

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE

RE: DOCUMENT NUMBER K083572

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.
BD BACTEC Plus Aerobic/F Blood culture Medium K921133
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
The Indications/Intended Use of the modified device has been reviewed and has not changed.
3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device has not changed.
The fundamental scientific technology of the modified device has not changed. The modifications were
 - The BD BACTEC Plus Aerobic/F Blood Culture medium volume from 25mL of broth to 30mL.
 - The modified BD BACTEC Plus Aerobic/F Blood Culture medium contains the addition of antioxidants and vitamins to stabilize the nutrients in the media during the manufacturing process.
 - The modified BD BACTEC Plus Aerobic/F Blood Culture medium contains an increase in the glucose (dextrose) and a reduction in the concentration of sucrose. The sugar content in the Blood culture medium (TSB) has not changed.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and

| | Similarities | |
|--------------|---|----------|
| | Current | Modified |
| Intended Use | BD BACTEC Plus Aerobic/F Blood Culture medium is used in a qualitative procedure for the aerobic culture and recovery of microorganisms (bacteria and yeast) from blood. The principle use of this medium is with BD BACTEC Fluorescent Series Instruments. | Same |
| Sample type | Blood | Same |
| System | BD BACTEC Fluorescent Series Instruments. | Same |

| | Differences | |
|----------------------------------|--------------------------------------|---|
| | Current | Modified |
| Medium volume | 25 mL (Blood to broth ratio 1 : 2.5) | 30 mL (Blood to broth ratio 1 : 3) |
| Addition of ingredients | None | Antioxidants and vitamins |
| Concentration of glucose/sucrose | Lower glucose, higher sucrose | Increase in glucose, reduction of sucrose |

5. **A Design Control Activities Summary** which includes:
- Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis were provided.
 - Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied were submitted.
 - A declaration of conformity with design controls. The declaration of conformity included:
 - A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
 - A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

The design control activities were performed and were acceptable.

Medium Modification validation protocols included equivalence testing of new formulation (test) and current formulation (control) by the Fluorescent Series Instruments. The organism list included reference strains of commonly isolated pathogens comprising of Gram negative, Gram positive organisms and yeasts (i.e. *C. albicans*, *C. glabrata* and *C. neoformans*). The protocols were:

- a) Without blood or supplement
- b) Validation testing to examine the extremes of blood volume range (0, 1, and 15 mL) expected in the clinical use
- c) Detection of very low densities of viable organisms
- d) Testing on delayed vial entry

Summary Analysis of viable organisms' recovery for medium modification validation

| Protocol | total | Test and Control pos | Test and Control neg | Test pos only | Control pos only | P value* |
|-----------------------------|-------|----------------------|----------------------|---------------|------------------|---------------|
| Without blood or supplement | 72 | 66 | 6 | 0 | 0 | - |
| Blood vol (0,1,and 15 mL) | 125 | 120 | 3 | 2 | 0 | 0.4795 |
| Low densities | 276 | 218 | 21 | 24 | 13 | 0.1002 |
| Total | 473 | 404 | 30 | 26 | 13 | 0.0820 |
| Delayed vial entry | 132 | 120 | 5 | 5 | 2 | 0.4497 |
| Yeast | 107 | 57 | 26 | 20 | 4 | 0.0022 |
| Yeast (3-10 mL blood) | 48 | 22 | 8 | 18 | 0 | 0.0001 |

*P value of <0.05 indicates a significant difference with a confidence of >95%

The yeast group (i.e. *C. albicans*, *C. glabrata* and *C. neoformans*) was analyzed separately and the data is acceptable.

A system validation (algorithm regression test) was performed by inoculating bottles with reference organisms and blood volumes. The modified algorithm is only active on the Aerobic Plus medium and the data indicated that the software algorithms have been implemented and the software can be used in validation. Results also indicated "PASS" in the regression test.

6. A Truthful and Accurate Statement, a 510(k) Summary and the Indications for Use Enclosure were provided.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.