Becton Dickinson Microbiology Systems
Sparks, Maryland 21152-0999

MAY 1 1998

K974883

BECTON DICKINSON

APPENDIX L

SUMMARY OF SAFETY & EFFICACY

SUBMITTED BY: BECTON DICKINSON MICROBIOLOGY SYSTEMS
7 LOVETON CIRCLE
SPARKS, MD 21152

CONTACT: Jody J. Hoffmann, Regulatory Affairs Associate
TELEPHONE: (410)316-4546

PREPARED: DECEMBER 29, 1997

DEVICE NAME: BACTEC® MGIT™ 960 System

PREDICATE DEVICES: BACTEC® 460 TB System
Conventional Media

INTENDED USE: The BACTEC® MGIT™ 960 System is an instrumented system using a modified 7H9 growth medium for the detection of mycobacteria growth from clinical specimens (except blood).

SUMMARY OF SAFETY & EFFICACY

DEVICE DESCRIPTION:

The BACTEC® MGIT™ 960 instrument is a self-contained incubation/detection unit which contains three drawers; each drawer holding up to 320 tubes of growth medium containing fluorescent indicator. Inoculated tubes are monitored by the instrument continuously for growth, based on the detection of fluorescence.

Mycobacteria metabolize nutrients and oxygen in the BBL® MGIT™ culture broth. The MGIT tubes contain a fluorescent indicator which reacts to the concentration of oxygen in the culture medium. As the microorganisms use the oxygen, the indicator begins to fluoresce when exposed to excitation light. The BACTEC® MGIT™ 960 instrument's photo detectors measure the level of fluorescence, which corresponds to microorganism growth.

Clinical specimens (except blood) are collected from patients and processed, when necessary, using standard digestion/decontamination procedures. Specimens are inoculated (0.5 ml) into prepared MGIT tubes (with MGIT OADC and MGIT PANTA, if necessary) and entered into the BACTEC® MGIT™ 960 System.

All tubes entered into the system are read every sixty minutes. When a MGIT tube is detected as positive, the positive tube indicator light is activated on the drawer front. Positive MGIT tubes are removed from the instrument for confirmation by acid-fast bacilli (AFB) smear, isolation and identification. Negative MGIT tubes remain in testing protocol for a minimum of 42 days. At the end of protocol, the negative tubes are removed and discarded.

DEVICE TECHNOLOGICAL CHARACTERISTICS:

Tables 1 through 3 summarize the similarities and differences between the BACTEC® MGIT™ 960 System and the predicate devices.

SUMMARY OF SAFETY & EFFICACY

Table 1: BACTEC® MGIT™ 960 System versus BACTEC® 460TB System

Intended Use	Growth and detection of mycobacteria from clinical specimens, except blood.	Growth and detection of mycobacteria from clinical specimens.
Sample type	Respiratory and other body fluids.	Respiratory and other body fluids.
Sample volume	0.5 mL	0.5 to 1.0 mL
Growth medium	7H9 Middlebrook broth base with nutrient additives.	7H12 Middlebrook broth base with nutrient additives.
Growth Medium Ingredients	APPROX. COMPOSITION/1000 mL Disodium phosphate 2.5 g L-Asparagine 1.25 Monopotassium phosphate 1.0 Sodium glutamate 0.5 Ammonium sulfate 0.5 Sodium citrate 0.1 Magnesium sulfate 0.05 Ferric ammonium citrate 0.04 Copper sulfate 1.0 mg Pyridoxine 1.0 Zinc sulfate 1.0 Biotin 0.5 Calcium chloride 0.5 Casein peptone 1.25 g Glycerol 3.1 mL	APPROX. COMPOSITION/1000 mL Disodium phosphate 2.5 g Monopotassium phosphate 1.0 Sodium glutamate 0.5 Ammonium sulfate 0.5 Sodium citrate 0.1 Magnesium sulfate 0.05 Ferric ammonium citrate 0.04 Copper sulfate 1.0 mg Pyridoxine 1.0 Zinc sulfate 1.0 Biotin 0.5 Calcium chloride 0.5 Casein hydrolysate 0.1 g
Additional Medium Growth Factors	BBL® MGIT™ OADC enrichment: Oleic Acid, Albumin, Dextrose, Catalase	Albumin, Catalase
Antimicrobial Supplement	BBL® MGIT™ PANTA™ antibiotic mixture: polymixin B, amphotericin B, nalidixic acid, trimethoprim & azlocillin.	BACTEC® PANTA™ PLUS: Polymixin B, amphotericin B, nalidixic acid, trimethoprim & azlocillin.
Growth detection	Fluorescent detection of O_2 consumption by microorganism growth.	Radiometric detection of CO_2 liberated by microorganism growth.
Incubation temp.	Instrument incubation at 37±1.5° C.	35 ± 2° C.
Detector	O_2 sensitive fluorescent sensor in silicone rubber base.	^{14}C labeled fatty acid present in the medium.

598

SUMMARY OF SAFETY & EFFICACY

Table 2: BACTEC® MGIT™ 960 System versus Lowenstein-Jensen media

Intended Use	Growth and detection of mycobacteria from clinical specimens, except blood.	Used for the cultivation of *Mycobacterium tuberculosis* and other mycobacterial species.
Sample type	Respiratory and other body fluids.	Respiratory and other body fluids.
Sample volume	0.5 mL	0.1 to 0.5 mL
Growth Medium Ingredients	APPROX. COMPOSITION/1000 mL Disodium phosphate 2.5 g L-Asparagine 1.25 Monopotassium phosphate 1.0 Sodium glutamate 0.5 Ammonium sulfate 0.5 Sodium citrate 0.1 Magnesium sulfate 0.05 Ferric ammonium citrate 0.04 Copper sulfate 1.0 mg Pyridoxine 1.0 Zinc sulfate 1.0 Biotin 0.5 Calcium chloride 0.5 Casein Peptone 1.25 g Glycerol 3.1 mL	APPROX. COMPOSITION/1000 mL L-Asparagine 6.0 g Monopotassium phosphate 4.2 Sodium citrate 1.0 Magnesium sulfate 0.4 Glycerol 20.0 mL Potato flour 50.0 g Malachite green 0.67 Whole egg 1667.0 mL
Additional Medium Growth Factors	BBL® MGIT™ OADC enrichment: Oleic Acid, Albumin, Dextrose, Catalase	None
Antimicrobial supplement	Polymixin B, amphotericin B, nalidixic acid, trimethoprim & azlocillin (PANTA).	None
Detector	Fluorescent indicator in silicone rubber base.	None
Growth detection	Fluorescent detection of O_2 consumption by microorganism growth.	Macroscopic observance of microorganism growth on medium surface.
Incubation temp.	Instrument incubation at 37±1.5° C.	35 ± 2° C.

Table 3: BACTEC® MGIT™ 960 System versus Middlebrook 7H11/7H11-S

Intended Use	Growth and detection of mycobacteria from clinical specimens, except blood.	Used for the isolation and cultivation of mycobacteria.
Sample type	Respiratory and other body fluids.	Respiratory and other body fluids.
Sample volume	0.5 mL	0.1 to 0.5 mL
Growth Medium Ingredients	APPROX. COMPOSITION/1000 mL	APPROX. COMPOSITION/1000 mL
	Disodium phosphate 2.5 g	Disodium phosphate 1.5 g
	L-Asparagine 1.25	L-Asparagine 3.6
	Monopotassium phosphate 1.0	Monopotassium phosphate 1.5
	Sodium glutamate 0.5	Sodium glutamate 0.5
	Ammonium sulfate 0.5	Ammonium sulfate 0.5
	Sodium citrate 0.1	Sodium citrate 0.4
	Magnesium sulfate 0.05	Magnesium sulfate 0.05
	Ferric ammonium citrate 0.04	Ferric ammonium citrate 0.04
	Copper sulfate 1.0 mg	Copper sulfate 1.0 mg
	Pyridoxine 1.0	Pyridoxine 1.0
	Zinc sulfate 1.0	Zinc sulfate 1.0
	Biotin 0.5	Biotin 0.5
	Calcium chloride 0.5	Calcium chloride 0.5
	Casein peptone 1.25 g	
	Glycerol 3.1 mL	Glycerol 5.0 mL
		Oleic acid 0.06
		Agar 13.5 g
		Bovine albumin V 5.0
		Dextrose 2.0
		Sodium chloride 0.85
		Pancreatic digest of casein 1.0
		Catalase 3.0 mg
		Malachite green 0.4

SUMMARY OF SAFETY & EFFICACY

SUMMARY OF DEVICE TESTING:

Internal testing of the BACTEC® MGIT™ 960 System demonstrated the ability to recover a wide variety of mycobacteria species. Additionally, internal testing showed comparable recovery between the BACTEC® MGIT™ 960 System and the BACTEC® 460TB System.

An external evaluation was performed at six (6) sites. All sites used the BACTEC® 460TB System and conventional media at reference methods for comparison to the BACTEC® MGIT™ 960 System. A total of 3330 specimens were tested during the study. A total of 353 specimens were positive which represented 362 isolates recovered during the study. The distribution of positives by specimen type is: respiratory (90%), tissue (7%), body fluids (1%), stool (0.85%) and bone marrow (0.65%).

Of the 362 isolates, 289 (80%) were recovered by the BACTEC® MGIT™ 960 System, 271 (75%) were recovered by the BACTEC® 460TB System and 250 (69%) were recovered by conventional solid media. Of the 3330 specimens tested in the clinical study, 27 (0.8%) MGIT 960 tubes were determined to be false positive (instrument-positive, smear and/or subculture-negative). Of the 313 MGIT 960 instrument positive tubes, 27 (8.6%) were determined to be false positive. The false negative rate (instrument-negative, smear and/or subculture-positive) was determined to be 0% based on terminal subcultures of ~ 15% of instrument negative vials. The average breakthrough contamination rate for the BACTEC® MGIT™ 960 System was 0.9%.

CONCLUSIONS:

Based on the internal and external evaluation of the BACTEC® MGIT™ 960 System, the overall performance of the BACTEC® MGIT™ 960 System is comparable to the BACTEC® 460TB System and conventional media; therefore, we believe the BACTEC® MGIT™ 960 System to be substantially equivalent[6] to these devices.

---

[6] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 1998

Jody J. Hoffmann
Regulatory Affairs Associate
Becton Dickinson
Becton Dickinson Microbiology Systems
P.O. Box 999
Sparks, Maryland 21152-0999

Re: K974883
Trade Name: Bactec® MGIT™ 960 System
Regulatory Class: I
Product Code: MDB
Dated: April 15, 1998
Received: April 16, 1998

Dear Ms. Hoffman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K974883

Device Name: BACTEC® MGIT™ 960 System

Indications For Use:

The BACTEC® MGIT™ 960 System is an *in vitro* diagnostic instrument designed and optimized for the rapid detection of mycobacteria from clinical specimens (except blood and urine). Samples are collected from patients, processed and inoculated into BBL® MGIT™ 7mL tubes supplemented with BBL® MGIT™ PANTA™ and BBL® MGIT™ OADC.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K974883

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)