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510(k) Summary

BacT/Alert MB/BacT Mycobacteria Detection System

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and the final rule under 21 CFR 807.92 published December 14, 1994.

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

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Date 510(k) Summary Prepared: July 11, 1996

(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: MB/BacT Mycobacteria Detection System

Common or Usual Name: Microbial Growth Monitor

Classification Name: Microbial Growth Monitor

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

Device Equivalent to: Manual Methods including Lowenstein Jensen (LJ) slants, Middlebrook 7H11 solid media and Bactec 460, all of which are pre amendment devices.

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

Device description: Automated system for growth and detection of mycobacteria organisms in clinical specimens other than blood.

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

Device Intended Use: MB/BacT Process bottles are used with the MB/BacT Mycobacteria Detection System in qualitative procedures for recovery and detection of mycobacteria in clinical specimens other than blood.

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

MB/BacT Mycobacteria Detection System detects the growth of mycobacteria in a broth culture bottle by colorimetric measurement of CO_2 production. Bactec 460 detects the growth of mycobacteria in a broth culture bottle by radiometric measurement of CO_2 production. Manual solid media methods such as Lowenstein Jensen slants or Middlebrook 7H11 plates, growth is detected by visual examination. MB/BacT cultures are continuously monitored while the other methods are monitored periodically. MB/BacT is a closed monitoring system once the specimen is inoculated into the bottle. This limits the technologist's exposure to potentially infectious organisms. This safety feature is not present in the other systems.

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

Growth promotion studies were performed on the MB/BacT Process System which consists of the media bottle, antibiotic supplement, and reconstitution fluid along with the MB/BacT instrument. These data were generated to demonstrate that the media was capable of growing several strains of mycobacteria in vitro. ATCC strains were used and clinical strains not commonly encountered were obtained from CDC for testing. These data demonstrate the MB/BacT Process System is capable of supporting growth of a variety of mycobacteria organisms. Colony counts were performed on select strains to determination the level of growth to trigger a positive reading by the instrument. These counts ranged from 10^6 to 10^8 CFU/ml. Data was generated on select strains of mycobacteria at different concentrations comparing MB/BacT to Bactec 460. Times to detection ranged from 7.9 to 17.1 days for MB/BacT and from 5 to 14 days for Bactec 460 (when a G.I. of 50 was considered positive).

(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.**

Comparison Studies were conducted at 4 clinical sites to evaluate the performance of the MB/BacT Mycobacteria Detection System compared to conventional solid media for growth and detection of mycobacteria. One of the sites also used the BACTEC 460 in addition to conventional solid media. The comparative methods used at the sites were as follows:

Site	Comparative Method
Site A	Lowenstein-Jensen Slants Middlebrook 7H11 bi-plates containing selective and non-selective media
Site B	Lowenstein-Jensen Slants Middlebrook 7H11 selective agar slants
Site C	Lowenstein-Jensen Slants Middlebrook 7H11 bi-plates containing selective and non-selective media

Site D Lowenstein-Jensen Slants
Middlebrook 7H11 bi-plates containing selective and non-selective media
BACTEC 460 TB

Site E Lowenstein-Jensen Slants
BACTEC 460TB

A summary of the organisms recovered and comparison to the predicate devices is provided in the following tables.

Recovery of Mycobacteria species - MB/BacT vs BACTEC

Mycobacteria species only	Total recovered	MB/BacT pos	MB/BacT pos only	Bactec pos	Bactec pos only	Solid pos	Solid pos
M. avium	67	52	4	61	10	43	0
M. chelonae	6	4	0	6	2	2	0
M. gordonae	21	17	14	7	2	3	0
M. intracellulare	1	1	0	0	0	1	0
M. kansasii	2	2	0	2	0	2	0
M. simiae	1	1	0	1	0	1	0
M. tuberculosis	79	74	4	71	2	65	0
M. xenopi	1	0	0	1	1	0	0
Atypical mycobacteria	1	0	0	1	1	0	0
Total isolates	179	151	22	150	18	117	0

Recovery of Mycobacteria species - MB/BacT vs Solid Media

Mycobacteria species	Total recovered	MB/BacT pos	MB/BacT pos only	Solid pos	Solid pos only
M. avium	132	111	38	94	21
M. chelonae	6	5	3	3	1
M. fortuitum	7	6	3	4	1
M. gordonae	31	30	24	7	1
M. kansasii	12	9	2	10	3
M. terrae	1	0	0	1	1
M. tuberculosis	205	173	18	187	32
M. xenopi	1	1	0	1	0
Total isolates	395	335	88	307	60

(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 performance characteristics of the new device are comparable to those of the predicate devices and typical of methods used for detection of mycobacteria. The data presented in the premarket notification demonstrate that the new device performs substantially equivalent to the predicate devices.