Special 510(k)
bioMérieux, Inc.
BacT/Alert SA Culture Bottle
Disk Sensor to LES

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

(a)(1) **The submitter's name, address, telephone and fax 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, USA

Submitter's Telephone: 919-620-2288

Submitter's Fax: 919-620-2548

Submitter's Contact: Anita M. McClernon Anita M. McClernon

Date 510(k) Summary Prepared: May 22, 2002

(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 SA Culture Bottle

Common or Usual Name: BacT/ALERT SA 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 Standard Aerobic Culture Bottle (with disk sensor)
510(k) Number: BK000042

Device Equivalent to: BacT/ALERT SA Culture Bottle (cleared for use with blood and other normally sterile body fluids).
510(k) Number: K993423

(a)(4) **A description of the device:**

Device Description: The BacT/ALERT SA Culture Bottle was developed for the same intended use as the current BacT/ALERT Standard Aerobic Culture Bottle, to provide suitable nutritional and environmental conditions for organisms commonly encountered in blood infections and normally sterile body fluids. BacT/ALERT SA Culture Bottles may also be used for quality control testing of leukocyte reduced apheresis platelet (LRAP) units. 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 SA Bottle.

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

Device Intended Use: BacT/ALERT SA Culture Bottles are used with the BacT/ALERT Microbial Detection System in qualitative procedures for the recovery and detection of aerobic microorganisms (bacteria and fungi) from blood and other normally sterile body fluids. BacT/ALERT SA Culture Bottles may also be used for quality control testing of leukocyte reduced apheresis platelet (LRAP) units.

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

The BacT/ALERT SA Culture Bottle utilizes the same detection technology as the BacT/Alert Standard Aerobic Culture Bottle. Similarities and differences as compared to the predicate device are listed in Table 11.1 on the following page.

Table 11.1

FEATURES	BacT/ALERT SA Culture Bottle	BacT/Alert Standard Aerobic Culture Bottle (BK000042)
Technology	Reflectance	Reflectance
Color change based on CO_2 production	YES	YES
Sensor	Liquid Emulsion Sensor	Disk Sensor
Indicator material	YES, Same as Standard Aerobic Bottle	YES
Growth of microorganisms	YES, Equivalent to Standard Aerobic Bottle	YES
Instrument Used	BacT/ALERT Microbial Detection Systems	BacT/ALERT Microbial Detection Systems
Sample Source	LRAP	LRAP
Target Population	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.**

Seeded studies were performed on 9 microorganisms diluted in platelets and inoculated into the BacT/ALERT SA Culture Bottle and the BacT/Alert Standard Aerobic 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 SA Culture Bottle (LES sensor) was substantially equivalent to the BacT/Alert Standard Aerobic Culture Bottle (Disk sensor) based on recovery of 8 of the 9 microorganisms included in the study. The one organism which was not recovered, *P.acnes*, is an anaerobe which would not be expected to grow in the oxygen rich atmosphere of the SA bottle. This organism was recovered in the companion BacT/ALERT SN Culture Bottle. Detection times were equivalent in both bottles.