March 24, 2023

Becton, Dickinson and Company
Susan Kircher
Staff Regulatory Affairs Specialist
7 Loveton Circle
Sparks, Maryland 21152

Re: K222591
Trade/Device Name: BD BACTEC Plus Aerobic/F Culture Vials
Regulation Number: 21 CFR 866.2560
Regulation Name: Microbial Growth Monitor
Regulatory Class: Class I, reserved
Product Code: MDB
Dated: August 25, 2022
Received: August 26, 2022

Dear Susan Kircher:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ribhi Shawar -S

Ribhi Shawar, Ph.D. (ABMM)
Branch Chief,
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222591

Device Name
BD BACTEC™ Plus Aerobic/F Culture Vials

Indications for Use *(Describe)*
BD BACTEC™ Plus Aerobic/F Culture Vials are used in a qualitative procedure for the aerobic culture and recovery of microorganisms (bacteria and yeast) from blood. The principal use of this medium is with the BD BACTEC™ fluorescent series instruments.

Additional information
The device aids in the diagnosis of disease caused by pathogenic microorganisms and is automated on the BD BACTEC™ fluorescent series instruments.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Special 510(k) Summary

Summary Preparation Date:
8/25/2022

A. 510(k) Number:

K222591

B. Purpose of Submission:

To obtain a substantial equivalence determination for a premarket notification for the modified BD BACTEC™ Plus Aerobic/F Culture Vials.

C. Measurand:

Aerobic microorganisms (bacteria and yeast) from blood

D. Type of Test:

Liquid culture medium for recovery of microorganisms from blood using fluorescent technology to detect increases in CO_2 produced by the growth of microorganisms.

E. Applicant:

BD Diagnostic Systems
Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Establishment Registration Number: 1119779

F. Proprietary and Established Name

BD BACTEC™ Plus Aerobic/F Culture Vials

G. Regulatory Information

Product Code	Classification	Regulation Section	Panel
MDB	Class I	21 CFR § 866.2560 Microbial Growth Monitor	83-Microbiology

H. Intended Use/Indications for Use:

1. Intended Use:

BD BACTEC™ Plus Aerobic/F Culture Vials are used in a qualitative procedure for the aerobic culture and recovery of microorganisms (bacteria and yeast) from blood. The principal use of this medium is with the BD BACTEC™ fluorescent series instruments.

Additional information
The device aids in the diagnosis of disease caused by pathogenic microorganisms and is automated on the BD BACTEC™ fluorescent series instruments.

2. Indication(s) for Use:

Same as Intended Use

3. Special Conditions for Use Statement:

RX - For Prescription Use Only

4. Special Instrument Requirements:

The BD BACTEC™ fluorescent series instruments (BD BACTEC™ FX, BD BACTEC™ FX40, BD BACTEC™ 9240 and BD BACTEC™ 9050) were evaluated using the software versions listed below.

Instrument	Software Version
BD BACTEC™ FX	6.40A
BD BACTEC™ 9240	4.95A
BD BACTEC™ 9050	2.01A2
BD BACTEC™ FX40	3.40A

I. Device Description

The BD BACTEC™ Plus Aerobic/F Culture Vials contain a bacterial growth medium intended for use in the qualitative culture and recovery of aerobic microorganisms (bacteria and yeast) from blood. It has been designed for blood volumes of three (3) to ten (10) milliliters and is used specifically with the BD BACTEC™ fluorescent-series instruments in monitoring of clinical blood specimens for the presence of microorganisms.

BD BACTEC™ Plus Aerobic/F Culture Vials are supplied in a carton containing 50 vials. It is a non-sterile product.

J. Substantial Equivalence[1] Information:

1. Predicate Device Name:

   BD BACTEC™ Plus Aerobic/F Culture Vials

2. Predicate Device 510(k) Number:

   K113558

3. Comparison with Predicate Device:

   The similarities between the modified BD BACTEC™ Plus Aerobic/F Culture Vials and the current legally marketed predicate device, BD BACTEC™ Plus Aerobic/F Culture Vials (K113558) are summarized in comparison Table 1**.** The modified device formulation differs from that of the predicate device in the concentration of vitamins.

   The modified BD BACTEC™ Plus Aerobic/F Culture Vials utilize the same specimens, test principles, and growth detection technology as the current legally marketed device.

[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended, and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Table 1. Comparison to the Predicate Device

	BD BACTEC™ Plus Aerobic/F Culture Vials Predicate Device	***BD BACTEC™ Plus Aerobic/F Culture Vials Modified Device***
Device Class	I	Same
Product Code	MDB	Same
Intended Use	BD BACTEC™ Plus Aerobic/F Culture Vials are used in a qualitative procedure for the aerobic culture and recovery of microorganisms (bacteria and yeast) from blood. The principal use of this medium is with the BD BACTEC™ fluorescent series instruments.	BD BACTEC™ Plus Aerobic/F Culture Vials are used in a qualitative procedure for the aerobic culture and recovery of microorganisms (bacteria and yeast) from blood. The principal use of this medium is with the BD BACTEC™ fluorescent series instruments. **Additional information** The device aids in the diagnosis of disease caused by pathogenic microorganisms and is automated on the BD BACTEC™ fluorescent series instruments.
Organisms Detected	Aerobic bacteria and yeasts	Same
Technology	If microorganisms are present in the test sample inoculated into the BD BACTEC™ vial, CO2 will be produced when the organisms metabolize the substrates present in the vial. Increases in the fluorescence of the vial sensor caused by the higher amount of CO2 are monitored by the BD BACTEC™ fluorescent series instrument. Analysis of the rate and amount of CO2 increase enables the BD BACTEC™ fluorescent series instrument to determine if the vial is positive, i.e., that the test sample contains viable organisms. This qualitative culture functions as an aid to diagnosis and is automated on the BD BACTEC™ fluorescent series instrument.	Same
Sample Type	Blood	Same
Bottle Material	Plastic	Same
Sample Volume	3-10 mL	Same
Growth Media	30 mL enriched Soybean-Casein Digest Broth	Same

K. Principle of Operation:

If microorganisms are present in a test sample that is inoculated into the BD BACTEC™ Plus Aerobic/F Culture Vials, CO_2 will be produced due to metabolism of substrates present in the vial. Increases in the fluorescence of the vial sensor caused by the higher amount of CO_2 are monitored by BD BACTEC™ fluorescent series instruments. Analysis of the rate and amount of CO_2 increase enables the BD BACTEC™ fluorescent series instrument to determine if the vial is positive, i.e., that the test sample contains viable organisms. This qualitative culture functions as an aid to diagnosis and is automated on the BD BACTEC™ fluorescent series instruments.

L. Performance Characteristics:

1. Analytical Performance

Six studies were conducted to demonstrate substantial equivalence between of the modified BD BACTEC™ Plus Aerobic/F Culture Vials to the current, legally marketed device, BD BACTEC™ Plus Aerobic/F Culture Vials (predicate). These studies included: Instrument Time to Detection, Percent Recovery (Sensitivity), False Negative Rate, False Positive Rate, BACTEC™ Instrument Compatibility, and Resin Performance (Antimicrobial Neutralization Capability).

Instrument Time to Detection

Instrument time to detection (TTD) was assessed using paired sets of the modified and predicate device. Three lots of each device were inoculated with blood volumes of 3 and 10 mL. All vials were inoculated with 44 organisms at a concentration of 10-100 CFU/vial. All vials were then placed into both a BACTEC™ FX and a BACTEC™ FX40 instrument resulting in a total of 264 vials at each blood volume condition. A subset of 15 organisms were also evaluated at a concentration of 0-1 and 1-10 CFU/vial at each blood volume on the BACTEC™ FX instrument for a total of 45 vials at each inoculum and blood volume condition. Data are summarized in Table 2.

There were two isolates that produced a > 10% difference at the 10-100 CFU inoculum level that were in favor of the predicate device, *Rothia mucilaginosa* and *Stenotrophomonas maltophilia*. Additional strains of each species were tested in triplicate. Results of this testing demonstrated the delay in TTD in the modified device was strain specific and not related to the organism species.

The results of this study indicate no statistically relevant difference in time to detection for the modified device when compared to the predicate device.

Table 2. Instrument Time to Detection Stratified by Organism, Inoculum and Blood Volume (Bootstrap analysis)

Organism	Target CFU	Blood Volume (mL)	Predicate Device TTD (95% CI) [N]	Modified Device TTD (95% CI) [N]	TTD Difference (95%CI) [N]
Abiotrophia defectiva A49176	10-100	3	16.46 (16.340, 16.893) [6]	17.17 (16.872, 17.728) [6]	0.582 (0.250, 1.251) [6]
		10	16.26 (16.009, 16.674) [6]	17.18 (16.951, 17.484) [6]	0.917 (0.583, 1.168) [6]
Acinetobacter lwoffii A17925	10-100	3	13.60 (13.242, 13.884) [6]	13.88 (13.771, 14.323) [6]	0.416 (-0.84, 0.916) [6]
		10	17.94 (14.579, 23.048) [6]	14.30 (14.106, 14.663) [6]	-3.751 (-8.835, 0.084) [6]
Aggregatibacter actinomycetemcomitans	10-100	3	25.57 (25.059, 26.572) [6]	25.40 (24.307, 26.573) [6]	-0.250 (-1.001, 0.334) [6]

Organism	Target CFU	Blood Volume (mL)	Predicate Device TTD (95% CI) [N]	Modified Device TTD (95% CI) [N]	TTD Difference (95%CI) [N]
NCTC 9710		10	25.90 (25.242, 26.317) [6]	26.09 (25.052, 26.242) [6]	-0.083 (-0.993, 1.000) [6]
Aerococcus viridins A11563	10-100	3	11.12 (10.851, 12.060) [6]	11.29 (11.016, 11.891) [6]	0.083 (-0.584, 0.666) [6]
		10	11.71 (11.430, 12.069) [6]	12.12 (11.707, 12.373) [6]	0.415 (-0.168, 0.749) [6]
Alcaligenes faecalis A8750	10-100	3	22.19 (21.250, 23.029) [6]	21.39 (21.080, 21.913) [6]	-0.834 (-1.417, 0.166) [6]
		10	24.16 (21.867, 26.865) [6]	21.03 (20.115, 22.738) [6]	-2.001 (-5.835, -1.168) [6]
Bacillus subtilis A82	10-100	3	25.32 (24.552, 26.172) [6]	24.31 (23.821, 24.839) [6[	-1.334 (-1.500, -0.249) [6]
		10	27.32 (27.073, 28.073) [6]	26.41 (25.814, 27.083) [6]	-1.000 (-1.500, -0.666) [6]
Candida albicans A18804	10-100	3	25.57 (25.237, 26.743) [6]	23.07 (22.403, 23.826) [6]	-3.083 (-3.501, -1.666) [6]
		10	26.08 (25.576, 27.823) [6]	23.91 (23.075, 25.655) [6]	-2.418 (-3.502, -0.917) [6]
	1-10	3	31.59 (31.423, 32.758) [3]	28.09 (27.089, 28.091) [3]	-4.501 (-4.666, -3.333) [3]
		10	35.09 (31.277, 37.252) [3]	28.92 (27.609, 29.084) [3]	-6.001 (-8.334, -3.668) [3]
	0-1	3	Only 1 paired detection*	Only 1 paired detection*	N/A
		10	Only 1 paired detection*	Only 1 paired detection*	N/A
Candida auris AR 0378	10-100	3	22.10 (19.895, 24.208) [6]	19.67 (18.989, 20.622) [6]	-2.253 (-3.835, -0.831) [6]
		10	19.34 (18.843, 23.283) [6]	19.17 (18.760, 19.427) [6]	-0.418 (-3.856, 0.166) [6]
Candida glabrata A15545	10-100	3	67.47 (60.632, 76.150) [6]	32.61 (30.880, 34.341) [6]	-34.364 (-42.309, 29.752) [6]
		10	60.13 (53.885, 72.461) [6]	35.44 (33.083, 37.708) [6]	-24.274 (-35.169, -20.803) [6]
Candida glabrata A66032	10-100	3	64.87 (61.875, 69.053) [6]	29.59 (28.448, 31.744) [6]	-35.531 (-37.947, -32.531) [6]
		10	47.85 (42.084, 54.609) [6]	28.11 (26.166, 29.345) [6]	-21.501 (-25.335, -14.084) [6]
	1-10	3	96.79 (88.624, 101.123) [3]	35.62 (34.122, 40.121) [3]	-56.667 (-67.000, -53.001) [3]
		10	100.28 (91.288, 105.620) [3]	40.45 (37.951, 48.453) [3]	-62.334 (-65.168, -42.835) [3]
	0-1	3	Only 1 paired detection*	Only 1 paired detection*	N/A
		10	Only 1 paired detection*	Only 1 paired detection*]	N/A
Cardiobacterium hominis NCTC 10426	10-100	3	45.15 (40.061, 49.911) [6]	44.90 (40.559, 50.410) [6]	0.082 (-0.501, 1.165) [6]
		10	45.57 (41.238, 51.321) [6]	45.48 (40.819, 50.821) [6]	-0.084 (-1.418, 0.499) [6]

Organism	Target CFU	Blood Volume (mL)	Predicate Device TTD (95% CI) [N]	Modified Device TTD (95% CI) [N]	TTD Difference (95%CI) [N]
Corynebacterium jeikeium A43216	10-100	3	28.98 (27.820, 30.150) [6]	28.57 (28.313, 30.649) [6]	0.499 (-0.668, 0.749) [6]
		10	30.94 (26.827, 38.814) [6]	31.35 (27.076, 39.813) [6]	0.249 (-0.918, 2.333) [6]
Cryptococcus neoformans A32045	10-100	3	64.54 (60.644, 68.285) [6]	57.30 (55.226, 58.950) [6]	-7.084 (-9.835, -5.084) [6]
		10	73.23 (66.305, 88.745) [6]	63.13 (59.888, 65.290) [6]	-10.269 (-23.536, -5.167) [6]
	1-10	3	69.99 (66.284, 71.491) [3]	66.11 (60.950, 66.452) [3]	-5.040 (-5.334, -3.873) [3]
		10	81.28 (77.613, 82.116) [3]	69.28 (68.611, 71.318) {3]	-10.798 (-12.670, -8.337_ [3]
	0-1	3	Only 1 paired detection*	Only 1 paired detection*	N/A
		10	82.80 (79.630, 90.300) [3]	73.40 (69.833, 76.963 (2]	-7.816 (-12.965, -2.667) [2]
Eikinella corrodens A23834	10-100	3	30.82 (29.809, 32.319) [6]	32.31 (31.309, 33.151) [6]	-0.001 (0.166, 1.999) [6]
		10	31.25 (30.054, 32.647) [6]	30.91 (29.558, 32.311) [6]	-0.501 (-1.418, 0.749) [6]
Enterobacter cloacae A35030	10-100	3	8.63 (8.525, 8.756) [6]	8.76 (8.527, 8.959) [6]	-0.000 (-0.001, 0.332) [6]
		10	9.03 (8.885, 9.420) [6]	9.11 (8.883, 9.503) [6]	0.082 (-0.168, 0.250) [6]
Enterococcus faecalis A29212	10-100	3	9.78 (9.589, 9.985) [6]	9.92 (9.775, 10.153) [6]	0.165 (-0.001, 0.333) [6]
		10	10.01 (9.926, 10.178) [6]	10.07 (9.785, 10.343) [6]	-0.001 (-0.251, 0.333) [6]
	1-10	3	11.63 (11.296, 11.631) [3]	11.21 (11.127, 11.296) [2]	-0.251 (-0.501, -0.001) [2]
		10	11.62 (11.459, 12.124) [3]	11.95 (11.625, 11.956) [3]	0.166 (-0.168, 0.333) [3]
	0-1	3	No paired detections*	No paired detections*	N/A
		10	No paired detections*	No paired detections*	N/A
Escherichia coli A25922	10-100	3	9.32 (9.153, 9.490) [6]	9.24 (9.142, 9.417) [6]	-0.084 (-0.334, 0.248) [6]
		10	9.57 (9.307, 9.992) [6]	9.48 (9.389, 10.072) [6]	-0.084 (-0.168, 0.332) [6]
	1-10	3	10.61 (10.279, 11.114) [3]	10.61 (10.444, 10.614) [3]	-0.168 (-0.500, 0.333) [3]
		10	11.78 (11.608, 12.109) [3]	10.78 (10.774, 11.444) [3]	-0.833 (-1.333, -0.334) [3]
	0-1	3	11.55 (11.465, 11.633) [2]	11.80 (11.465, 12.131) [2]	0.249 (-0.167, 0.666) [2]
		10	12.13 (12.126, 12.127) [2]	12.13 (11.959, 12.294) [2]	-0.004 (-0.167, 0.160) [2]
Granulicatella adiacens A43205	10-100	3	15.92 (15.318, 16.428) [6]	15.59 (15.234, 15.832) [6]	-0.501 (-0.834, 0.332) [6]
		10	16.91 (15.992, 17.252) [6]	16.75 (15.741, 17.084) [6]	-0.251 (-0.501, 0.166) [6]
Haemophilus influenzae A19418	10-100	3	16.08 (14.383, 17.662) [6]	15.95 (14.634, 17.579) [6]	-0.000 (-0.293, 0.334) [6]
		10	15.09 (14.631, 17.057) [6]	15.51 (14.844, 17.223) [6]	0.330 (-0.084. 0.581) [6]

Organism	Target CFU	Blood Volume (mL)	Predicate Device TTD (95% CI) [N]	Modified Device TTD (95% CI) [N]	TTD Difference (95%CI) [N]
	1-10	3	15.78 (15.609, 16.108) [3]	15.94 (15.774, 16.276) [3]	0.166 (-0.334, 0.666) [3]
		10	16.27 (15.940, 16.606) [3]	16.44 (16.270, 16.606) [3]	-0.001 (-0.168, 0.666) [3]
	0-1	3	No paired detections*	No paired detections*	N/A
		10	No paired detections*	No paired detections*	N/A
Haemophilus influenzae, type a A9006	10-100	3	16.45 (15.042, 17.271) [6]	16.28 (14.625, 17.936) [6]	-0.001 (-0.584, 0.666) [6]
		10	16.44 (13.453, 18.931) [6]	16.52 (13.787, 19.680) [6]	0.416 (-0.084, 0.833) [6]
Haemophilus influenzae, type b A10211	10-100	3	17.63 (15.724, 19.783) [6]	18.04 (15.392, 21.281) [6]	0.416 (-0.585, 1.749) [6]
		10	18.45 (14.137, 23.932) [6]	20.20 (14.219, 27.097) [6]	1.416 (-0.084, 3.667) [6]
Haemophilus parainfluenzae A33392	10-100	3	64.67 (54.259, 83.760) [6]	68.34 (56.343, 82.507) [6]	0.582 (-8.501, 12.416) [6]
		10	53.20 (45.585, 61.004) [6]	52.53 (49.085, 63.586) [6]	2.583 (-2.168, 5.000) [6]
	1-10	3	79.99 (77.319, 94.656) [3]	69.49 (68.822, 74.987) [3]	-7.833 (-25.834, -5.001) [3]
		10	68.65 (56.652, 73.986) [3]	75.49 (62.985, 77.985) [3]	1.500 (-5.668, 21.333) [3]
	0-1	3	No paired detections*	No paired detections*	N/A
		10	No paired detections*	No paired detections*	N/A
Kingella kingae A23330	10-100	3	16.32 (15.902, 16.653) [6]	16.65 (15.995, 17.726) [6]	0.416 (-0.334, 1.415) [6]
		10	16.56 (15.388, 18.325) [6]	16.81 (15.302, 18.574) [6]	0.083 (-0.251, 0.582) [6]
Klebsiella pneumoniae A33495	10-100	3	8.62 (8.596, 8.771) [6]	8.53 (8.427, 8.689) [6]	-0.166 (-0.252, 0.083) [6]
		10	8.78 (8.615, 9.102) [6]	8.78 (8.772, 9.104) [6]	0.081 (-0.168, 0.248) [6]
Leuconostoc species A21435	10-100	3	32.22 (30.386, 34.989) [6]	32.14 (28.562, 37.90) [6]	-0.667 (-4.668, 6.333) [6]
		10	32.81 (30.901, 48.995) [6]	32.82 (30.813, 42.313) [6]	-0.584 (-6.681, 0.499) [6]
Micrococcus luteus A4698	10-100	3	34.59 (33.819, 35.107) [6]	33.84 (33.319, 34.855) [6]	-0.251 (-1.501, 0.249) [6]
		10	36.59 (36.090, 37.340) [6]	36.75 (35.077, 37.852) [6]	0.166 (-1.751, 1.249) [6]
	1-10	3	38.17 (37.172, 39.670) [3]	37.67 (37.669, 40.671) [3]	-0.501 (-2.000, 3.500) [3]
		10	39.17 (39.166, 41.665) [3]	32.75 (24.832, 40.666) [2]	-7.667 (-16.833, 1.500) [2]
	0-1	3	No paired detections*	No paired detections*	N/A
		10	Only 1 paired detection*	Only 1 paired detection*	N/A
Neisseria gonorrhoeae A10150	10-100	3	23.09 (22.511, 23.265) [6]	23.11 (22.586, 23.259) [6]	0.083 (-0.582, 0.584) [6]
		10	23.51 (22.608, 24.246) [6]	23.09 (22.277, 23.579) [6]	-0.500 (-1.001, 0.084) [6]

Organism	Target CFU	Blood Volume (mL)	Predicate Device TTD (95% CI) [N]	Modified Device TTD (95% CI) [N]	TTD Difference (95%CI) [N]
	1-10	3	26.40 (25.400, 26.401) [3]	26.57 (26.563, 27.064) [3]	0.167 (0.166, 1.664) [3]
		10	24.94 (24.608, 26.730) [3]	26.11 (25.729, 26.276) [3]	1.333 (-1.001, 1.499) [3]
	0-1	3	Only 1 paired detection*	Only 1 paired detection*	N/A
		10	Only 1 paired detection*	Only 1 paired detection*	N/A
Neisseria meningitidis A13090	10-100	3	33.57 (28.284, 46.981) [6]	36.57 (25.934, 44.647) [6]	-2.334 (-6.970, 7.618) [6]
		10	18.27 (17.639, 18.821) [6]	18.19 (17.939, 18.354) [6]	-0.085 (-0.585, 0.416) [6]
	1-10	3	27.08 (26.581, 27.084) [3]	24.58 (24.581, 27.083) [3]	-2.000 (-2.501, -0.000) [3]
		10	20.41 (20.412, 20.577) [3]	19.58 (19.076, 19.911) [3]	-0.834 (-1.501, -0.500) [3]
	0-1	3	No paired detections*	No paired detections*	N/A
		10	No paired detections*	No paired detections*	N/A
Pediococcus acidilactici A25740	10-100	3	23.01 (22.067, 22.619) [6]	23.84 (23.065, 25.369) [6]	1.248 (0.582, 1.750) [6]
		10	20.62 (20.569, 20.842) [6]	21.59 (21.400, 22.449) [6]	1.000 (0.749, 1.667) [6]
Proteus mirabilis A8259	10-100	3	12.67 (12.441, 12.975) [6]	11.72 (11.468, 11.971) [6]	-1.084 (-1.336, -0.501) [6]
		10	15.14 (13.188, 19.930) [6]	11.94 (11.722, 12.264) [6]	-3.168 (-7.918, -1.250) [6]
Providencia stuartii A25825	10-100	3	10.62 (10.531, 10.866) [6]	10.37 (10.194, 10.621) [6]	-0.251 (-0.584, -0.001) [6]
		10	11.28 (10.950, 11.455) [6]	11.03 (10.784, 11.203) [6]	-0.251 (-0.418, -0.000) [6]
Pseudomonas aeruginosa A27853	10-100	3	14.19 (14.091, 14.473) [6]	14.30 (14.090, 14.354) [6]	0.082 (-0.251, 0.166) [6]
		10	15.31 (14.515, 16.265) [6]	14.97 (14.515, 15.182) [6]	-0.501 (-1.167, 0.249) [6]
	1-10	3	16.09 (15.584, 16.753) [3]	16.09 (15.919, 17.253) [3]	0.334 (-0.000, 0.501) [3]
		10	16.42 (16.415, 16.580) [3]	17.08 (17.082, 17.247) [3]	0.666 (0.666, 0.667) [3]
	0-1	3	17.10 (16.433, 17.430) [3]	17.27 (16.932, 17.763) [3]	0.333 (-0.166, 0.833) [3]
		10	17.34 (17.259, 17.426) [2]	17.76 (17.757, 18.427) [3]	0.416 (0.333, 0.498) [2]
Rothia mucilaginosa NCTC 10663	10-100	3	15.55 (14.882, 16.469) [6]	25.80 (23.551, 27.799) [6]	9.999 (7.999, 12.250) [6]
		10	15.80 (14.544, 16.811) [6]	20.38 (18.544, 21.810) [6]	4.667 (3.582, 5.332) [6]
Saccharomyces cerevisiae A9763	10-100	3	45.64 (40.508, 48.241) [6]	24.24 (23.505, 25.554) [6]	-21.334 (-23.168, -16.585) [6]
		10	31.06 (28.740, 33.835) [6]	25.32 (23.310, 27.085) [6]	-6.168 (-8.084, -3.668) [6]

Organism	Target CFU	Blood Volume (mL)	Predicate Device TTD (95% CI) [N]	Modified Device TTD (95% CI) [N]	TTD Difference (95%CI) [N]
Staphylococcus aureus A25923	10-100	3	12.17 (11.785, 12.402) [6]	11.48 (11.256, 11.701) [6]	-0.751 (-0.918, -0.252) [6]
		10	11.42 (11.225, 11.613) [6]	10.61 (10.418, 10.892) [6]	-0.751 (-1.167, -0.418) [6]
	1-10	3	14.43 (13.927, 14.429) [3]	12.92 (12.595, 13.259) [3]	-1.501 (-1.834, -0.668) [3]
		10	12.75 (12.583, 12.923) [3]	12.42 (12.089, 12.750) [3]	-0.168 (-0.834, -0.001) [3]
	0-1	3	Only 1 paired detection*	Only 1 paired detection*	N/A
		10	Only 1 paired detection*	Only 1 paired detection*]	N/A
Staphylococcus epidermidis A12228	10-100	3	17.31 (17.091, 17.742) [6]	15.07 (14.719, 15.757) [6]	-2.087 (-2.674, -1.833) [6]
		10	15.91 (15.563, 16.671) [6]	14.91 (14.389, 15.503) [6]	-1.089 (-1.338, -0.920) [6]
	1-10	3	19.23 (19.068, 21.069) [3]	16.23 (16.066, 17.902) [3]	-3.167 (-3.168, -2.834) [3]
		10	17.73 (17.563, 18.064) [3]	17.56 (16.398, 18.562) [3]	-0.501 (-1.334, -0.999) [3]
	0-1	3	Only 1 paired detection*	Only 1 paired detection*	N/A
		10	Only 1 paired detection*	Only 1 paired detection*	N/A
Stenotrophomonas maltophilia A13637	10-100	3	27.07 (26.342, 27.610) [6]	29.34 (28.567, 32.775) [6]	2.494 (1.493, 5.666) [6]
		10	26.59 (24.081, 29.353) [6]	32.51 (28.155, 35.103) [6]	5.0245 (4.074, 6.418) [6]
Streptococcus agalactiae A12928	10-100	3	8.79 (8.594, 9.070) [6]	8.96 (8.840, 9.317) [6]	0.248 (-0.003, 0.415) [6]
		10	9.21 (8756, 9.661) [6]	9.12 (8.921, 9.326) [6]	-0.167 (-0.335, 0.248) [6]
Streptococcus pneumoniae A6301	10-100	3	11.52 (11.282, 11.630) [6]	11.46 (11.043, 11.590) [6]	-0.007 (-0.587, 0.249) [6]
		10	12.20 (11.731, 12.380) [6]	12.04 (11.604, 12.230) [6]	-0.254 (-0.675, 0.499) [6]
Streptococcus pneumoniae A6303	10-100	3	11.15 (10.887, 11.542) [6]	11.13 (10.952, 11.396) [6]	-0.004 (-0.424, 0.333) [6]
		10	11.47 (11.131, 11.809) [6]	11.73 (11.372, 11.965) [6]	0.328 (-0.338, 0.662) [6]
Streptococcus pneumoniae A6305	10-100	3	12.95 (12.697, 13.364) [6]	12.44 (12.277, 12.943) [6]	-0.421 (-0.588, -0.336) [6]
		10	13.38 (12.788, 13.941) [6]	13.19 (12.841, 13.462) [6]	-0.084 (-1.016, 0.488) [6]
	1-10	3	13.27 (13.264, 13.762) [3]	14.10 (13.928, 15.436) [3]	0.832 (0.166, 2.166) [3]
		10	14.93 (13.261, 15.593) [3]	15.34 (15.093, 15.591) [2]	0.083 (-0.499, 0.666) [2]
	0-1	3	No paired detections*	No paired detections*	N/A
		10	No paired detections*	No paired detections*	N/A
Streptococcus pneumoniae	10-100	3	12.11 (12.005, 12.402) [6]	12.17 (12.003, 12.504) [6]	-0.001 (-0.168, 0.333) [6]

Organism	Target CFU	Blood Volume (mL)	Predicate Device TTD (95% CI) [N]	Modified Device TTD (95% CI) [N]	TTD Difference (95%CI) [N]
A700673		10	12.59 (12.432, 12.827) [6]	12.68 (12.502, 12.910) [6]	0.166 (-0.251, 0.332) [6]
Streptococcus pyogenes A19615	10-100	3	10.16 (10.003, 10.387) [6]	10.41 (10.085, 10.554) [6]	0.249 (-0.084, 0.333) [6]
		10	10.81 (10.482, 10.982) [6]	10.57 (10.396, 10.896) [6]	-0.168 (-0.501, 0.249) [6]
Streptococcus sanguinis A10556	10-100	3	14.60 (14.078, 15.364) [6]	15.01 (14.576, 15.281) [6]	0.499 (-0.167, 0.499) [6]
		10	14.76 (14.429, 15.017) [6]	14.86 (14.513, 15.167) [6]	0.166 (-0.251, 0.416) [6]
	1-10	3	16.56 (16.557, 16.892) [3]	18.06 (17.226, 19.056) [3]	1.166 (0.666, 2.499) [3]
		10	17.05 (16.721, 19.389) [3]	17.22 (17.053, 17.388) [3]	0.166 (-2.001, 0.333) [3]
	0-1	3	No paired detections*	No paired detections*	N/A
		10	Only 1 paired detection*	Only 1 paired detection*	N/A
All organisms	10-100	3	16.66 (15.809, 19.113) [264]	17.331 (15.523, 20.786) [264]	-0.002 (-0.168, -0.001) [264]
		10	17.083 (16.089, 18.906) [264]	17.328 (15.387, 19.012) [264]	-0.168 (-0.334, -0.001) [264]
	1-10	3	19.23 (16.108, 27.083) [45]	18.56 (16.150, 27.074) [44]	-0.501 (-2.417, -0.000) [44]
		10	18.06 (16.580, 24.943) [45]	17.56 (17.053, 25.729) [43]	-0.499 (-1.001, -0.001) [43]
	0-1	3	21.08 (16.433, 39.617) [N=17)	17.75 (14.443, 31.697) [N=16]	-0.167 (-10.016, 0.499) [N=10]
		10	20.08 (13.274, 42.679) [N=15]	24.82 (18.093, 41.637) [N=20]	-0.167 (-2.667, 0.498) [N=7]

* At least two distinct values are required to generate a confidence interval

Percent Recovery

The percent recovery was also assessed using the same organisms, blood volumes, vial lots, instruments, and inoculum levels as defined in the TTD study.

The results of this testing indicated no statistically relevant difference in recovery and are summarized in Table 3.

Table 3. Percent Recovery Stratified by Organism, Inoculum and Blood Volume

Organism	Target CFU	Blood Volume (mL)	Predicate Device Percent Recovery (# positive bottles/# total bottles	Modified Device Percent Recovery (# positive bottles/ # total bottles)
Abiotrophia defectiva A49176	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Acinetobacter lwoffii A17925	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Aggregatibacter actinomycetemcomitans NCTC 9710	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Aerococcus viridins A11563	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Alcaligenes faecalis A8750	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Bacillus subtilis A82	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Candida albicans A18804	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
	1-10	3	100.0% (3/3)	100.0% (3/3)
		10	100.0% (3/3)	100.0% (3/3)
	0-1	3	100.0% (3/3)	33.3% (1/3)
		10	33.3% (1/3)	66.7% (2/3)
Candida auris AR 0378	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Candida glabrata A15545	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Candida glabrata A66032	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
	1-10	3	100.0% (3/3)	100.0% (3/3)
		10	100.0% (3/3)	100.0% (3/3)
	0-1	3	33.3% (1/3)	33.3% (1/3)
		10	33.3% (1/3)	66.7% (2/3)
Cardiobacterium hominis NCTC 10426	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Corynebacterium jeikeium A43216	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Cryptococcus neoformans A32045	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
	1-10	3	100.0% (3/3)	100.0% (3/3)
		10	100.0% (3/3)	100.0% (3/3)
	0-1	3	66.7% (2/3)	33.3% (1/3)
		10	100.0% (3/3)	66.7% (2/3)
Eikinella corrodens	10-100	3	100.0% (6/6)	100.0% (6/6)

Organism	Target CFU	Blood Volume (mL)	Predicate Device Percent Recovery (# positive bottles/# total bottles	Modified Device Percent Recovery (# positive bottles/ # total bottles)
A23834		10	100.0% (6/6)	100.0% (6/6)
Enterobacter cloacae A35030	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Enterococcus faecalis A29212	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
	1-10	3	100.0% (3/3)	66.7% (2/3)
		10	100.0% (3/3)	100.0% (3/3)
	0-1	3	0.0% (0/3)	66.7% (2/3)
		10	33.3% (1/3)	0.0% (0/3)
Escherichia coli A25922	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
	1-10	3	100.0% (3/3)	100.0% (3/3)
		10	100.0% (3/3)	100.0% (3/3)
	0-1	3	66.7% (2/3)	66.7% (2/3)
		10	66.7% (2/3)	66.7% (2/3)
Granulicatella adiacens A43205	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Haemophilus influenzae A19418	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
	1-10	3	100.0% (3/3)	100.0% (3/3)
		10	100.0% (3/3)	100.0% (3/3)
	0-1	3	0.0% (0/3)	33.3% (1/3)
		10	0.0% (0/3)	0.0% (0/3)
Haemophilus influenzae A9006	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Haemophilus influenzae A10211	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Haemophilus parainfluenzae A33392	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
	1-10	3	100.0% (3/3)	100.0% (3/3)
		10	100.0% (3/3)	100.0% (3/3)
	0-1	3	0.0% (0/3)	33.3% (1/3)
		10	0.0% (0/3)	33.3% (1/3)
Kingella kingae A23330	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Klebsiella pneumoniae A33495	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Leuconostoc species A21435	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Micrococcus luteus A4698	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
	1-10	3	100.0% (3/3)	100.0% (3/3)
		10	100.0% (3/3)	66.7% (2/3)
	0-1	3	0.0% (0/3)	33.3% (1/3)
		10	33.3% (1/3)	33.3% (1/3)
Neisseria gonorrhoeae A10150	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)

Organism	Target CFU	Blood Volume (mL)	Predicate Device Percent Recovery (# positive bottles/# total bottles	Modified Device Percent Recovery (# positive bottles/ # total bottles)
	1-10	3	100.0% (3/3)	100.0% (3/3)
		10	100.0% (3/3)	100.0% (3/3)
	0-1	3	66.7% (2/3)	33.3% (1/3)
		10	33.35 (1/3)	66.7% (2/3)
Neisseria meningitidis A13090	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
	1-10	3	100.0% (3/3)	100.0% (3/3)
		10	100.0% (3/3)	100.0 (3/3)
	0-1	3	0.0% (0/3)	0.0% (0/3)
		10	0.0% (0/3)	0.0% (0/3)
Pediococcus acidilactici A25740	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Proteus mirabilis A8259	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Providencia stuartii A25825	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Pseudomonas aeruginosa A27853	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
	1-10	3	100.0% (3/3)	100.0% (3/3)
		10	100.0% (3/3)	100.0% (3/3)
	0-1	3	100.0% (3/3)	100.0% (3/3)
		10	66.7% (2/3)	100.0% (3/3)
Rothia mucilaginosa NCTC 10663	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Saccharomyces cerevisiae A9763	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Staphylococcus aureus A25923	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
	1-10	3	100.0% (3/3)	100.0% (3/3)
		10	100.0% (3/3)	100.0% (3/3)
	0-1	3	66.7% (2/3)	33.3% (1/3)
		10	33.3% (1/3)	66.7% (2/3)
Staphylococcus epidermidis A12228	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
	1-10	3	100.0% (3/3)	100.0% (3/3)
		10	100.0% (3/3)	100.0% (3/3)
	0-1	3	66.7% (2/3)	33.3% (1/3)
		10	33.3% (1/3)	66.7% (2/3)
Stenotrophomonas maltophilia A13637	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Streptococcus agalactiae A12928	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Streptococcus pneumoniae A6301	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Streptococcus pneumoniae A6303	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Streptococcus pneumoniae	10-100	3	100.0% (6/6)	100.0% (6/6)

Organism	Target CFU	Blood Volume (mL)	Predicate Device Percent Recovery (# positive bottles/# total bottles	Modified Device Percent Recovery (# positive bottles/ # total bottles)
A6305		10	100.0% (6/6)	100.0% (6/6)
	1-10	3	100.0% (3/3)	100.0% (3/3)
		10	100.0% (3/3)	66.7% (2/3)
	0-1	3	0.0% (0/3)	0.0% (0/3)
		10	0.0% (0/3)	0.0% (0/3)
Streptococcus pneumoniae A700673	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Streptococcus pyogenes A19615	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
Streptococcus sanguinis A10556	10-100	3	100.0% (6/6)	100.0% (6/6)
		10	100.0% (6/6)	100.0% (6/6)
	1-10	3	100.0% (3/3)	100.0% (3/3)
		10	100.0% (3/3)	100.0% (3/3)
	0-1	3	0.0% (0/3)	0.0% (0/3)
		10	33.3% (1/3)	33.3% (1/3)
All organisms	10-100	3	100.0% (264/264)	100.0% (264/264)
		10	100.0% (264/264)	100.0% (264/264)
	1-10	3	100.0% (45/45)	97.8% (44/45)
		10	100.0% (45/45)	95.6% (43/45)
	0-1	3	37.8% (17/45)	35.6% (16/45)
		10	33.3% (15/45)	44.4% (20/45)

False Negative Rate

The false negative rate was determined from the Percent Recovery study which was conducted on the BACTEC™ FX Instrument, resulting in a total of 444 vials (264 + 90 + 90 per device). Following the 120-hour incubation protocol, there were 115 instrument negative vials (57 in the modified device and 58 in the predicate device). All negative vials failed to yield growth upon terminal subculture. As a result, there were no false negative vials observed in this study.

False Positive Rate

False positive rate was assessed by inoculating the modified and the predicate device with various volumes of blood. Eight replicates from each of 3 lots were inoculated with either 2, 4, 6, 8 or 10 mL of freshly drawn human blood without organism for a total of 120 vials per each device. All vials were negative following the 120-hour incubation protocol. No false positive vials were observed in this study.

Instrument Compatibility

The instrument compatibility study was designed to assess performance equivalency (Recovery and TTD) of the modified and predicate device across four BACTEC™ Fluorescent Series Instruments (BACTEC™ FX, BACTEC™ FX40, BACTEC™ 9240 and BACTEC™ 9050). Testing on the BACTEC™ FX and BACTEC™ FX40 utilized an inoculum of 10-100 CFU/vial and the same study design and blood volumes as described in the TTD study for a total of 264 paired sets per instrument. Testing on the BACTEC™ 9240 and BACTEC™ 9050 utilized a subset of 16 organisms at the same inoculum level and blood volumes as used in the BACTEC™ FX and BACTEC™ FX40 testing for a total of 96 pairs.

There were no recovery failures in any of the instruments for either the modified or predicate device. Additionally, there were no significant differences in TTD and these results are summarized in Table 4 and Table 5.

Table 4. BACTEC™ FX and BACTEC™ FX40 TTD (Bootstrap Analysis)

BACTEC™ Instrument	Total Number Positive Vials	Predicate Device [TTD (95% CI)]	Modified Device [TTD (95% CI)]	TTD Difference (95% CI)
BACTEC™ FX	264	16.28 (15.37, 17.81)	16.42 (15.14, 18.47)	-0.001 (-0.168, -0.000)
BACTEC™ FX40	264	17.40 (16.48, 19.56)	18.07 (16.07, 20.11)	-0.168 (-0.334, -0.001)

Table 5. BACTEC™ FX, BACTEC™ 9240 and BACTEC™ 9050 TTD (Bootstrap Analysis)

BACTEC™ Instrument	Total Number Positive Vials	Predicate Device [TTD (95% CI)]	Modified Device [TTD (95% CI)]	TTD Difference (95% CI)
BACTEC™ FX	96	13.52 (11.75, 15.46)	13.12 (11.51, 14.61)	-0.167 (-0.415, 0.001)
BACTEC™ 9240	96	13.50 (11.09, 15.67)	12.82 (11.00, 13.84)	-0.333 (-0.500, 0.000)
BACTEC™ 9050	96	13.92 (11.67, 16.50)	13.17 (11.25, 14.67)	-0.167 (-0.334, 0.000)

The results of this testing support the use of the modified device on all four BACTEC™ Fluorescent Series Instruments.

Resin Performance

Resin performance was assessed using 7 mL of blood, 17 antimicrobials and organisms representing a diversity of MICs to each antimicrobial agent, for a total of 314 antibiotic/organism combinations per lot of media. The recovery was stratified for each lot of the modified and the predicate device and is summarized in Table 6. There was no statistically significant difference observed between lot pairs. All negative vials were also negative on terminal subculture.

Table 6. Percent Recovery Stratified by Device and Lot

Device and Lot	Total Vials Tested	Negative Vials	Percent Recovery
Predicate Device – Lot A	314	164	47.77
Modified Device – Lot A	314	166	47.13
Predicate Device – Lot B	314	151	51.91
Modified Device – Lot B	314	163	48.09
Predicate Device – Lot C	314	162	48.41
Modified Device – Lot C	314	159	49.36
Combined data	1884	965	48.78

2. Clinical Studies

Not applicable; seeded analytical studies were performed to compare the modified BD BACTEC™ Plus Aerobic/F Culture Vials to the predicate BD BACTEC™ Plus Aerobic/F Culture Vials.

M. Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

N. Conclusion:

The studies conducted support the performance of the modified BD BACTEC™ Plus Aerobic/F Culture Vials as substantially equivalent to the predicate device.