

K962210

AUG - 8 1996

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

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PREPARED: June 6, 1996

DEVICE NAME: BACTEC® 9050 System

COMMON NAME: Blood Culture Instrument

**CLASSIFICATION
NAME:** Monitor, Microbial Growth

**PREDICATE
DEVICE:** BACTEC® 9240 System

INTENDED USE: A non-radiometric automated blood culturing system which is designed for the monitoring and detection of clinical cultures of blood for the presence of microorganisms.

SUMMARY: Table 1 summarizes the similarities and differences between the BACTEC 9050 and the BACTEC 9240/9120.

Nonclinical tests were conducted to determine the substantial equivalence of the BACTEC 9050 to the BACTEC 9240. A total of 485 paired seeded vials were detected in both systems using 23 organisms that were chosen for their clinical relevancy and are representative of the organisms for which the various media types are designed to support growth. The current available media was used in the tests along with the recommended minimum and maximum blood volumes. The difference in recovery between the BACTEC 9240 and the BACTEC 9050 systems was 0.2% with a mean time to detection for microorganisms being equal (<0.01 hours). The BACTEC 9050 performed equivalent to the BACTEC 9240.

Table 1**Comparison of BACTEC 9240/9120 and BACTEC 9050**

	BACTEC 9240/9120	BACTEC 9050
Number of Specimens	240/120	50
Intended Use	Growth and detection of clinical cultures of blood for the presence of microorganisms	Same
Sample Type	Blood	Same
Culture Analysis	Positivity Algorithms by Media Type	Same
Agitation State During Testing	Off	On
Detection Optics	Florescence Detector (LED)	Same
Incubation Temperature	35° C ± 1.5° C	Same
Protocol Length	1 to 30 Days	4 to 7 Days
Reagents	Florescent Series Media	Same
Specimen Testing Frequency	Every 10 Minutes	Same
Power Supplies	Low Voltage DC	Same
Display Screen	Displays 6 racks/3 racks	Displays 1 rack (Rotor)
Dimensions	52"W x 38"H x 22.5"D/52"W x 24"H x 22.5"D	24"W x 28.5"H x 25.5"D