September 21, 2018

Becton,Dickinson and Company
Monica Giguere
Regulatory Affairs Project Manager
7 Loveton Circle MC 694
Sparks, Maryland 21152

Re: K181665
Trade/Device Name: BD Phoenix Automated Microbiology System - BD Phoenix CPO detect - GN
Regulation Number: 21 CFR 866.1645
Regulation Name: Fully automated short-term incubation cycle antimicrobial susceptibility system
Regulatory Class: Class II
Product Code: LON
Dated: June 19, 2018
Received: June 25, 2018

Dear Monica Giguere:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Steven R. Gitterman -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)*
K181665

Device Name
BD Phoenix™ Automated Microbiology System - BD Phoenix™ CPO detect - GN

Indications for Use *(Describe)*
The BD Phoenix Automated Microbiology System is intended for the in vitro rapid identification (ID) and quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of Gram Negative aerobic and facultative anaerobic bacteria belonging to the family Enterobacteriaceae and non-Enterobacteriaceae.

BD Phoenix CPO detect is a qualitative confirmatory test that uses a growth-based algorithm intended to phenotypically detect carbapenemase-production in Enterobacteriaceae, Pseudomonas aeruginosa, and Acinetobacter baumannii on Gram-negative ID/AST or AST only Phoenix panels. The test also provides the Ambler classification (Class A, Class B and Class D) of the carbapenemase produced. One of three test configurations are available per panel for carbapenemase detection with/without Ambler classification for the target organism groups. BD Phoenix CPO detect does not report multiple classes of carbapenemases from a single isolate.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

SUBMITTED BY: Becton, Dickinson and Company
7 Loveton Circle MC 694
Sparks, MD 21152
Phone: 410-316-4827
Fax: 410-316-4499

CONTACT NAME: Monica Giguere, RAC
Regulatory Affairs Project Manager

DATE PREPARED: June 19, 2018

DEVICE TRADE NAME: BD Phoenix™ Automated Microbiology System –
BD Phoenix™ CPO detect - GN

DEVICE COMMON NAME: Antimicrobial susceptibility test system-short incubation

DEVICE CLASSIFICATION: 21 CFR 866.1645
Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System.
(Product Code LON)

PREDICATE DEVICES: BD Phoenix™ Automated Microbiology System – GN
BD Phoenix™ Confirmatory ESBL Test

INTENDED USE: The BD Phoenix Automated Microbiology System is intended for the *in vitro* rapid identification (ID) and quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of Gram Negative aerobic and facultative anaerobic bacteria belonging to the family *Enterobacteriaceae* and non-*Enterobacteriaceae*.

DEVICE DESCRIPTION:

The BD Phoenix Automated Microbiology System (Phoenix System) is an automated system for the rapid identification (ID) and antimicrobial susceptibility testing (AST) of clinically relevant bacterial isolates. The system includes the following components:

- BD Phoenix instrument and software.
- BD Phoenix panels containing biochemicals for organism ID testing and antimicrobial agents for AST determinations.
- BD Phoenix ID Broth used for performing ID tests and preparing AST Broth inoculum.
- BD Phoenix AST Broth used for performing AST tests only.
- BD Phoenix AST Indicator solution added to the AST Broth to aid in bacterial growth determination.

The Phoenix panel is a sealed and self-inoculating molded polystyrene tray with 136 micro-wells containing dried reagents. Organisms for susceptibility testing must be a pure culture and preliminarily identified as a Gram-negative or Gram-positive isolate. Phoenix panels are inoculated with a specified organism density and placed into the instrument. Inoculum for use with the Phoenix system may be prepared either manually or may be automated using the BD Phoenix™ AP System.

The Phoenix AST method is a broth based microdilution test. The Phoenix System utilizes a redox indicator for the detection of organism growth in the presence of an antimicrobial agent. Measurements of changes to the indicator as well as bacterial turbidity are used in the determination of bacterial growth. Each AST panel configuration contains several antimicrobial agents with a wide range of two-fold doubling dilution concentrations.

The instrument houses the panels where they are continuously incubated at a nominal temperature of 35° ± 1°C. The instrument takes readings of the panels every 20 minutes. The readings are interpreted to give an identification of the isolate, minimum inhibitory concentration (MIC) values and category interpretations, S, I, R or N (susceptible, intermediate, resistant or not susceptible.

DEVICE COMPARISON:

The BD Phoenix CPO detect test and the predicate device (BD Phoenix™ Confirmatory ESBL Test, K033458, May 28, 2004) have the following similarities:

- Both tests are included on BD Phoenix™ GN panels
- Both use isolated colonies taken from culture
- Both are prepared from colonies using the direct inoculation method
- Both use the same inoculum concentration
- Both tests use automated growth-based technology
- Both incubate for <16 hours

The BD Phoenix CPO detect test differs from the predicate device in the following ways:

- BD Phoenix™ CPO detect is a qualitative confirmatory growth-based test intended to phenotypically detect carbapenemase-production in *Enterobacteriaceae, Pseudomonas aeruginosa*, and *Acinetobacter baumannii.* The test also provides the Ambler classification of the carbapenemase produced. The BD Phoenix™ Confirmatory ESBL Test is a confirmatory test for the detection of organisms that produce extended spectrum β-lactamase (ESBL) in *Escherichia coli, Klebsiella pneumoniae* and *Klebsiella oxytoca*.

- CPO detect includes set concentrations of meropenem, doripenem, temocillin, and cloxacillin alone and in combination with various chelators and beta- lactamase inhibitors used in a decision tree. BD Phoenix ESBL test includes set concentrations of Ceftriaxone, Cefotaxime, Ceftazidime plus screening antibiotics used in a decision tree.

SUMMARY OF SUBSTANTIAL EQUIVALENCE TESTING:

The BD Phoenix™ Automated Microbiology System has demonstrated substantially equivalent performance when compared to the reference method. The system has been evaluated as defined in the FDA guidance document, "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA", August 28, 2009. Shelf life (stability data) for the test is being collected and will be maintained on file at BD as indicated in the guidance document.

Site Reproducibility

Intra- and inter-site reproducibility of this antimicrobial agent in the BD Phoenix System was evaluated at three sites using a panel of Gram-negative isolates. Each site tested the isolates in triplicate on three different days using Gram Negative Phoenix panels containing CPO detect and associated reagents. The results of the study demonstrate that for the CPO detect test and the Gram-negative organisms tested there was an overall reproducibility across test sites of greater than 95% agreement when compared to the expected result.

Clinical Studies

Clinical fresh and stock isolates were tested across multiple sites to demonstrate the performance of the BD Phoenix™ CPO detect test with multiple lots of BD Phoenix Gram Negative panels. Challenge isolates obtained from domestic and international sources were also tested at these sites. Phoenix System results for Challenge set isolates were compared to the expected results. Phoenix System results for clinical isolates were compared to the results obtained from the composite reference method. Phenotypic testing to detect the presence of carbapenemase expression included the CLSI-recommended modified Carbapenem Inactivation Method (mCIM) assay and carbapenem MIC results. Genotypic testing was used to assign the Ambler classification of the enzyme based on detection of gene or genes using multiplex PCR.

Accuracy of the CPO detect test to detect carbapenemase producing organisms was measured by calculating the number of false positive and false negative results. The performance for carbapenemase classification as Ambler Class A, Class B, or Class D was evaluated using positive percent agreement (PPA) and negative percent agreement (NPA).

The following tables summarize the performance for Clinical and Challenge isolates tested in this study.

Performance of BD Phoenix™ Automated Microbiology System for Gram-negative Organisms

	Total	TP	FN	TN	FP	PPA	NPA
BD Phoenix™ CPO detect Detection of carbapenemase	1452	476	10	932	34	97.9%	96.5%

BD Phoenix™ CPO detect: Carbapenemase Classification 9 Well Configuration

	N=1357*	N=1452**
Class A	Positive Percent Agreement = 122/128 = 95.3%	Positive Percent Agreement = 123/147 = 83.7%
	Negative Percent Agreement = 1221/1229 = 99.3%	Negative Percent Agreement = 1290/1305 = 98.9%
Class B	Positive Percent Agreement = 126/134 = 94.0%	Positive Percent Agreement = 128/168 = 76.2%
	Negative Percent Agreement = 1205/1223 = 98.5%	Negative Percent Agreement = 1265/1284 = 98.5%
Class D	Positive Percent Agreement = 134/141 = 95.0%	Positive Percent Agreement = 135/157 = 86.0%
	Negative Percent Agreement = 1208/1216 = 99.3%	Negative Percent Agreement = 1282/1295 = 99.0%

*****Unclassified isolates in either the Phoenix or reference system are not included in these calculations
**All isolates are included in these performance calculations. Positive Percent Agreement errors are CPO detect positives with an incorrect or incomplete Ambler classification, CPO detect positives with no Ambler classification, or negative CPO detect results.

BD Phoenix™ CPO detect: Carbapenemase Classification* 6 Well Configuration

	N = 1039*	N = 1099**
Class A	Positive Percent Agreement = 106/112 = 94.6%	Positive Percent Agreement = 107/128 = 83.6%
	Negative Percent Agreement = 927/927 = 100.0%	Negative Percent Agreement = 964/971 = 99.3%
Class B	Positive Percent Agreement = 81/84 = 96.4%	Positive Percent Agreement = 82/108 = 75.9%
	Negative Percent Agreement = 942/955 = 98.6%	Negative Percent Agreement = 978/991 = 98.7%
Class D	Positive Percent Agreement = 97/98 = 99.0%	Positive Percent Agreement = 97/105 = 92.4%
	Negative Percent Agreement = 938/941 = 99.7%	Negative Percent Agreement = 991/994 = 99.7%

*****Unclassified isolates in either the Phoenix or reference system are not included in these calculations
**All isolates are included in these performance calculations. Positive Percent Agreement errors are CPO detect positives with an incorrect or incomplete Ambler classification, CPO detect positives with no Ambler classification, or negative CPO detect results.

Conclusions Drawn from Substantial Equivalence Studies

The BD Phoenix™ CPO detect test is substantially equivalent to the Confirmatory ESBL test on the BD Phoenix™ Automated Microbiology System (K033458, May 28, 2004) which is a legally marketed device for the antimicrobial susceptibility testing of bacteria. The BD CPO detect test and the BD Phoenix™ Confirmatory ESBL test both determine bacterial resistance using automated growth-based technology using bacterial colonies from pure culture. The performance of CPO detect was evaluated in a multi-site study utilizing a composite reference method combining phenotypic and genotypic testing. The results of the study demonstrated that the performance of the CPO detect test is substantially equivalent to the predicate device.