510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K233986

B Applicant

Becton, Dickinson and Company

C Proprietary and Established Names

BD Phoenix Automated Microbiology System - GN Ciprofloxacin (0.0156-4 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:

1. Reporting range extension of ciprofloxacin to the BD Phoenix Gram Negative ID/AST and AST only Phoenix panels from 0.25 – 4 µg/mL to 0.0156 – 4 µg/mL to accommodate the updated FDA-recognized breakpoints for *Salmonella* species as published in the FDA STIC website. The reporting range extension only applies to *Salmonella* species.

2. Update the BD Phoenix Gram negative ID/AST and AST only Phoenix panels (0.25 – 4 µg/mL) for the current reporting range to include updated FDA-recognized breakpoints for Enterobacterales and *Pseudomonas aeruginosa,* as published in the FDA STIC website.

3. Establish a Pre-Determined Change Control Plan (PCCP) to address future revisions to device labeling in response to breakpoint changes that are recognized on the FDA STIC webpage.

B Measurand:

Ciprofloxacin (0.0156–4 µg/mL), for *Salmonella* spp.
Ciprofloxacin (0.25–4 µg/mL), for Enterobacterales and *Pseudomonas aeruginosa*

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 family 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 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 BD Phoenix Automated Microbiology System with Ciprofloxacin at a concentration of 0.0156-4 µg/mL. Ciprofloxacin 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:

Citrobacter koseri
Citrobacter freundii
Enterobacter cloacae
Escherichia coli
Klebsiella pneumoniae
Morganella morganii
Proteus mirabilis
Proteus vulgaris
Providencia rettgeri
Providencia stuartii
Pseudomonas aeruginosa
Salmonella typhi
Serratia marscescens
Shigella boydii
Shigella dysenteriae
Shigella flexneri
Shigella sonnei

Active In Vitro but clinical significance is unknown:

Edwardsiella tarda
*Klebsiella aerogenes (*formerly *Enterobacter aerogenes)*
Klebsiella oxytoca
Salmonella enteritidis

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

Results for the following antimicrobic/organism combination(s) are suppressed from reporting by the BD Phoenix System:

- Ciprofloxacin: *Stenotrophomonas maltophilia*

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 range extension of a single antimicrobial cleared for use on BD Phoenix ID/AST or AST only panels. The ID portion of the ID/AST combination panel was not subject to 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 - Moxifloxacin-0.125-8 and Ciprofloxacin-0.25 - 4 µg/ml

B Predicate 510(k) Number(s):
K060217

C Comparison with Predicate(s):

Device & Predicate Device(s):	Device K233986	Predicate K060217
Device Trade Name	BD Phoenix Automated Microbiology System – GN Ciprofloxacin (0.0156-4 µg/mL)	BD Phoenix Automated Microbiology System – GN Ciprofloxacin (0.25 – 4 µg/mL)
General Device Characteristic Similarities		
Intended Use/Indications For Use	The BD Phoenix Automated Microbiology System is intended for the *in vitro* rapid identification (ID) and quantitative determination of antimicrobial susceptibility by	Same

Device & Predicate Device(s):	Device K233986	Predicate K060217
	minimal inhibitory concentration (MIC) of Gram Negative aerobic and facultative anaerobic bacteria belonging to the family Enterobacterales and non-Enterobacterales	
Antimicrobial Agent	Ciprofloxacin	Same
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
Result Reported	Report results as minimum inhibitory concentration (MIC) and categorical interpretation (S, I, R)	Same
Incubation Time	< 16 hours	Same
General Device Characteristic Differences		
Indicated Organisms	Active *In Vitro* and in Clinical Infections Against: *Citrobacter koseri* *Citrobacter freundii* *Enterobacter cloacae* *Escherichia coli* *Klebsiella pneumoniae* *Morganella morganii* *Proteus mirabilis* *Proteus vulgaris* *Providencia rettgeri* *Providencia stuartii* *Pseudomonas aeruginosa* *Salmonella typhi* *Serratia marscescens* *Shigella boydii* *Shigella dysenteriae* *Shigella flexneri* *Shigella sonnei* Active *In Vitro* but clinical significance is unknown: *Edwardsiella tarda* *Klebsiella aerogenes* (formerly *Enterobacter aerogenes*)	Gram negative aerobic and facultative anaerobic bacteria belonging to *Enterobacterales* and non – *Enterobacterales*

Device & Predicate Device(s):	Device K233986	Predicate K060217
	Klebsiella oxytoca *Salmonella enteritidis*	
Breakpoints	Enterobacterales: (S/I/R) ≤0.25 / 0.5 / ≥1 *P. aeruginosa:* (S/I/R) ≤0.5 / 1 / ≥2 *Salmonella* spp.: (S/I/R) ≤0.0625 / 0.125 – 0.5 / ≥ 1	Enterobacterales: (S/I/R) ≤1 / 2 / ≥4 *P. aeruginosa:* (S/I/R) ≤1 / 2 / ≥4 *Salmonella* spp.: (S/I/R) ≤1 / 2 / ≥4
Reporting Range	Enterobacterales: 0.25 – 4 µg/mL *P. aeruginosa:* 0.25 – 4 µg/mL *Salmonella* spp.: 0.0156-4 µg/mL	0.25 – 4 µg/mL

VI Standards/Guidance Documents Referenced:

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*. 33rd ed. CLSI supplement M100. Clinical and Laboratory Standards Institute; 2023.

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 Ciprofloxacin (0.0156-4 µg/mL) was conducted at three clinical sites using a panel of 12 *Salmonella* isolates with on-scale MICs. 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 *Salmonella enterica* ssp. enterica serovar Paratyphi A (1), and *Salmonella* species (11). 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. Quality control performed during performance of the reproducibility study was determined to be acceptable. The results of the study demonstrate that for ciprofloxacin with *Salmonella* spp., there was an overall reproducibility across test sites of greater than 95% (± 1 dilution) agreement when compared to the test mode; results were determined to be acceptable. (Table 1)

Table 1. Reproducibility for Ciprofloxacin (0.0156-4 µg/mL)

Inoculation Method	Best Case Reproducibility
Manual	100%
Phoenix AP	99.7%

As there is no change in the reporting range when testing Enterobacterales and *P. aeruginosa* with the BD Phoenix Automated Microbiology System – GN Ciprofloxacin (0.25-4 µg/mL), reproducibility data remains the same as was previously evaluated during review of K060217 and was determined to be acceptable (refer to the K060217 Decision Summary).

2. Linearity:

   Not applicable

3. Analytical Specificity/Interference:

   Not applicable

4. Assay Reportable Range:

   This submission is for the extension of the ciprofloxacin concentrations tested and reporting range for *Salmonella* spp. The reporting range for Enterobacterales and *P. aeruginosa* remain at 0.25 – 4 µg/mL.

Table 2. Reporting Ranges for Ciprofloxacin

Organism	Testing/Reporting Range
Salmonella spp.	0.0156-4 µg/mL
Enterobacterales	0.25-4 µg/mL
P. aeruginosa	0.25-4 µg/mL

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

   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. QC strains were tested using both manual and Phoenix AP inoculation methods and read by the BD Phoenix instrument. Results were acceptable for greater than 95% of tests performed using both inoculation methods.

Table 3. Quality Control for Ciprofloxacin

Organism	Concentration (µg/mL)	Reference	BD Phoenix Results	
			Manual Inoculation	Phoenix AP Inoculation
E. coli ATCC 25922 CLSI Expected Range: 0.004-0.016 µg/mL	≤0.015	128		
	0.03	4		
	0.06	1		
	0.12			
	0.25*		89	82
	0.5			
	1			
	2			
	4			
P. aeruginosa ATCC 27853 CLSI Expected Range: 0.12 – 1 µg/mL	≤0.015			
	0.03			
	0.06			
	0.12			
	0.25*	80		
	0.5	53	87	80
	1		1	2
	2			
	4			

Grey shaded rows indicate the BD Phoenix Automated Microbiology System - GN Ciprofloxacin (0.25-4 µg/mL) expected range.
*The lower end range extension only applies to the *Salmonella* species. Therefore, the BD Phoenix instrument will not report an MIC below 0.25 µg/mL for *E. coli* or *P. aeruginosa*. Obtaining a value of ≤0.25 µg/mL for *E. coli* ATCC 25922 was considered an indicator that the quality control test results were acceptable. The expected range for *E. coli* remains ≤0.25 µg/mL and *P. aeruginosa* remains ≤0.25-1 µg/mL (refer to the K060217 Decision Summary).

Inoculum Density Check: The BD PhoenixSpec Nephelometer (primary inoculation method) 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 ability of the BD Phoenix AP instrument to prepare an appropriate inoculum was evaluated with 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 inoculum preparation methods was 0%.

Purity Check: Purity check plates were prepared for all isolates from each inoculation preparation method. 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:

Ciprofloxacin (0.0156 - 4 µg/mL)
Results obtained with the BD Phoenix Automated Microbiology System – GN Ciprofloxacin (0.0156 - 4 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 Ciprofloxacin panel (0.0156 – 4 µg/mL).

Medium: BD Phoenix AST Broth – a cation-adjusted formulation of Mueller Hinton broth used in conjunction with the AST Indicator Solution, a redox indicator.

Inoculum: The BD Phoenix Spec Nephelometer, the primary inoculation method, was used to obtain a suspension approximating a 0.50 ‑ 0.60 McFarland standard for all challenge and clinical isolates.

Incubation: 35° C ± 1° C

Clinical testing was conducted at three U.S. sites using 47 *Salmonella* isolates (7 contemporary [14.9%] and 40 stock [85.1%]) isolates. The low number of contemporary isolates tested was considered acceptable due to the prevalence of *Salmonella* spp. Strains tested included: *Salmonella enterica* ssp. arizonae (2 isolates), *Salmonella enterica* spp. enterica serovar Cholerasuis (3 isolates), *Salmonella enterica* spp. enterica serovar Typhi (4 isolates) and *Salmonella* spp. (38 isolates).

A total of 82 challenge isolates were evaluated at 3 sites. Strains tested included *Salmonella enterica* spp. enterica serovar Paratyphi A (9 isolates), *Salmonella enterica* spp. enterica serovar Typhi (3 isolates) and *Salmonella* spp. (70 isolates).

Results obtained for tests inoculated manually were acceptable.

Table 4. Ciprofloxacin (0.0156 - 4 µg/mL) Results, Manual Inoculation

	Tot	EA N	EA %	Eval Tot	Eval EA N	Eval EA %	CA Tot	CA %	No. R	No S	min	maj	vmj
***Salmonella enterica* ssp. arizonae**													
Clinical	2	1	50	2	1	50	2	100	1	0	0	0	0
Total	2	1	50	2	1	50	2	100	1	0	0	0	0
***Salmonella enterica* ssp. enterica serovar Choleraesuis**													
Clinical	3	3	100	1	1	100	3	100	0	2	0	0	0
Total	3	3	100	1	1	100	3	100	0	2	0	0	0
***Salmonella enterica* ssp. enterica serovar Paratyphi A**													
Challenge	9	9	100	5	5	100	8	88.9	0	8	1	0	0
Total	9	9	100	5	5	100	8	88.9	0	8	1	0	0
***Salmonella enterica* ssp. enterica serovar Typhi**													

	Tot	EA N	EA %	Eval Tot	Eval EA N	Eval EA %	CA Tot	CA %	No. R	No S	min	maj	vmj
Clinical	4	4	100	1	1	100	4	100	3	0	0	0	0
Challenge	3	3	100	0	0	NA	3	100	0	3	0	0	0
Total	7	7	100	1	1	100	7	100	3	3	0	0	0
***Salmonella* spp. not differentiated**													
Clinical	38	37	97.4	30	29	96.7	38	100	8	13	0	0	0
Challenge	70	70	100	50	50	100	64	91.4	2	43	6	0	0
Total	108	107	99.1	80	79	98.8	102	94.4	10	56	6	0	0
All *Salmonella* spp. and serovars Combined													
Clinical	47	45	95.8	34	32	94.1	47	100	12	15	0	0	0
Challenge	82	82	100	55	55	100	75	91.5	3	54	7	0	0
Total	129	127	98.4	89	87	97.8	122	94.6	15	69	7	0	0

EA - Essential Agreement
CA - Category Agreement
Eval – Evaluable isolates
R - Resistant isolates
S – Susceptible isolates
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.

The BD Phoenix AP instrument, the secondary inoculation method, was evaluated using challenge, QC, and reproducibility isolates. The BD Phoenix AP instrument is designed to standardize the ID broth inoculum equivalent to the BD Phoenix Spec Nephelometer. Following suspension standardization, the instrument adds the preset amount of AST indicator broth to the AST broth tube and transfers the required aliquot of ID broth inoculum to AST broth tubes. Results obtained for tests inoculated using the BD Phoenix AP instrument were acceptable.

Table 5. Ciprofloxacin (0.0156 - 4 µg/mL) Results, Phoenix AP Inoculation Method

	Tot	EA N	EA %	Eval Tot	Eval EA N	Eval EA %	CA Tot	CA %	No. R	No. S	min	maj	vmj
***Salmonella enterica* ssp. enterica serovar Paratyphi A**													
Challenge	9	9	100	5	5	100	8	88.9	0	8	1	0	0
Total	9	9	100	5	5	100	8	88.9	0	8	1	0	0
***Salmonella enterica* ssp. enterica serovar Typhi**													
Challenge	3	3	100	0	0	NA	3	100	0	3	0	0	0
Total	3	3	100	0	0	NA	3	100	0	3	0	0	0
***Salmonella* spp.**													
Challenge	70	70	100	35	35	100	67	95.7	1	44	3	0	0
Total	70	70	100	35	35	100	67	95.7	1	44	3	0	0
All *Salmonella* spp. and serovars Combined													
Challenge	82	82	100	40	40	100	78	95.1	1	55	4	0	0
Total	82	82	100	40	40	100	78	95.1	1	55	4	0	0

Ciprofloxacin (0.25 - 4 µg/mL)

The BD Phoenix Automated Microbiology System - GN Ciprofloxacin (0.25-4 µg/mL) was originally cleared in K060217 and contained broad indications for testing gram-negative aerobic and facultative anaerobic bacteria belonging to the family of *Enterobacteriaceae* and non-*Enterobacteriaceae* species. Since FDA no longer recognizes breakpoints for

Acinetobacter spp. and other Non-Enterobacterales, the indications for use has been revised and limited to *P. aeruginosa* and specific Enterobacterales species, as noted on the FDA drug label for ciprofloxacin.

Since no changes were made to the design or dilution range for testing species other than for testing *Salmonella*, the performance of the BD Phoenix Automated Microbiology System - GN Ciprofloxacin (0.25-4 µg/mL) with Enterobacterales and *P. aeruginosa* using revised interpretive criteria currently recognized by the FDA, the sponsor provided their reanalysis of the original data to confirm that performance continues to be met in accordance with the AST Special Controls Guidance.

The combined clinical and challenge data for 2836 isolates (tested with the manual inoculation method) were re-analyzed with the updated breakpoints. This re-analysis included 2,169 Enterobacterales (2,085 clinical isolates and 84 challenge isolates) and 532 *P. aeruginosa* (524 clinical isolates and 8 challenge isolates). In addition, results from 152 non-indicated species (147 clinical isolates and 5 challenge isolates, representing <10% of the total number of isolates tested) were also re-analyzed. The performance data included in the device labeling included combined performance for Enterobacterales, *P. aeruginosa* and non-indicated species. To provide clarity on the performance provided in the device labeling, the following was included in a footnote to the performance table:

> *Enterobacterales (2169), Pseudomonas aeruginosa (532) and non-indicated species (152) were included in the above combined performance.*

When applying the new breakpoints, the CA for Enterobacterales was >90% and considered acceptable. Reanalyzed results for *P. aeruginosa* breakpoints, showed a CA of 88.7% due mainly to an increased percentage of minor errors. The EA of evaluable results was 85.3%. To address the unacceptable CA, the following limitation was added to the device labeling:

> *Due to the occurrence of a high number of minor errors, isolates of P. aeruginosa that provide MICs of 1 µg/mL should be retested with an alternate method.*

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. Results that are not clearly at least one dilution lower, at least one dilution higher or in exact agreement with the CLSI reference method are not considered in the trending analysis.

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.

Results for *Salmonella* spp. showed high trending for *Salmonella enterica* spp. arizonae, *Salmonella enterica* spp. enterica serovar Cholerasuis and *Salmonella enterica* spp. enterica

serovar Paratyphi A but were not statistically significant. Results for *Salmonella* spp. overall showed no trending.

Table 7. Trending of Ciprofloxacin (0.0156 - 4 µg/mL) Results

Organism	Total Evaluable for Trending	≥ 1 Dilution lower No. (%)	Exact No. (%)	≥ 1 Dilution Higher No. (%)	Percent Difference (CI)	Trending Noted
Salmonella enterica ssp. arizonae	2	1 (50)	1	0 (0)	-50% (-91% to 27%)	Yes*
Salmonella enterica ssp. enterica serovar Choleraesuis	2	0 (0)	1	(50)	50% (-27% to 91%)	Yes*
Salmonella enterica ssp. enterica serovar Paratyphi A	9	1 (11.1)	4	4 (44.4)	33% (-8 to 64%)	Yes*
Salmonella enterica ssp. enterica serovar Typhi	1	0 (0)	1	0 (0)	0% (-79% to 79%)	No
Salmonella species	91	10 (11.0)	65	16 (17.6)	7% (-4% to 17%)	No
All *Salmonella*	105	12 (11.4)	72	21 (20)	9% (-1% to 18%)	No

*Not statistically significant.

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 8. FDA-Identified Interpretive Criteria for Ciprofloxacin[a]

Organism	Interpretive Criteria for Ciprofloxacin (µg/mL)		
	Susceptible	Intermediate	Resistant
Salmonella spp.	≤0.0625	0.125 – 0.5	≥ 1
Enterobacterales	≤ 0.25	0.5	≥ 1
P. aeruginosa	≤ 0.5	1	≥ 2

[a]According to CLSI M100-Ed33 and FDA STIC Website
https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm410971.htm

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 reviewed and accepted by FDA, as described in the Antimicrobial Susceptibility Test (AST) System Devices – Updating Breakpoints in Device Labeling guidance. 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 Becton, Dickinson and Company intends to use to evaluate the BD Phoenix Automated Microbiology System - GN Ciprofloxacin when revised breakpoints for ciprofloxacin are published on the FDA STIC webpage. The PCCP included with the submission indicated that if specific criteria are met, Becton, Dickinson and Company will update the BD Phoenix Automated Microbiology System - GN Ciprofloxacin 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.