



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 25, 2016

BECTON DICKINSON AND COMPANY
ASHANTI BROWN
REGULATORY SPECIALIST
7 LOVETON CIRCLE, MC 694
SPARKS MD 21152

Re: K151866

Trade/Device Name: BD BACTEC Peds Plus/F Culture Vials (plastic)

Regulation Number: 21 CFR 866.2560

Regulation Name: Microbial growth monitor

Regulatory Class: I

Product Code: MDB

Dated: February 4, 2016

Received: February 8, 2016

Dear Ms. Brown:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Ribhi Shawar -S

For Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151866

Device Name

BD BACTEC Peds Plus™/F Culture Vials (plastic)

Indications for Use (Describe)

BD BACTEC Peds Plus™/F Culture Vials (enriched Soybean-Casein Digest broth with CO₂) are for aerobic blood cultures. Principal use is with the BACTEC fluorescent series instruments for the qualitative culture and recovery of aerobic microorganisms (mainly bacteria and yeast) from pediatric and non-pediatric blood specimens which are generally less than 5 mL in volume.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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The following information is provided as required by 21 C.F.R. § 807.87 for BD's 510(k) premarket notification for BD BACTEC Peds Plus™/F Culture Vials (plastic):

510(k) SUMMARY**K151866****SUBMITTED BY:**

BECTON, DICKINSON AND COMPANY
7 LOVETON CIRCLE
SPARKS, MD 21152
Phone: 410-316-4766
Fax: 410-316-4188

CONTACT NAME:

Ashanti Brown
Regulatory Affairs Specialist

DATE PREPARED:

July1, 2015

DEVICE TRADE NAME:

BD BACTEC Peds Plus™/F Culture Vials (plastic)

DEVICE COMMON NAME:

Aerobic blood culture medium

DEVICE CLASSIFICATION:

21 CFR§866.2560, Class I

PREDICATE DEVICE:

BD BACTEC Peds Plus/F medium
(K954927)

INTENDED USE:

BD BACTEC Peds Plus™/F culture vials (enriched Soybean-Casein Digest broth with CO₂) are for aerobic blood cultures. Principal use is with the **BACTEC** fluorescent series instruments for the qualitative culture and recovery of aerobic microorganisms (mainly bacteria and yeast) from pediatric and non-pediatric blood specimens which are generally less than 5 mL in volume.

DEVICE DESCRIPTION:

The sample to be tested is inoculated into one or more vials which are inserted into the BD BACTEC fluorescent series instrument for incubation and periodic reading. Each vial contains a chemical sensor which can detect increases in CO₂ produced by the growth of microorganisms. The sensor is monitored by the instrument every ten minutes for an increase in its fluorescence, which is proportional to the amount of CO₂ present. A positive reading indicates the presumptive presence of viable microorganisms in the vial. Detection is limited to microorganisms that will grow in a particular type of medium.

DEVICE COMPARISON:

The BD BACTEC Peds Plus™/F Culture Vials (plastic) medium differs from the BD BACTEC Peds Plus/F (glass) medium in the following ways:

- The medium in the modified device is contained in a multilayer polycarbonate/nylon/polycarbonate plastic bottle; whereas, the medium in the predicate device is contained in a glass bottle.
- The modified device contains 2.6 g of sensor per bottle; whereas, the predicate device contains 1.75 g of sensor per bottle.
 - The volume of sensor has been adjusted for the plastic bottle to accommodate for differences in bottle geometry (thickness and shape) compared to the glass bottle.
- The indicator and red dye concentrations in the modified device have been increased to yield signals that are equivalent to the glass bottle.
 - The bromocresol purple indicator (BCP) in the modified device's sensor has been increased from a ratio of 1.8 mg per gram of sensor in the predicate device to a ratio of 6.5 mg per gram of sensor in the modified device.
 - The radglo red dye in the modified device's sensor has been increased from a ratio of 1.09 mg per gram of sensor in the predicate device to a ratio of 4.0 mg per gram of sensor in the modified device.
 - The concentrations used in the plastic bottle accommodate for differences in overall sensor volume per bottle.
- A clear, inert adhesion promoter has been added to the modified device's sensor to ensure adhesion of the sensor to the polycarbonate surface of the plastic bottle. The glass surface of the predicate device does not require an adhesion promoter.
 - The modified device's sensor contains 13 mg per bottle of the adhesion promoter 3-glycidoxypropyl trimethoxysilane (GOP). This is not used in the predicate device.
- The modified bottle weighs 20.9g compared to the predicate device bottle weight of 113g.
- The modified device measures 5.0 inches high compared to the predicate device height of 5.6 inches.

The BD BACTEC Peds Plus™/F Culture Vials (plastic) medium is similar to the BD BACTEC Peds Plus/F (glass) medium in the following ways:

- Both the modified and predicate devices are used for the qualitative aerobic culture and recovery of microorganisms from human blood.
- Both devices are intended to be used with the BD BACTEC fluorescent-series of blood culture instruments.
- The BD BACTEC fluorescent-series of blood culture instruments apply the same incubation and agitation parameters to both devices.
- The BD BACTEC fluorescent-series of blood culture instruments apply the same growth and detection algorithms to both devices.
- Both devices are incubated at 35° C ($\pm 1.5^\circ$ C) for a period of up to 120 hours.
- Both devices incorporate a sensor that detects increases in CO₂ within the bottle as a result of organism growth.
- Both devices require a sample volume of 0.5 – 5.0 mL of blood.
- Both devices incorporate resins for the adsorption of antimicrobials that may be present in clinical samples.
- Both devices utilize the same formulation of enriched soybean casein digest broth as the growth medium.

SUMMARY OF PERFORMANCE DATA

Analytical Studies:

Instrument Time to Detection

A total of 473 paired sets were positive in both the modified and predicate devices. The Wilcoxon estimated median TTD difference for the 473 positive sets is -0.250 hours (15 minutes), favoring the modified device. The data indicate that the effect of differences between the modified and predicate devices on TTD under these test conditions was minimal and that the modified device performs equivalently to the predicate device.

Percent Recovery

There was a significant difference in recovery between the BD BACTEC Peds Plus/F blood culture medium contained in plastic bottles and the predicate device contained in glass bottles, favoring the modified device contained in plastic vials. A total of 1344 paired sets were evaluated in the Percent Recovery comparison. Of those, 953 paired sets were positive in both the modified and predicate devices. The McNemar p-value for this data set equals 0.2673.

Microbial Detection Limit

A total of 360 inoculated cultures were inoculated of this group 196 grew and detected in both the modified and predicate devices. Forty-two cultures grew and detected in the predicate device only. Fifty-seven cultures grew and detected in the modified device only. There were sixty-five paired sets that were not detected in either the modified or predicate devices. The McNemar chi-square analysis of the data indicates that there was no statistically significant difference in recovery ($p=0.1594$) between the modified and predicate devices; of the 164 sets 62.2% had plate counts of 0 CFU per vial.

False Positive Rate

A total of 288 paired sets were used to execute this study. The 288 paired sets were comprised of 96 bottles from each of 3 lots. The paired sets were inoculated with fresh human blood at varying levels as specified by the test protocol and entered into the BACTEC blood culture instrument. It was expected that each bottle would be instrument-negative following the complete protocol (120 hours). There were no false positive bottles of the modified device observed within blood volumes (0.5 to 1mL).

False Negative Rate

A total of 83 paired sets were end of protocol negative in the modified and predicate devices and were evaluated for the determination of the False Negative Rate. Additionally, there were 129 sets where only the predicate device detected and 146 sets where the modified device only detected. All vials that did not detect were evaluated for false negativity via terminal subculture. Of these, forty -five (45) were false negative bottles (i.e., instrument-negative, subculture positive). Twenty - five (25) false negative results were observed in the predicate device contained in the glass bottle. Twenty (20) false negative results were observed in the modified device contained in the plastic bottle. Due to the high number of false negatives among the *Haemophilus* species; the cross functional team met and agreed to retest the original set with fresh blood (0.5mL and 1mL) ; subsequently three *Haemophilus influenzae* strains were detected in both predicate and modified vials when tested with 0.5mL fresh blood.

A Chi-square analysis using the parameters of 1299 correct, with the modified (plastic) only correct 25 times and the predicate (glass) only correct 20 times, with neither correct 0 times gives a p-value of 0.456, indicating that there is no significant difference favoring the modified device contained in the plastic bottle.

Antimicrobial Neutralization Capability

Eleven drugs representative of their classes were evaluated at the MIC level of selected strains to demonstrate equivalent performance of the modified device to the predicate device. There was no statistically significant difference in recovery between the modified and predicate devices observed during this evaluation (McNemar's test p-value = 1.000). A total of 51 paired sets of medium were tested. The predicate device detected positive 48 times (94%) and the modified device detected positive 49 times (96%). The drugs evaluated were: Meropenem, Gentamicin, Ciprofloxacin, Clindamycin, Vancomycin, Cefazolin, Cefoxitin, Cefotaxime, Cefepime, Piperacillin/Tazobactam and Fluconazole.

Reproducibility

The modified device was evaluated for reproducibility across three lots in the Time to Detection and Percent Recovery studies. There was no statistical difference observed across lots comparison.