

510(k) Summary

- (a)(1) **The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;**

Submitter's Name: bioMérieux, Inc.
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Date 510(k) Summary Prepared: July 12, 2005

- (a)(2) **The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;**

Trade or Proprietary Name: BacT/ALERT BPA Culture Bottle
Common or Usual Name: BacT/ALERT BPA Culture Bottle
Classification Name: Microbial Growth Monitor

- (a)(3) **An identification of the legally marketed device to which the submitter claims substantial equivalence;**

Device Equivalent to: 5% sheep blood agar plates

- (a)(4) **A description of the device.**

Device Description: The BacT/ALERT BPA Plastic Culture Bottle with liquid emulsion sensor (LES) was developed for quality control testing of leukocyte reduced apheresis platelet (LRAP) units, and both leukocyte reduced single and a pool of up to 6 units of leukocyte reduced whole blood platelet concentrates (LRWBPC). The BacT/ALERT BPA Culture Bottles support the growth of aerobic microorganisms (bacteria and fungi). An inoculated bottle is placed into the BacT/ALERT Microbial Detection Instruments where it is incubated and continuously monitored for the presence of microorganisms that will grow in the BacT/ALERT BPA Culture Bottle.

- (a)(5) **A statement of the intended use of the device.**

Device Intended Use: BacT/ALERT BPA Culture Bottles are used with the BacT/ALERT Microbial Detection System for quality control testing of leukocyte reduced apheresis platelet (LRAP) units, and both leukocyte reduced single and a pool of up to 6 units of leukocyte reduced whole blood platelet concentrates (LRWBPC). BacT/ALERT BPA culture bottles support the growth of aerobic microorganisms (bacteria and fungi).

Traditional 510(k)
BioMerieux, Inc.
BacT/ALERT BPA Culture Bottle
Expanded Indication for Quality Control Testing of a Pool of Up to 6 Units of LRWBPC
(a)(6) A summary of the technological characteristics of the new device in comparison to those of the predicate device.

The data contained in this submission and the information contained below support the claim that the BacT/ALERT BPA Plastic Culture Bottle is substantially equivalent to the 5% sheep blood agar plates (pre-amendment device) in terms of intended use and performance for expanded indication of quality control testing of a pool of up to 6 units of leukocyte reduced whole blood platelet concentrates (LRWBPC). The similarities and/or differences with marketed device are listed in Table 10.1.

TABLE 10.1

FEATURES	BACT/ALERT BPA PLASTIC CULTURE BOTTLE (P/N 279018)	5% Sheep Blood Agar Plates
<i>Intended Use</i>	BacT/ALERT BPA Culture Bottles are used with the BacT/ALERT Microbial Detection System for quality control testing of leukocyte reduced apheresis platelet (LRAP) units, and both leukocyte reduced single and a pool of up to 6 units of leukocyte reduced whole blood platelet concentrates (LRWBPC). BacT/ALERT BPA culture bottles support the growth of aerobic microorganisms (bacteria and fungi).	Multi-purpose media for the growth of micro-organisms in specimens including blood components
<i>Device</i>	In-vitro	In-vitro
<i>Category</i>	Pre-market Notification 510(k)	Exempt (Pre-Amendment)
<i>Technology</i>	Growth of organisms in standard media bottles incubated at 37°C in an automated detection instrument	Growth of organisms in standard media plates incubated at 35°C detected using conventional manual method
<i>Media</i>	Nutritional Media, Nutritional Supplements, Reducing Agents plus oxygen for aerobic bottles and nitrogen for anaerobic bottles	Nutritional Media, Nutritional Supplements, Reducing Agents plus oxygen for aerobic bottles and nitrogen bottles
<i>Growth of microorganisms</i>	96.3% recover of Facultative Organisms and Strict Aerobes in the clinical trial (95% CI)	71.5% recovery in the clinical trial (95% CI)
<i>Detection Used</i>	BacT/ALERT Microbial Detection Systems	Manual Methodology
<i>Sample Source</i>	Leukocyte Reduced Platelets	Leukocyte Reduced Platelets
<i>Target Population</i>	Adult	Adult

(b)(1) **A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalency.**

Testing was performed to establish the performance characteristics of the new device including:

Seeded studies were performed on 10 organisms. Each of the 10 organisms were diluted into one unit of LRWBPC and pooled with 5 non seeded units of LRWBPC to make a 6 unit pool. The 6 unit pool of leukocyte reduced whole blood platelet concentrates (LRWBPC) were then inoculated into the BacT/ALERT BPA Plastic Culture bottle and the 5% sheep blood agar plate.

(b)(2) **A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalency.**

Not Applicable

(b)(3) **The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performed as well or better than the legally marketed device identified in (a)(3).**

The BacT/ALERT BPA Plastic Culture Bottle was substantially equivalent to the 5% sheep blood agar plate based on recovery of low levels of the 10 microorganisms included in the study.