K083572

DEC 24 2008

510(k) SUMMARY

SUBMITTED BY: BECTON, DICKINSON AND COMPANY
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CONTACT NAME: Dennis Mertz, Sr. Manager, Regulatory Affairs

DATE PREPARED: November 26, 2008

DEVICE TRADE NAME: BD BACTEC™ Plus Aerobic/F Blood Culture Medium

DEVICE COMMON NAME: Microbial Growth Monitor

DEVICE CLASSIFICATION: 21 CFR § 866.2560 Class I

PREDICATE DEVICES: BD BACTEC™ Plus Aerobic/F Blood Culture Medium (K921133)

INTENDED USE:

BD BACTEC Plus Aerobic/F Blood Culture medium is used in a qualitative procedure for the aerobic culture and recovery of microorganisms (bacteria and yeast) from blood. The principle use of this medium is with BD BACTEC Fluorescent Series Instruments.

DEVICE DESCRIPTION:

BD BACTEC Plus Aerobic/F Blood Culture medium is a bacterial growth medium intended for use in the qualitative culture and recovery of aerobic microorganisms (bacteria and yeast) from human blood. It has been design for blood volumes of three (3) to ten (10) milliliters and is used specifically with the BD BACTEC Fluorescent Series Instruments in monitoring of clinical blood specimens for the presence of microorganisms.

DEVICE COMPARISON:

The modified BD BACTEC Plus Aerobic/F Blood Culture medium differs from the current legally marketed BD BACTEC Plus Aerobic/F Blood Culture medium in the following ways:

- The modified BD BACTEC Plus Aerobic/F Blood Culture medium contains 30mL of broth whereas the current BD BACTEC Plus Aerobic/F Blood Culture medium contains 25mL of broth.
- The modified BD BACTEC Plus Aerobic/F Blood Culture medium contains the addition of antioxidants and vitamins to stabilize the nutrients in the media during the manufacturing process whereas the current BD BACTEC Plus Aerobic/F Blood Culture medium does not contain these ingredients.
- The modified BD BACTEC Plus Aerobic/F Blood Culture medium contains an increase in the glucose (dextrose) and a reduction in the concentration of sucrose in order to enhance the nutritional content of the medium whereas the current BD BACTEC Plus Aerobic/F Blood Culture medium has a lower concentration of glucose but a higher concentration of sucrose.
- An algorithm modification will be made for processing late protocol (>35 hours) growth that will be incorporated into the BACTEC Fluorescent Series instruments to compliment the formulation changes to the medium. Both the modified and current BD BACTEC Plus Aerobic/F Blood Culture medium will utilize this modified algorithm.

SUBSTANTIAL EQUIVALENCE

The modified BD BACTEC Plus Aerobic/F Blood Culture medium is substantially equivalent[1] to the current legally marketed device, BD BACTEC Plus Aerobic/F Blood Culture medium. Modifications made to the BD BACTEC Plus Aerobic/F Blood Culture medium did not change the intended use of the device or the fundamental scientific technology.

Modifications to the BACTEC Plus Aerobic/F medium are as follows:

Modification	**Potential Impact of Modification**
Reagent Modifications	Stability of aerobic environment over shelf life
Increase medium volume	Blood to broth ratio
Algorithm modification	Time to detection for slow growing yeast

Included in this Special 510(k), are the Hazard Analysis and the associated validations and verifications conducted to address individual hazards/risks identified for this modification. The Hazard Analysis did not identify any changes that raised new issues with safety and effectiveness. The parameters listed below were evaluated in internal studies conducted by BD Diagnostic Systems according to appropriate Design Control procedures. The modified BD BACTEC Plus Aerobic/F Blood Culture medium met all current product claims for performance.

Parameter	**Result**
Medium Sensitivity/Specificity	Overall medium performance for the modified formulation is equivalent to the current formulation
False Positive Rate	False positive rate for the modified formulation is equivalent to the current formulation
False Negative Rate	False negative rate for the modified formulation is equivalent to the current formulation
Instrument Compatibility	The modified formulation can be used in any BD BACTEC Fluorescent Series Instrument

[1]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

Mr. Dennis Mertz
Regulatory Affairs Specialist
BD Diagnostic System
Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

DEC 24 2008

Re: k083572
Trade/Device Name: BD BACTEC™ Plus Aerobic/F Blood Culture Medium
Regulation Number: 21 CFR § 866.2660
Regulation Name: Microbial Growth Monitor
Regulatory Class: I
Product Code: MDB
Dated: December 2, 2008
Received: December 3, 2008

Dear Mr. Mertz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K083572

Device Name: BD BACTEC Plus Aerobic/F Blood Culture medium

Indication For Use:

BD BACTEC Plus Aerobic/F blood Culture medium is used in a qualitative procedure for the aerobic culture and recovery of microorganisms (bacteria and yeast) from blood. The principle use of this medium is with BD BACTEC Fluorescent Series Instruments.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 083572