

Traditional 510(k)
bioMérieux, Inc.
BacT/ALERT BPN Culture Bottle
Glass Culture Bottle to Plastic Culture Bottle

BK030034

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.
Submitter's Address: 100 Rodolphe Street,
Durham, North Carolina 27712
Submitter's Telephone: (919) 620-2682
Submitter's Contact: Troy C. Quander
Date 510(k) Summary Prepared: May 30, 2003

- (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 BPN Culture Bottle

Common or Usual Name: BacT/ALERT BPN 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: BacT/Alert SN Glass Culture Bottle

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

Device Description: The BacT/ALERT BPN Plastic Culture Bottle was developed for the same intended use as the current BacT/ALERT SN Glass Culture Bottle, but specifically designed to be used for quality control testing of leukocyte reduced apheresis platelet (LRAP) units. The BacT/ALERT BPN Culture Bottles support the growth of anaerobic and facultative anaerobic microorganisms (bacteria). 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 BPN Culture Bottle

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

Device Intended Use: BacT/ALERT BPN Culture Bottles are used with the BacT/ALERT Microbial Detection System for quality control testing of leukocyte reduced apheresis platelet (LRAP) units. BacT/ALERT BPN culture bottles support the growth of anaerobic and facultative anaerobic microorganisms (bacteria).

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(a)(6) A summary of the technological characteristics of the new device in comparison to those of the predicate device.

The BacT/ALERT BPN Plastic Culture Bottle utilizes the same detection technology as the BacT/ALERT SN Glass Culture Bottle. The similarities and/or differences with marketed device are listed in Table (a) (6) 1.

TABLE (a)(6).1

FEATURES	BACT/ALERT BPN PLASTIC CULTURE BOTTLE	BACT/ALERT SN GLASS CULTURE BOTTLE (BK020023)
<i>Intended Use</i>	BacT/ALERT BPN Culture Bottles are used with the BacT/ALERT Microbial Detection System for quality control testing of leukocyte reduced apheresis platelet (LRAP) units. BacT/ALERT BPN culture bottles support the growth of anaerobic and facultative anaerobic microorganisms (bacteria).	The BacT/ALERT SN Culture Bottles are used with the BacT/ALERT Microbial Detection System in qualitative procedures for the recovery and detection of anaerobic microorganisms (bacteria) from blood and other normally sterile body fluids. BacT/ALERT SN Culture Bottles may also be used for quality control testing of leukocyte reduced platelet (LRAP) units.
<i>Culture Bottle Material</i>	Plastic	Glass
<i>Product Code</i>	MZC	MZC
<i>Technology</i>	Reflectance	Reflectance
<i>Color change based on CO₂ production</i>	YES	YES
<i>Sensor</i>	Emulsion	Emulsion
<i>Indicator material</i>	Xylenol Blue in Silicone Emulsion	Xylenol Blue in Silicone Emulsion
<i>Growth of microorganisms</i>	Same	Same
<i>Instrument Used</i>	BacT/ALERT Microbial Detection Systems	BacT/ALERT Microbial Detection Systems
<i>Sample Source</i>	LRAP	LRAP
<i>Target Population</i>	Adult	Adult
<i>Media Formulation</i>	Formulation change from glass bottle	Same

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- (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 9 organisms diluted in platelets and inoculated into the BacT/ALERT BPN Plastic Culture bottle and the BacT/ALERT SN Glass Culture bottle.

- (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 BPN Plastic Culture Bottle was substantially equivalent to the BacT/ALERT SN Glass Culture Bottle based on recovery of low levels of the 9 microorganisms included in the study. Detection times were equivalent in both bottles.