DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 24, 2014

BECTON, DICKINSON AND COMPANY
MONICA GIGUERE
REGULATORY AFFAIRS PROJECT MANAGER
7 LOVETON CIRCLE, MC 694
SPARKS MD 21152

Re: K142170
Trade/Device Name: BD Phoenix Automated Microbiology System - Tigecycline (0.0313-4µg/ml) GP
Regulation Number: 21 CFR 866.1645
Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System
Regulatory Class: II
Product Code: LON
Dated: August 4, 2014
Received: August 7, 2014

Dear Ms. Giguere:

This letter corrects our substantially equivalent letter of October 28, 2014.

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,

Uwe Scherf -S for

Sally Hojvat, M.Sc., PhD.
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K142170

Device Name

BD Phoenix™ Automated Microbiology System for use with the antimicrobial agent **Tigecycline (0.0313-4 µg/mL)** – Gram-positive ID/AST or AST only Phoenix Panels.

Indications for Use *(Describe)*

The BD Phoenix™ Automated Microbiology System is intended for *in vitro* quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of most Gram-negative aerobic and facultative anaerobic bacteria isolates from pure culture for *Enterobacteriaceae* and Non-*Enterobacteriaceae* and most Gram-positive bacteria isolates from pure culture belonging to the genera *Staphylococcus*, *Enterococcus* and *Streptococcus*.

This premarket notification is for the addition of the antimicrobial agent **tigecycline** at concentrations of **0.0313-4 µg/mL** to Gram-positive ID/AST or AST only Phoenix panels. **Tigecycline** has been shown to be active *in vitro* against most strains of microorganisms listed below, as described in the FDA-approved package insert for this antimicrobial agent.

Active *In Vitro* and in Clinical Infections Against:
Enterococcus faecalis (vancomycin-susceptible isolates)
Staphylococcus aureus (methicillin-susceptible and -resistant isolates)

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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"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 Sparks, MD 21152 Phone: 410-316-4287 Fax: 410-316-4188
CONTACT NAME:	Monica E. Giguere, RAC Regulatory Affairs Project Manager
DATE PREPARED:	August 4, 2014
DEVICE TRADE NAME:	BD Phoenix™ Automated Microbiology System – Tigecycline (0.0313-4 µg/mL)
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:	VITEK® System (PMA No. N50510)
INTENDED USE:	The BD Phoenix™ Automated Microbiology System is intended for *in vitro* quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of most Gram-negative aerobic and facultative anaerobic bacteria isolates from pure culture for *Enterobacteriaceae* and Non-*Enterobacteriaceae* and most Gram-positive bacteria isolates from pure culture belonging to the genera *Staphylococcus*, *Enterococcus* and *Streptococcus*.

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™ Automated Microbiology System demonstrated substantially equivalent performance for inoculum prepared manually and inoculum prepared with the BD Phoenix™ AP instrument when compared with the CLSI reference broth microdilution method. This premarket notification provides data supporting the use of the BD Phoenix™ Automated Microbiology System Gram positive ID/AST or AST only Phoenix panels with this antimicrobial agent.

SUMMARY OF SUBSTANTIAL EQUIVALENCE TESTING:

The BD Phoenix™ Automated Microbiology System has demonstrated substantially equivalent performance when compared to the CLSI reference broth microdilution method (AST panels prepared according to CLSI M7). 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 drug 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-positive isolates. Each site tested the isolates in triplicate on three different days using one lot of Gram Positive Phoenix panels containing this antimicrobial agent and associated reagents.

The results of the study demonstrate that for this antimicrobial agent and the Gram-positive organisms tested there was an overall reproducibility across test sites of greater than 95% (+/- 1 dilution) agreement when compared to the test mode.

Clinical Studies

Clinical, stock and challenge isolates were tested across multiple geographically diverse sites across the United States to demonstrate the performance of the Phoenix antimicrobial susceptibility test with a Gram Positive Phoenix Panel containing this antimicrobial agent. 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 CLSI reference broth microdilution method.

The performance of the Phoenix System was assessed by calculating Essential Agreement (EA) and Category Agreement (CA) to expected/reference results for all isolates tested. Essential Agreement (EA) occurs when the BD Phoenix™ Automated Microbiology System agrees exactly or within ± one two-fold dilution to the reference result. Category Agreement (CA) occurs when the BD Phoenix™ Automated Microbiology System agrees with the reference method with respect to the FDA categorical interpretive criteria (susceptible, intermediate, resistant or not susceptible).

The following table summarizes the performance for Clinical and Challenge isolates tested in this study.

Performance of BD Phoenix System for Gram-Positive Organisms by Tigecycline

Antimicrobial	Concentration	EA (n)	EA (%)	CA (n)	CA (%)
Tigecycline	0.0313-4 µg/mL	1021	98.0	1021	100.0

Conclusions Drawn from Substantial Equivalence Studies

The data collected from the substantial equivalence studies demonstrate that testing on the BD Phoenix™ Automated Microbiology System with this antimicrobial agent is substantially equivalent as outlined in the FDA guidance document, "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA", August 28, 2009. Technological characteristics of this system are substantially equivalent to those used in the VITEK® system, which received approval by the FDA under PMA number N50510.