DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 9, 2017

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

Re: K161810
Trade/Device Name: BD BACTEC Standard/10 Aerobic/F Culture Vials
Soybean-Casein Digest Broth in a Plastic Vial
Regulation Number: 21 CFR 866.2560
Regulation Name: Microbial growth monitor
Regulatory Class: I
Product Code: MDB
Dated: January 16, 2017
Received: January 18, 2017

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 -A

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 Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration **Indications for Use**	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 *See PRA Statement below.*

510(k) Number *(if known)*
K161810

Device Name
BD BACTEC™ Standard/10 Aerobic/F Culture Vials
Soybean-Casein Digest Broth in a Plastic Vial

Indications for Use *(Describe)*

BD BACTEC™ Standard/10 Aerobic/F culture vials (enriched Soybean-Casein Digest broth with CO_2) are for aerobic blood cultures. Principal use is with the **BD BACTEC** fluorescent series instruments for the qualitative culture and recovery of aerobic microorganisms (bacteria and yeast) from blood.

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

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510(k) Summary

BD BACTEC™ Standard/10 Aerobic/F Culture Vials
Soybean-Casein Digest Broth in a Plastic Vial

Summary Preparation Date:

6/30/2016

Submitted by: Ashanti C. Brown

BD Diagnostic Systems
Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Contact:
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Regulatory Specialist

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Proprietary Names:

BD BACTEC™ Standard/10 Aerobic/F Culture Vials
Soybean-Casein Digest Broth in a Plastic Vial

Common Names:

Aerobic blood culture medium

Regulatory Information

Classification: 21 CFR§866.2560, Class I

Product Code(s): MDB

Predicate Device
BD BACTEC™ Standard/10 Aerobic/F Culture Vial (K954921)

Device Establishment
Becton Dickinson Caribe Ltd.
Vicks Drive Lot #6
Cayey, PR 00737
Registration Number: 2647876

Intended Use

BD BACTEC™ Standard/10 Aerobic/F culture vials (enriched Soybean-Casein Digest broth with CO_2) are for aerobic blood cultures. Principal use is with the **BD BACTEC** fluorescent series instruments for the qualitative culture and recovery of aerobic microorganisms (bacteria and yeast) from blood.

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 CO_2 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 CO_2 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 Standard/10 Aerobic/F Culture Vials (plastic) differs from the BD BACTEC Standard/10 Aerobic/F Culture Vials (glass) 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.

BD BACTEC Standard/10 Aerobic/F Culture Vials (plastic) is similar to the BD BACTEC Standard/10 Aerobic/F Culture Vials (plastic) 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 (± 1.5° 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 3.0-10.0 mL of blood.
- Both devices utilize the same formulation of enriched soybean casein digest broth as the growth medium.

Analytical Studies

Instrument Time to Detection

A total of 682 paired sets recovered organisms in both the modified and predicate devices. The estimated median TTD difference for the 682 positive sets is -1.084 hour, favoring the modified device. The modified device meets the acceptance criteria of "No relevant difference from current product." 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

Recovery was equivalent between the modified and predicate devices. A total of 984 paired sets were evaluated in the Percent Recovery comparison. Of those, 948 paired sets were positive in both the modified and predicate devices at inoculum level 10-100CFU. Four cultures grew and detected in the predicate device only. Nine cultures grew and detected in the modified device only. There were twenty-three paired sets that were not detected in either the modified or predicate devices. The McNemar chi-square analysis of 0.2673 indicates no relevant difference between devices.

Microbial Detection Limit

A total of 360 paired sets were tested; 207 of the inoculated cultures grew and detected in both the modified and predicate devices. Thirty-seven cultures grew and detected in the predicate device only. Forty-eight cultures grew and detected in the modified device only. There were sixty-eight paired sets that were not detected in either the modified or predicate devices. The McNemar chi-square analysis of 0.2781 indicates no relevant difference between the modified and predicate devices.

False Positive Rate

A total of 240 paired sets were used to execute this study. The 240 paired sets were comprised of 40 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 positives in the modified device. There was one anomaly observed in the predicate device. This device was positive in the BACTEC FX instrument at 16.98 hours. The vials utilized in this study are inoculated with fresh blood, no organisms were added to the bottle; the vial found to be false positive had an organism present due to contamination during the inoculation process. A statistical analysis could not be performed due insufficient failures within the test.

False Negative Rate

A total of 91 paired sets were instrument negative. Additionally, there were 41 modified devices and 57 predicate devices that were instrument negative. All of the instrument negatives were evaluated by terminal subculture. There were34 false negatives (instrument negative subculture positive). Of the 34 false negatives 18 were observed in the predicate device and 16 were observed in the modified device. The McNemar chi-square analysis of the data indicates that there was no statistically significant difference in recovery (p=0.8638) between the modified and predicate devices.

Reproducibility

The modified device was evaluated for reproducibility across lots in terms of time to detection and recovery. There was no statistical difference in time to detection and recovery observed between lot comparisons.