March 16, 2018

Becton Dickinson and Company
Ashanti Brown
Regulatory Affairs Specialist
7 Loveton Circle MC:694
Sparks, Maryland 21152

Re: K173873
Trade/Device Name: BD BACTEC Peds Plus/F Culture Vials Soybean-Casein Digest Broth with Resins in a Plastic Vial
Regulation Number: 21 CFR 866.2560
Regulation Name: Microbial growth monitor
Regulatory Class: Class I
Product Code: MDB
Dated: December 19, 2017
Received: December 20, 2017

Dear Ashanti 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 Part 801 and Part 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173873

Device Name
BD BACTEC™ Peds Plus™/F Culture Vials Soybean-Casein Digest Broth with Resins in a Plastic Vial

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 BD 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 3 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.

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510(k) Summary
BD BACTEC™ Peds Plus™/F Culture Vials Soybean-Casein Digest Broth with Resins in a Plastic Vial
Summary Preparation Date:

12/11/2017

Submitted by:
BD Diagnostic Systems
Becton Dickinson and Company
7 LOVETON CIRCLE
SPARKS, MD 21152

Contact:
Ashanti Brown
Regulatory Affairs Specialist

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Email: ashanti.brown@bd.com

Proprietary Names:
For the media: BD BACTEC™ Peds Plus™/F Culture Vials Soybean-Casein Digest Broth with Resins in a Plastic Vial

Common Names:
For the instrument: BD BACTEC™ Instrument Syste*m*
For the media: BD BACTEC™ Peds Plus™/F (in Plastic)

Regulatory Information
Regulation section: 21 CFR §866.2560

Classification: Class I

Product Code(s): MDB

Predicate Device

BD BACTEC™ Peds Plus™/F Culture Vials Soybean-Casein Digest Broth with Resins (K954927)

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

Performance Standards
No performance standards have been developed under Section 514 of the Food, Drug and Cosmetic Act.

Intended Use of Predicate

BD BACTEC Peds Plus™/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 (mainly bacteria and yeast) from pediatric and other blood specimens which are generally less than 3 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 CO_2 produced by the growth of microorganisms. The sensor's fluorescence measurement is detected at regular intervals to determine the change in CO2 present in the system. A positive reading indicates the presumptive presence of viable microorganisms in the vial. **BD BACTEC Peds Plus™**/F culture vial detection is limited to microorganisms that will grow in a particular type of medium.

Analytical Performance

The Analytical Performance inclusive of the antimicrobial neutralization capability study demonstrate substantial equivalence[1] of the test device (plastic) to the control device (glass) when inoculated with 3mL of blood at 0-1, 1-10, and 10-100 CFU; supporting the amendment of the blood volumes listed in the package insert, amending blood volumes on vial labeling, updating language surrounding the *Haemophilus* species, and removing the Fluconazole limitation listed in current package insert.

Summary of Analytical Performance

Instrument Time to Detection

A total of 672 paired sets were evaluated. Of these, 596 paired sets were positive in both the test and control devices. The Wilcoxon estimated median TTD difference for the 596 positive sets was approximately 30 minutes, favoring the test device. There is a statistically detectable difference in the TTD in the test device compared to control device. This median difference in TTD is <10% and is therefore determined not clinically relevant.

Percent Recovery

Of the 672 paired sets evaluated in the Instrument Time to Detection comparison, 492 paired sets (10-100 CFU) were evaluated for Percent Recovery. Both the test and control devices were positive in all of the 492 paired sets. McNemar p-value could not be calculated because there are no recovery failures in the control or test devices. There was no difference from the control.

Microbial Detection Limit

Of the 672 paired sets evaluated in the Instrument Time to Detection comparison a total of 180 paired sets (0-1, 1-10 CFU) were evaluated for microbial detection limit. Of these, 104 grew and detected in both the test and control devices. Twenty three were positive in the control device only. Nineteen were positive in the test device only. There were thirty-four paired sets that were negative in both the test and control devices. The McNemar chi-square analysis of the data indicates that there was no statistically significant difference in recovery (p=0.644) between the test and control devices.

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[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.

False Negative Rate
There were no false negatives observed in either the control or test device.

Antimicrobial Neutralization
One drug representative of its class was evaluated at the MIC level for the selected strains to demonstrate equivalent performance of the test device to the control device. There was no statistically significant difference in recovery between the test and control devices observed during this evaluation; because recovery was the same in the test and control devices p-value could not be determined.