510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K251713

B Applicant

Becton, Dickinson and Company

C Proprietary and Established Names

BD Phoenix Automated Microbiology System - GN Eravacycline (0.125-2 µg/mL)

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LON	Class II	21 CFR 866.1645 - Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

Addition of eravacycline to the BD Phoenix Gram negative ID/AST only Phoenix panels

B Measurand:

Eravacycline 0.125-2 µg/mL

C Type of Test:

Antimicrobial susceptibility test (quantitative) colorimetric, oxidation-reduction, growth based

III Intended Use/Indications for Use:

A Intended Use(s):

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 order Enterobacterales and non-Enterobacterales.

B Indication(s) for 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 Enterobacterales and Non-Enterobacterales and most Gram-positive bacteria isolates from pure culture belonging to the genera *Staphylococcus*, *Enterococcus*, and *Streptococcus*.

This premarket notification is for the BD Phoenix Automated Microbiology System with Eravacycline at a concentration of 0.125-2 µg/mL. Testing is indicated for Enterobacterales as recognized by the FDA Susceptibility Test Interpretive Criteria (STIC).

The BD Phoenix Automated Microbiology System - GN Eravacycline (0.125-2 µg/mL) has demonstrated acceptable performance with the following organisms:

Enterobacterales (*Citrobacter amalonaticus*, *Citrobacter braakii*, *Citrobacter farmeri*, *Citrobacter freundii*, *Citrobacter koseri*, *Citrobacter youngae*, *Enterobacter cloacae*, *Escherichia coli*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, and *Klebsiella pneumoniae*)

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

The ability of the BD Phoenix AST system to detect non-susceptibility to eravacycline in the following species is unknown because non-susceptible strains were not available or insufficient at the time of comparative testing: C. freundii, C. koseri, C. amalonaticus, C. braakii, C. farmeri, C. youngae and K. oxytoca.

For Enterobacter cloacae, two of the five potential very major errors were within essential agreement when compared to the reference method. Due to the susceptible-only category, the potential very major error rate was adjusted to 15.8% (3/19). If deemed necessary for patient care, confirmatory testing with an alternate method could be performed for this organism before reporting Phoenix MIC results of 0.25 µg/mL.

For Klebsiella pneumoniae, eight of the eleven potential very major errors were within essential agreement when compared to the reference method. Due to the susceptible-only category, the potential very major error rate was adjusted to 8.1% (3/37). If deemed necessary for patient care, confirmatory testing with an alternate method could be performed for this organism before reporting Phoenix MIC results of 0.25 µg/mL.

For Klebsiella aerogenes, neither of the two potential very major errors were within essential agreement when compared to the reference method. Due to the susceptible-only category, the potential very major error rate was adjusted to 20% (2/10). If deemed necessary for patient care,

confirmatory testing with an alternate method could be performed for this organism before reporting Phoenix MIC results of 0.25 µg/mL.

For Escherichia coli, none of the three potential very major errors were within essential agreement when compared to the reference method. Due to the susceptible-only category, the potential very major error rate was not adjusted and remained at 100% (3/3). These errors occurred with a very low percentage of the total isolates evaluated (3/376, 0.8%). If deemed necessary for patient care, confirmatory testing with an alternate method could be performed for this organism before reporting Phoenix MIC results of ≤0.125 µg/mL or 0.25 µg/mL.

D Special Instrument Requirements:

BD Phoenix Automated Microbiology System and software (V2.20.0.0 or higher)
PhoenixSpec Nephelometer
BD Phoenix AP Instrument

IV Device/System Characteristics:

A Device Description:

This submission is for a single drug in the Gram-negative ID/AST or AST only panel. The ID portion of the ID/AST combination panel was not subject for review in this submission.

The Phoenix AST method is a broth-based microdilution test. The Phoenix panel is a sealed and self-inoculating molded polystyrene tray with 136 micro-wells containing dried reagents. The ID/AST combination panel includes an ID side (51 wells) with dried substrates for bacterial identification and an AST side (85 wells). The AST panel contains a wide range of two-fold doubling dilution concentrations of antimicrobial agents and growth and fluorescent controls at appropriate well locations. The AST panel does not include wells for isolate identification. The Phoenix System utilizes a redox indicator for the detection of organism growth in the presence of an antimicrobial agent. The organism to be tested must be a pure culture and be preliminarily identified as gram-positive or gram-negative. Colonies are then suspended in ID broth and equated to a 0.5 McFarland suspension using a nephelometer device. A further dilution is made into AST broth (a cation-adjusted formulation of Mueller-Hinton broth containing 0.010% Tween 80), to which the redox-buffered oxidation-reduction AST indicator solution is added producing a blue color in the wells. The concentration of organisms in the final AST broth suspension is approximately 5 X 10^5 CFU/mL.

The Phoenix AST Broth is poured into the inoculation port of the AST panel and the inoculum flows into the panel, filling panel wells. Polyethylene caps are applied to seal the inoculation ports. An air admittance port is located in the panel lid to ensure adequate oxygen tension in the panel for the duration of the test. Inoculated panels are barcode scanned and loaded into the BD Phoenix Automated Microbiology System instrument where panels are continuously incubated at 35°C ± 1°C.

Continuous measurements of changes to the indicator as well as bacterial turbidity are used in the determination of bacterial growth. The instrument takes readings every 20 minutes. Organisms growing in the presence of a given antimicrobial agent reduce the indicator (changing

it to a pink color). This signals organism growth and resistance to that antimicrobial agent. Organisms killed or inhibited by the antimicrobial agent do not cause reduction of the indicator and therefore do not produce a color change. The Phoenix instrument reads and records the results of the antimicrobial tests contained in the panel and interprets the reactions (based on the organism identification) to give a minimal inhibitory concentration (MIC) value and category interpretations (susceptible, intermediate, resistant, or not susceptible). AST results are available within 16 hours. This is an auto read result; no manual readings are possible with this system. Additional comments concerning specific organism/antimicrobial combinations are provided from the software-driven expert system (BDXpert), using rules derived from CLSI documentation and/or the FDA-approved drug labeling.

B Principle of Operation:

The BD Phoenix Automated Microbiology System is a broth-based microdilution method that utilizes a redox indicator (colorimetric oxidation-reduction) to enhance detection of organism growth. The MIC is determined by comparing growth in wells containing serial two-fold dilutions of an antibiotic to the growth in "growth control wells" that contain no antibiotic.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Bd Phoenix Automated Microbiology System - GN Tigecycline (0.25-16 µg/mL)

B Predicate 510(k) Number(s):
K132909

C Comparison with Predicate(s):

Device & Predicate Device(s):	Device K251713	Predicate K132909
Device Trade Name	BD Phoenix Automated Microbiology System – GN Eravacycline (0.125-2 µg/mL)	BD Phoenix Automated Microbiology System – GN Tigecycline (0.25-16 µg/mL)
General Device Characteristic Similarities		
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 order Enterobacterales and non-Enterobacterales.	Same

Device & Predicate Device(s):	Device K251713	Predicate K132909
Source of Microorganisms for Testing	Bacterial colonies isolated from culture	Same
Technology	Automated growth-based detection	Same
Methodology	Determination of MIC using serial two-fold dilution format	Same
Read Method	Automated	Same
Inoculation Methods	Manual: BD PhoenixSpec nephelometer Automated: BD Phoenix AP Instrument	Same
Incubation Time	<16 hours	Same
General Device Characteristic Differences		
Antimicrobial Agent	Eravacycline	Tigecycline
Reporting Range	0.125-2 µg/mL	0.25-16 µg/mL
Result Reported	Report results as minimum inhibitory concentration (MIC) and categorical interpretation (S, NS)	Report results as minimum inhibitory concentration (MIC) and categorical interpretation (S, I, R)
Tested Organisms	*Citrobacter amalonaticus* *Citrobacter braakii* *Citrobacter farmeri* *Citrobacter freundii* *Citrobacter koseri* *Citrobacter youngae* *Enterobacter cloacae* *Escherichia coli* *Klebsiella aerogenes* *Klebsiella oxytoca* *Klebsiella pneumoniae*	*Enterobacter cloacae* *Escherichia coli* *Klebsiella pneumoniae* *Klebsiella oxytoca* *Citrobacter freundii* *Citrobacter koseri* *Enterobacter aerogenes* *Serratia marcescens*

VI Standards/Guidance Documents Referenced:

1. *Guidance for Industry and FDA, Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems*, August 28, 2009.

2. CLSI. *Performance Standards for Antimicrobial Susceptibility Testing*. 35th ed. CLSI supplement M100. Clinical and Laboratory Standards Institute; 2025.

3. CLSI. *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically*. 11th ed. CLSI supplement M07. Clinical Laboratory Standards Institute; 2018.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Reproducibility of the BD Phoenix Automated Microbiology System - GN Eravacycline (0.125-2 µg/mL) was conducted at three sites using a panel of 12 non-fastidious gram-negative organisms with on-scale results. The isolates were tested at each site in triplicate over three different days using both inoculation methods (manual and BD Phoenix AP) resulting in 324 data points (12 strains x 3 replicates x 3 sites x 3 days = 324) for each inoculation method. The isolates tested in the reproducibility study included *Citrobacter freundii* (1), *Enterobacter cloacae* (5), *Klebsiella oxytoca* (1) and *Klebsiella pneumoniae* (5). The reproducibility was calculated based on MIC values falling within ±1 dilution of the mode value for each isolate. As all results were on-scale, there was no calculation of worst case scenario results. The best-case reproducibility was calculated as described in the AST Special Controls Guidance document. The reproducibility results were acceptable as shown in Table 1.

Table 1. Reproducibility for Eravacycline (0.125-2 µg/mL)

Inoculation Method	Best Case Reproducibility
Manual PhoenixSpec Nephelometer	100% (324/324)
Phoenix AP Instrument	100% (324/324)

2. Linearity:

Not applicable

3. Analytical Specificity/Interference:

Not applicable

4. Assay Reportable Range:

Not applicable

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Quality Control Testing:
The CLSI recommended QC organisms (*E. coli* ATCC 25922 and *P. aeruginosa* ATCC 27853) were tested a sufficient number of times (i.e., at least 20/site) at each of three testing sites. The strains were tested using both manual and Phoenix AP inoculation methods and read by the BD Phoenix instrument. Although the majority of QC results were off-scale, the expected range for *P. aeruginosa* ATCC 27853 was partially on-scale and the expected ranges of the two QC strains included values that span the reporting range. The results are summarized in Table 2. Results were acceptable for greater than 95% of tests performed using both inoculation methods.

Table 2. Quality Control Results - Eravacycline

Organism	Concentration (µg/mL)	Reference	BD Phoenix	
			Manual Inoculation (PhoenixSpec)	Phoenix AP Inoculation
E. coli ATCC 25922† Expected Range: 0.016-0.125 µg/mL	≤0.125	133	89	82
	0.25			
	0.5			
	1			
	2			
	>2			
P. aeruginosa ATCC 27853†† Expected Range: 2-16 µg/mL	≤0.125	3		
	0.25	1		
	0.5	1		
	1	4		
	2	12	33	20
	>2	111	55	62

†The lowest dilution of the BD Phoenix Automated Microbiology System – GN Eravacycline MIC range is ≤0.125 µg/mL. Obtaining this value was considered an indicator that the quality control test results were acceptable.

††The highest dilution of the BD Phoenix Automated Microbiology System – GN Eravacycline MIC range is >2 µg/mL. Obtaining this value was considered an indicator that the quality control test results were acceptable.

Inoculum Density Check:
The BD PhoenixSpec Nephelometer was used to prepare the inocula for testing of the clinical, challenge, reproducibility, and QC isolates. The same inoculum suspension was used for both the Phoenix System and the reference method testing. The BD Phoenix AP instrument was used to standardize the inocula for challenge, QC, and reproducibility isolates. Validation data for both the PhoenixSpec and the Phoenix AP instrument was provided and found to be acceptable.

Growth Failure Rate:
The growth failure rate for both inoculation methods was 0%.

Purity Check:
Purity check plates were performed on all isolates from each inoculum preparation. Results were only included for pure cultures.

6. Detection Limit:

   Not applicable

7. Assay Cut-Off:

   Not applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:

Results obtained with the BD Phoenix Automated Microbiology System - GN Eravacycline (0.125-2 µg/mL) panel were compared to results obtained with the CLSI frozen broth microdilution reference panel. Reference panels were prepared according to CLSI M07 guidelines. The range of dilutions evaluated with the reference panels was the same as that used for the BD Eravacycline panel. The BD Phoenix Spec Nephelometer, the primary inoculation method, was used to obtain a 0.50 – 0.60 McFarland for all challenge, clinical, QC, and reproducibility isolates. The BD Phoenix AP instrument, the secondary inoculation method, was used to test challenge, QC, and reproducibility isolates. It is designed to standardize the ID broth inoculum equivalent to the BD Phoenix Spec Nephelometer, add the preset amount of AST indicator broth to the AST broth tube, and transfer the required aliquot of ID broth inoculum to AST broth tubes.

Clinical:
Clinical testing was conducted at two external sites and one internal site using 626 (79.7%) fresh and 159 (20.3%) stock isolates for a total of 785 clinical isolates. These consisted of *Citrobacter freundii* (23 isolates), *Citrobacter koseri* (26 isolates), *Citrobacter amalonaticus* (3 isolates), *Citrobacter braakii* (4 isolates), *Citrobacter farmeri* (1 isolate), *Citrobacter youngae* (1 isolate), *Enterobacter cloacae* (60 isolates), *Escherichia coli* (359 isolates), *Klebsiella aerogenes* (57 isolates), *Klebsiella oxytoca* (51 isolates), and *Klebsiella pneumoniae* (200 isolates).

Challenge:
A total of 84 challenge isolates were evaluated at three U.S. sites using *Citrobacter freundii* (3 isolates), *Citrobacter koseri* (2 isolates), *Enterobacter cloacae* (21 isolates), *Escherichia coli* (17 isolates), *Klebsiella aerogenes* (4 isolates), *K. oxytoca* (3 isolates) and *Klebsiella pneumoniae* (34 isolates). Four (4) of the challenge isolates (two (2) *E. cloacae* and two (2) *K. pneumoniae* isolates) were only tested with the manual inoculation method.

A total of 71 non-susceptible strains of Enterobacterales were evaluated. No non-susceptible strains of the following species were evaluated: *C. freundii, C. amalonaticus*, *C. braakii*, *C. farmeri*, and *C. youngae*. Only one isolate each of *C. koseri* and *K. oxytoca* was non-susceptible. As a result, the following limitation was added to the device labeling:

> *The ability of the BD Phoenix AST system to detect non-susceptibility to eravacycline in the following species is unknown because non-susceptible strains were not available or insufficient at the time of comparative testing: C. freundii, C. koseri, C. amalonaticus*, *C. braakii*, *C. farmeri*, *C. youngae and K. oxytoca.*

In addition, since no interpretive category is defined other than "susceptible" for eravacycline, the following general statement in the device labeling applies:

> *For some organism/antimicrobial combinations, the absence or rare occurrence of resistant strains precludes defining any result categories other than susceptible. For strains yielding results suggestive of a nonsusceptible category, organism*

identification and antimicrobial susceptibility test results should be confirmed. Subsequently, the isolates should be saved and submitted to a reference laboratory that will confirm the result using the CLSI reference dilution method.

Results for clinical and challenge isolates were evaluated separately and combined. The performance of testing eravacycline using the manual inoculation method is illustrated in Table 3 below.

Table 3. Eravacycline (0.125-2 µg/mL) Results, Manual Inoculation

	Tot	EA No.	EA %	Eval Tot	Eval EA No.	Eval EA %	CA Tot	CA %	No. NS	No. S	min	maj	vmj
Enterobacterales [≤ 0.5 (S)]													
Clinical	785	769	98.0	348	332	95.4	768	97.8	41	744	NA	2	15
Challenge	84	81	96.4	55	52	94.6	76	90.5	30	54	NA	2	6
Combined	869	850	97.8	403	384	95.3	844	97.1	71	798	NA	4	21

EA - Essential Agreement
CA - Category Agreement
Eval – Evaluable isolates
NS – Non-Susceptible isolates
S – Susceptible isolates
NA – Not Applicable
min – Minor errors
maj – Major errors
vmj - Very Major errors

Essential Agreement (EA) occurs when there is agreement between the MIC result of the reference method and that of the BD Phoenix within plus or minus one serial two-fold dilution of the antibiotic. Evaluable results are those that are on scale for both the BD Phoenix and the reference method or those in which an off-scale result is at least two doubling dilutions from the on-scale result. Category Agreement (CA) occurs when the interpretation of the result of the reference method agrees exactly with the interpretation of the BD Phoenix.

For Enterobacterales using manual inoculation method, the combined clinical and challenge results (869 isolates) were acceptable at 97.8% and 97.1% for EA and CA respectively. There were four (4) potential major errors and 21 potential very major errors (Table 3). Since no interpretive category is defined other than "susceptible" for eravacycline for all organisms evaluated, isolates for which the MIC values are above the susceptible breakpoint are reported as non-susceptible. When categorical errors occur, these are considered potential errors. Additionally, due to the lack of a category other than "susceptible" for eravacycline when testing Enterobacterales, further analysis of the errors is performed, and adjustments are made by considering the MIC values where the errors occurred. All four (4) of the potential major errors had MIC values that were in essential agreement with the reference MIC value; therefore, the adjusted potential major error rate is 0% (0/798) and is acceptable. Ten (10) of the 21 potential very major errors had MIC values that were in essential agreement with the reference MIC values; therefore, the adjusted potential very major error rate is 15.5% (11/71).

When evaluating by individual species, three (3) adjusted potential very major errors were due to *E. cloacae* isolates (15.8% (3/19)); three (3) adjusted potential very major errors were due to *E. coli* isolates (100% (3/3)); two (2) adjusted potential very major errors were due to *K. aerogenes* (20% (2/10)); and three (3) adjusted potential very major errors were due to *K. pneumoniae* (8.1% (3/37)). Based on the total number of isolates evaluated in the clinical study, the high EA and CA performance for each species, and additional labeling mitigations, the performance was considered acceptable.

To address the high adjusted potential very major error rate with *E. cloacae*, *E. coli*, *K. aerogenes* and *K. pneumoniae*, the following limitations were added to the device labeling:

Enterobacter cloacae
For Enterobacter cloacae, two of the five potential very major errors were within essential agreement when compared to the reference method. Due to the susceptible-only category, the potential very major error rate was adjusted to 15.8% (3/19). If deemed necessary for patient care, confirmatory testing with an alternate method could be performed for this organism before reporting Phoenix MIC results of 0.25 µg/mL.

Escherichia coli
For Escherichia coli, none of the three potential very major errors were within essential agreement when compared to the reference method. Due to the susceptible-only category, the potential very major error rate was not adjusted and remained at 100% (3/3). These errors occurred with a very low percentage of the total isolates evaluated (3/376, 0.8%). If deemed necessary for patient care, confirmatory testing with an alternate method could be performed for this organism before reporting Phoenix MIC results of ≤0.125 µg/mL or 0.25 µg/mL.

Klebsiella pneumoniae
For Klebsiella pneumoniae, eight of the eleven potential very major errors were within essential agreement when compared to the reference method. Due to the susceptible-only category, the potential very major error rate was adjusted to 8.1% (3/37). If deemed necessary for patient care, confirmatory testing with an alternate method could be performed for this organism before reporting Phoenix MIC results of 0.25 µg/mL.

Klebsiella aerogenes
For Klebsiella aerogenes, neither of the two potential very major errors were within essential agreement when compared to the reference method. Due to the susceptible-only category, the potential very major error rate was adjusted to 20% (2/10). If deemed necessary for patient care, confirmatory testing with an alternate method could be performed for this organism before reporting Phoenix MIC results of 0.25 µg/mL.

The performance of testing eravacycline using the BD Phoenix AP inoculation method is illustrated in Table 4 below.

Table 4. Eravacycline (0.125-2 µg/mL) Results, Phoenix AP Inoculation

	Tot	EA No.	EA %	Eval Tot	Eval EA No.	Eval EA %	CA Tot	CA %	No. NS	No. S	min	maj	vmj
Enterobacterales [≤ 0.5 (S)]													
Challenge	80	78	97.5	48	46	95.8	74	92.5	22	58	NA	5	1

EA - Essential Agreement NS – Non-Susceptible isolates min – Minor errors

CA - Category Agreement	S – Susceptible isolates	maj – Major errors
Eval – Evaluable isolates	NA – Not Applicable	vmj - Very Major errors

Essential Agreement (EA) occurs when there is agreement between the MIC result of the reference method and that of the BD Phoenix within plus or minus one serial two-fold dilution of the antibiotic. Evaluable results are those that are on scale for both the BD Phoenix and the reference method or those in which an off-scale result is at least two doubling dilutions from the on-scale result. Category Agreement (CA) occurs when the interpretation of the result of the reference method agrees exactly with the interpretation of the BD Phoenix.

For Enterobacterales using the BD Phoenix AP inoculation method, the challenge results (80) were acceptable at 97.5% and 92.5% for EA and CA respectively. There were five potential major errors and one potential very major error (Table 4). Since no category is defined other than "susceptible" for eravacycline for all organisms evaluated, isolates for which the MIC values are above the susceptible breakpoint are reported as non-susceptible. When categorical errors occur, these are considered potential errors. Additionally, due to the lack of a category other than "susceptible" for eravacycline when testing Enterobacterales, further analysis of the errors is performed, and adjustments are made by considering the MIC values where the errors occurred. All five (5) of the potential major errors had MIC values that were in essential agreement with the reference MIC values; therefore, the adjusted potential major error rate is 0% (0/58) which is acceptable. The one potential very major error had an MIC value that was in essential agreement with the reference MIC value; therefore, the adjusted potential very major error rate is 0% (0/22) and is acceptable.

MIC Trending

A trending analysis was conducted using the combined data (clinical and challenge) obtained from the manual inoculation method. This trending calculation takes into account MIC values that are determined to be one or more doubling dilutions lower or higher than the reference method irrespective of whether the device MIC values are on-scale or not.

Organism groups or species for which the difference between the percentage of isolates with higher vs. lower readings was >30% and for which the confidence interval was determined to be statistically significant were considered to show evidence of trending. Trending that showed higher or lower MIC values compared to the reference is addressed in the labeling.

Evaluation of results for species within Enterobacterales with eravacycline using the manual inoculation method are summarized in Table 5. A trend toward lower MIC values was observed for *Citrobacter freundii, Citrobacter koseri,* and *Escherichia coli* when compared to the CLSI broth microdilution reference method.

To address the MIC trending, the following footnote was added to the device labeling:

> *BD Phoenix Eravacycline MIC values tended to be in exact agreement or at least one doubling dilution lower when testing Citrobacter freundii, Citrobacter koseri, and Escherichia coli compared to the reference broth microdilution method.*

Table 5. Trending of Eravacycline (0.125-2 µg/mL) Results with Manual Inoculation

Organism	Total Evaluable for Trending	≥ 1 Dilution Lower No. (%)	Exact No.	≥ 1 Dilution Higher No. (%)	Percent Difference (CI)	Trending Noted
Citrobacter freundii	22	11 (50.0)	10	1 (4.6)	-45% (-65%, -20)	Yes, Low
Citrobacter koseri	14	10 (71.4)	4	0 (0.0)	-71% (-88%, -38%)	Yes, Low
Enterobacter cloacae	78	24 (30.8)	49	5 (6.4)	-24% (-36%, -12%)	No
Escherichia coli	94	75 (79.8)	14	5 (5.3)	-74% (-82%, -63%)	Yes, Low
Klebsiella aerogenes	58	14 (24.1)	40	4 (6.9)	-17% (-30%, -4%)	No
Klebsiella oxytoca	34	9 (26.5)	12	13 (38.2)	12% (10%, 32%)	No
Klebsiella pneumoniae	227	40 (17.6)	162	25 (11.0)	-7% (-13%, 0%)	No

As required under 511A(2)(2)(B) of the Federal Food, Drug and Cosmetic Act, the following statement is added to the Precautions section of the device labeling:

Per the FDA-Recognized Susceptibility Test Interpretive Criteria website, the safety and efficacy of antimicrobial drugs for which antimicrobial susceptibility is tested by this AST device, may or may not have been established in adequate and well-controlled clinical trials for treating clinical infections due to microorganisms outside of those found in the indications and usage in the drug label. The clinical significance of susceptibility information in those instances is unknown. The approved labelling for specific antimicrobial drugs provides the uses for which the antimicrobial drug is approved.

2. Matrix Comparison:

   Not applicable

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable

2. Clinical Specificity:

   Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

Table 6. FDA-Recognized Interpretive Criteria for Eravacycline

Organisms	Minimum Inhibitory Concentrations (µg/mL)[a]		
	Susceptible	Intermediate	Resistant
Enterobacterales[b]	≤0.5	-	-

[a]According to the FDA STIC Webpage

[b] Clinical efficacy was shown for *Citrobacter freundii*, *Enterobacter cloacae*, *Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae.*

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

To support the implementation of changes to FDA-recognized susceptibility test interpretive criteria (i.e., breakpoints), this submission included a predetermined change control plan (PCCP) that was previously reviewed and accepted by FDA in submission K233986 cleared on March 15, 2024. This PCCP addresses future revisions to device labeling in response to breakpoint changes that are recognized on the FDA STIC webpage (https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm410971.htm). The PCCP outlined the specific procedures and acceptance criteria that BD intends to use to evaluate the BD Phoenix Automated Microbiology System – GN Eravacycline when revised breakpoints for eravacycline are published on the FDA STIC webpage. The PCCP included with the submission indicated that if specific criteria are met, BD will update the eravacycline device label to include (1) the new breakpoints, (2) an updated performance section after re-evaluation of data in this premarket notification with the new breakpoints, and (3) any new limitations as determined by their evaluation.