CI (-0.495, -0.08),

favoring the modified plastic vial. The TTD study demonstrated that the modified plastic device performed equivalently when compared to the predicate glass device.

Recovery (Detection) Study

The percent recovery (detection) was evaluated in a study of 984 paired sets at the standard inoculum level of 10- 100 CFU/vial on four instruments across three lots using a diverse set of microorganisms frequently isolated in blood. Of the 984 paired sets, 953 sets recovered organisms in both the plastic vial and the glass vial and 18 were negative by both vials. Nine paired sets were recovered in the plastic vials but not in the glass vials and four were recovered in the glass vials but not in the plastic vials. The performance is demonstrated in Table 6A and 6B.

Table 6A: Recovery Study Results

		Predicate (Glass)		
		Detected	Not Detected	Total
Modified (Plastic)	Detected	953	9	962
	Not Detected	4	18	22
	Total	957	27	984

In summary, the percent recovery was:

- 97.76%, (962)/(984) for the modified plastic vial
- 97.26%, (957)/(984) for the predicate glass vial

The percent recovery study demonstrated that the modified plastic vial performed equivalently when compared to the predicate glass vial.

The performance was evaluated for each organism and this information is shown in Table 6B.

Table 6B: Percent Recovery (10- 100 CFU/vial) Summary by Organisms

Organism Name	Number of Samples	Percent recovery for Modified vial (Plastic)	Percent recovery for Predicate vial (Glass)	Difference in recovery between Plastic and Glass	95% CI Lower bound	95% CI Upper bound
<i>Abiotrophia defectiva</i>	24	100	100	0	-11.55	11.55
<i>Acinetobacter lwoffii</i>	24	100	100	0	-11.55	11.55
<i>Aerococcus viridans</i>	24	100	100	0	-11.55	11.55
<i>Aggregatibacter actinomycetemcomitans</i>	24	100	100	0	-11.55	11.55
<i>Alcaligenes faecalis</i>	24	100	100	0	-11.55	11.55
<i>Bacillus subtilis</i>	24	100	100	0	-11.55	11.55
<i>Candida albicans</i>	24	75	70.83	4.17	-17.38	25.71
<i>Candida glabrata</i>	24	100	100	0	-11.55	11.55
<i>Cardiobacterium hominis</i>	24	100	100	0	-11.55	11.55
<i>Corynebacterium jeikeium</i>	24	100	100	0	-11.55	11.55

Organism Name	Number of Samples	Percent recovery for Modified vial (Plastic)	Percent recovery for Predicate vial (Glass)	Difference in recovery between Plastic and Glass	95% CI Lower bound	95% CI Upper bound
<i>Cryptococcus neoformans</i>	24	100	100	0	-11.55	11.55
<i>Eikenella corrodens</i>	24	100	100	0	-11.55	11.55
<i>Enterobacter cloacae</i>	24	100	100	0	-11.55	11.55
<i>Enterococcus faecalis</i>	24	95.83	100	-4.17	-18.21	9.88
<i>Escherichia coli</i>	24	100	100	0	-11.55	11.55
<i>Granulicatella adiacens</i>	24	100	100	0	-11.55	11.55
<i>Haemophilus influenzae</i>	24	100	100	0	-11.55	11.55
<i>Haemophilus influenzae</i> biotype	48	79.17	79.17	0	-8.17	8.17
<i>Haemophilus parainfluenzae</i> biotype I	24	79.17	62.5	16.67	-2.19	35.53
<i>Kingella kingae</i>	24	100	100	0	-11.55	11.55
<i>Klebsiella pneumoniae</i>	24	100	100	0	-11.55	11.55
<i>Leuconostoc citreum</i>	24	100	100	0	-11.55	11.55
<i>Micrococcus luteus</i>	24	100	100	0	-11.55	11.55
<i>Neisseria gonorrhoeae</i>	24	100	100	0	-11.55	11.55
<i>Neisseria meningitidis</i>	24	100	100	0	-11.55	11.55
<i>Pediococcus acidilactici</i>	24	100	95.83	4.17	-9.88	18.21
<i>Proteus mirabilis</i>	24	100	100	0	-11.55	11.55
<i>Providencia stuartii</i>	24	100	100	0	-11.55	11.55
<i>Pseudomonas aeruginosa</i>	24	100	100	0	-11.55	11.55
<i>Rothia mucilaginosa</i>	24	100	100	0	-11.55	11.55
<i>Staphylococcus aureus</i>	24	100	100	0	-11.55	11.55
<i>Staphylococcus epidermidis</i>	24	100	100	0	-11.55	11.55
<i>Stenotrophomonas maltophilia</i>	24	100	100	0	-11.55	11.55
<i>Streptococcus agalactiae</i> (Group B Strep)	24	100	100	0	-11.55	11.55
<i>Streptococcus pneumoniae</i>	96	100	100	0	-2.89	2.89
<i>Streptococcus pyogenes</i> (Group A Strep.)	24	100	100	0	-11.55	11.55
<i>Streptococcus sanguinis</i>	24	100	100	0	-11.55	11.55

False Positive Rates (Instrument-positive, subculture-negative)

False positivity was assessed with vials inoculated with fresh human blood of 0.5, 3, and 5 mL, but no organisms were added to the vials. There were a total of 288 pair sets across three lots using BACTEC FX and BACTEC 9240 to be completed at the protocol of 120 hours incubation.

48 vials x 3 lots x 2 instruments= 288 vials per device

No instrument false positive signals were detected. The modified device performed equivalently when compared to the predicate device in the false positive study.

False Negative Rates (Instrument-negative, subculture positive)

All inoculated paired sets (1344; 984+ 360) that were instrument negative at the end of protocol (120 hours) were subcultured onto appropriate culture media plates. This combined data set was evaluated for the false negative rates. A false negative is a vial that was instrument-negative at the end of protocol yet contains viable organisms upon subculturing onto appropriate culture media. There were a total of 83 paired sets where both the modified and the predicate devices were negative at 120 hours; there were 46 sets where the predicate device only detected (i.e. 46 plastic vials subcultured) and 66 vials where the new device detected (i.e. 63 glass vials subcultured, 3 vials discarded inadvertently).

$$(83 \times 2) + 46 + 63 = 275$$

Of the 275 vials subcultured, 129 were plastic vials and 146 were glass vials. There were 20 false negatives (1.49%, 20/1344) from the plastic vials and 25 false negatives (1.86%, 25/1344) from the glass vials. There was no significant difference in false negative rates between the predicate and the modified devices. The false negative rates with 95% CI were demonstrated in Table 7.

Table 7: False Negative Rate (BACTEC Instrument Negative, Terminal Subculture Positive)

Total paired sets	Percent False Neg Rate for Modified (Plastic)	Percent False Neg Rate for Predicate (Glass)	Difference in False Rates between Plastic and Glass	95% CI (lower bound)	95% CI (Upper bound)
1344	1.49 (20/1344)	1.86 (25/1344)	-0.37	-1.01	0.26

The majority of the false negatives were *Haemophilus* species with 0.5 mL of bagged blood added. The *Haemophilus* species were detected at target inoculum of 1-10, 10-100 CFU with increased volume of 5 mL blood. Further, the original set of *Haemophilus* species were re-tested with 0.5mL of fresh blood and all detected in both vials.

The *Haemophilus* species false negatives are noted in the limitations section of the Package Insert (PI). The recommended limitation states: “If the blood specimen volume is very small (0.5 mL or less), an appropriate supplement may be required for recovery of these organisms.”

BD BACTEC Instrument Compatibility Study

The BACTEC instrument compatibility study was evaluated from the Percent Recovery study (i.e. 984 paired sets) dataset across four fluorescent- series instruments: BD BACTEC FX, FX40, 9240, and 9050. The study included 0.5 and 5.0mL of blood at inoculum level of 10-100CFU per vial. There were 953 sets recovered organisms in both the plastic vial and the glass vial and the Time To Detection (TTD) comparison between the modified plastic and the predicate glass vials was evaluated. The performance data is shown in in Table 8.

Table 8: TTD Difference (Modified Plastic TTD- Predicate Glass TTD)

Instrument	Blood (mL)	Detected in modified and Predicate	Median Difference (hour)
BACTEC FX	0.5, 5	238	-0.250
BACTEC FX40	0.5, 5	240	-0.333
BACTEC 9240	0.5, 5	235	-0.250
BACTEC 9050	0.5, 5	240	0.000
Combined		953	-0.249

The study demonstrated that the four instruments performed equivalently and they are compatible.

Antimicrobial Neutralization Capability

The study was to demonstrate the nonionic and cationic resins in the culture media to enhance the recovery of organisms by adsorption of commonly used antibiotics in the blood samples. The non-resin vials, BACTEC Standard /10 Aerobic/F were inoculated at the same time to demonstrate the antimicrobial activity (no growth) in the vial. Eleven antimicrobials representative of their classes were evaluated at the MIC level of selected organisms. The antimicrobials evaluated were: Meropenem, Gentamicin, Ciprofloxacin, Clindamycin, Vancomycin, Cefazolin, Cefoxitin, Cefotaxime, Cefepime, Piperacillin/Tazobactam and Fluconazole. The performance data is shown in Table 9.

Table 9: Antimicrobial-Organism Recovery Comparison at MIC level

Antimicrobial	Organism	Strain	MIC	Test conc. (µg/mL)	Number Detected		
					Glass (resin)	Plastic (resin)	Non-resin medium
Meropenem	<i>Enterococcus faecalis</i>	29212	4	5	3	3	0
	<i>Staphylococcus aureus</i>	25923	0.065	0.65	0	1	0
Gentamycin	<i>Escherichia coli</i>	25922	2	4	3	3	0
	<i>Staphylococcus aureus</i>	25923	0.25	1	3	3	0
Ciprofloxacin	<i>Staphylococcus aureus</i>	25923	0.5	1	3	3	0
Clindamycin	<i>Escherichia coli</i>	25922	4	4	3	3	3
	<i>Staphylococcus aureus</i>	25923	0.125	1	3	3	0
Vancomycin	<i>Staphylococcus aureus</i>	25923	2	5	3	3	0
	<i>Enterococcus faecalis</i>	29212	4	5	3	3	0
Cefazolin	<i>Escherichia coli</i>	25922	0.5	4	3	3	0
	<i>Staphylococcus aureus</i>	25923	2	4	3	3	0

Antimicrobial	Organism	Strain	MIC	Test conc. (µg/mL)	Number Detected		
					Glass (resin)	Plastic (resin)	Non-resin medium
Cefoxitin	<i>Escherichia coli</i>	25922	4	5	3	3	0
	<i>Staphylococcus aureus</i>	25923	2	4	3	3	0
Cefotaxime	<i>Staphylococcus aureus</i>	25923	1	2	3	3	0
Cefepime	<i>Staphylococcus aureus</i>	25923	1	1.5	3	3	0
Piperacillin/Tazobactam	<i>Enterobacter aerogenes</i>	13048	4	4	3	3	0
Fluconazole	<i>Candida albicans</i>	18804	1	4	3	3	3

The study indicated some degree of neutralization with *Candida albicans* and fluconazole. However, the results were inconclusive for the antifungal neutralization in the BACTEC Peds Plus/F culture media. The statement below is included in the limitation section of the PI:

“Based on the neutralization study with *Candida albicans* and Fluconazole, the media showed some degree of neutralization; however the results were inconclusive. The adequacy of antifungal neutralization by resins in the BD BACTEC Peds Plus/F vial (plastic) is unknown.”

E. coli is intrinsically resistant to clindamycin and the result was as expected. The modified device performed equivalently when compared to the predicate device during antimicrobial neutralization evaluation.

b. Matrix comparison:

In seeded analytical studies, the performance of BD BACTEC Peds Plus/F culture medium in plastic vial was compared to that in glass vial, with two human blood volumes, 15 common blood bloodstream pathogens (bacteria and yeast) across four fluorescent series instruments: BACTEC FX, FX40, BACTEC 9240, and BACTEC 9050.

3. Clinical studies:

Not applicable; seeded analytical studies to compare the new plastic blood culture vials to the glass blood culture vials (predicate).

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

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:

Seeded analytical studies demonstrated equivalent performance of the BD BACTEC Peds Plus/F (plastic) blood culture medium when compared to the BD BACTEC Peds Plus/F (glass) blood culture medium.

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.