December 21, 2022

Becton Dickinson, and Company
Kamisha Gray
Senior Regulatory Affairs Specialist
7 Loveton Circle
Sparks, Maryland 21152-0999

Re: K221826
Trade/Device Name: BD BBL Sensi-Disc Cefiderocol 30ug (FDC-30)
Regulation Number: 21 CFR 866.1620
Regulation Name: Antimicrobial Susceptibility Test Disc
Regulatory Class: Class II
Product Code: JTN
Dated: June 20, 2022
Received: June 23, 2022

Dear Kamisha Gray:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Ribhi Shawar, Ph.D. (ABMM)
Branch Chief
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221826

Device Name
BD BBL™ Sensi-Disc™ Cefiderocol 30µg (FDC-30)

Indications for Use *(Describe)*

Intended Use/Indications for Use:
BD BBL Sensi-Disc Antimicrobial Susceptibility Test (AST) Discs are used in the semi-quantitative agar diffusion test method for in vitro susceptibility testing.

BD BBL Sensi-Disc Cefiderocol Disc 30 µg (FDC-30) can be used to determine susceptibility to Cefiderocol against the following bacteria, as described in the FDA-approved package insert for this antimicrobial agent.

Active in vitro and in Clinical Infections Against:

Complicated Urinary Tract Infections, Including Pyelonephritis
Gram-negative Bacteria
Escherichia coli
Enterobacter cloacae complex
Klebsiella pneumoniae
Proteus mirabilis
Pseudomonas aeruginosa

Active in vitro Against:
Citrobacter freundii complex
Citrobacter koseri
Klebsiella aerogenes
Klebsiella oxytoca
Morganella morganii
Proteus vulgaris
Providencia rettgeri

Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP)
Gram-negative Bacteria
Acinetobacter baumannii complex
Escherichia coli
Enterobacter cloacae complex
Klebsiella pneumoniae
Pseudomonas aeruginosa
Serratia marcescens

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.

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510(k) Summary

Summary Preparation Date:
6/22/2022

I Background Information

A 510(k) Number

K221826

B Applicant

BD Diagnostic Systems
Becton, Dickinson and Company
7 Loveton Circle
Sparks, Maryland 21152
Establishment Registration Number: 1119779

C Proprietary and Established Name

BD BBL™ Sensi-Disc™ Cefiderocol 30 µg (FDC30)

D Regulatory Information

Product Code	Classification	Regulation Section	Panel
JTN	Class II	21 CFR 866.1620 – Antimicrobial Susceptibility Test Disc	MI – Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain substantial equivalence determination for Cefiderocol Antimicrobial Susceptibility Test Disc.

B Measurand:

Cefiderocol Disc 30 µg (FDC30)

C Type of Test:

Antimicrobial Susceptibility Test Disc

III Intended Use/Indications for Use:

A Intended Use:

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See Indication for Use below.

B Indications for Use:

BD BBL Sensi-Disc Antimicrobial Susceptibility Test (AST) Discs are used in the semi-quantitative agar diffusion test method for *in vitro* susceptibility testing.

BD BBL Sensi-Disc Cefiderocol Disc 30 µg (FDC30) can be used to determine susceptibility to Cefiderocol against the following bacteria, as described in the FDA-approved package insert for this antimicrobial agent.

Active *in vitro* and in Clinical Infections Against:

Complicated Urinary Tract Infections, Including Pyelonephritis
Gram-negative Bacteria
Escherichia coli
Enterobacter cloacae complex
Klebsiella pneumoniae
Proteus mirabilis
Pseudomonas aeruginosa

Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP)
Gram-negative Bacteria
Acinetobacter baumannii complex
Escherichia coli
Enterobacter cloacae complex
Klebsiella pneumoniae
Pseudomonas aeruginosa
Serratia marcescens

Active *in vitro* Against:
Citrobacter freundii complex
Citrobacter koseri
Klebsiella aerogenes
Klebsiella oxytoca
Morganella morganii
Proteus vulgaris
Providencia rettgeri

C Special Conditions for Use Statement(s):

- Rx – For Prescription Use Only
- 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 labeling for specific antimicrobial drugs provides the uses for which the antimicrobial drug is approved.
- Limitations:
  - The ability of the BD BBL Sensi Disc to detect resistance with the following combination(s) is unknown because an insufficient number of resistant strains were encountered at the time of comparative testing: Cefiderocol (30µg) and Enterobacterales

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group, *P. aeruginosa* and *Acinetobacter baumannii*. If such a strain is encountered, it should be submitted to a reference laboratory for further testing.

- While the categorical agreement for BD BBL Sensi-Disc Cefiderocol compared to FDA cleared Disk analysis was >95% for *Pseudomonas aeruginosa* and *Acinetobacter baumannii* complex, categorical agreement for BD BBL Sensi-Disc Cefiderocol compared to historical BMD MIC values was below 90%, caused by the occurrence of false susceptible results and minor errors. Test results for Cefiderocol/*P. aeruginosa* which provide a disc zone of inhibition ≥ 22 mm, and test results for Cefiderocol/*A. baumannii* complex which provide a disc zone of inhibition ≥ 19 mm, should be interpreted in conjunction with other clinical and laboratory information.

- While the categorical agreement for BD BBL Sensi-Disc Cefiderocol compared to FDA cleared Disk analysis was > 95% for Enterobacterales group organisms, categorical agreement for BD BBL Sensi-Disc Cefiderocol compared to historical BMD MIC values resulted in false susceptible results. *Citrobacter freundii* complex, *Citrobacter koseri*, *Klebsiella pneumoniae*, *Morganella morganii*, and *Proteus mirabilis* isolates that provide a disc zone of inhibition ≥ 16 mm should be interpreted in conjunction with other clinical and laboratory information.

D Special Instrument Requirements:

Not applicable.

IV Device/System Characteristics:

A Device Description:

The BD BBL™ Sensi-Disc™ Cefiderocol 30 µg (FDC30) device is a 6 mm disc prepared by impregnating high quality absorbent paper with accurately determined amounts of Cefiderocol. Discs are clearly marked on both sides with the code FDC30. The code designates the agent Cefiderocol (FDC) and the drug content (30 µg).

BD BBL™ Sensi-Disc ™ Antimicrobial Susceptibility Test Discs are furnished in cartridges containing 50 discs each. The last disc in each cartridge is marked "X" and contains the drug as coded. BD BBL™ Sensi-Disc ™ Antimicrobial Susceptibility Test Discs can be dispensed using a BD BBL™ Sensi-Disc ™ Dispenser.

B Principle of Operation:

A suitable therapeutic agent can be determined using filter paper discs impregnated with specified concentrations of antimicrobial agents placed on the surface of a suitable test medium. The test is performed by inoculating pure cultures of clinical isolates onto the test medium and placing the AST disc on the surface of the medium. The antibiotic within the disc diffuses into the agar. After incubation, the zones of inhibition around the discs are measured and compared against

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recognized zone diameter ranges for the specific antimicrobial agent/organism combinations being tested.

V Substantial Equivalence Information:

A FDA Cleared Disk Name:

HardyDisk AST Cefiderocol 30µg (FDC30)

B FDA Cleared Disk 510(k) Number:

K193504

C Comparison with FDA Cleared Device:

Device & FDA Cleared Device (Predicate):	**Device:** K221826	**FDA Cleared Device (Predicate):** K193504
Device Trade Name	BD BBL™ Sensi-Disc™ Cefiderocol 30 µg (FDC30)	HardyDisk™ AST Cefiderocol 30 µg (FDC30)
General Device Characteristic Similarities		
Regulation	866.1620	Same
Product Code	JTN	Same
Intended Use/ Indications for Use	Semi-quantitative *in vitro* susceptibility testing by standardized agar diffusion test procedures.	Same
Antimicrobial Agent	Cefiderocol	Same
Antimicrobial Agent Concentration	30 µg	Same
Interpretation	The user will interpret the zone diameter according to the established interpretive criteria for the drug.	Same
Methodology	Kirby-Bauer Disk Diffusion Susceptibility Test Protocol requires the user to determine categorical interpretations (S/I/R) using the measured zone diameters.	Same
Result Interpretation Method	Measurement of zone size.	Same
General Device Characteristic Differences		
Manufacturing Specifications	BD's specifications	Hardy Diagnostics' specifications

VI Standards/Guidance Documents Referenced:

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- Antibacterial Susceptibility Test Interpretive Criteria (FDA STIC) Cefiderocol Injection. Food and Drug Administration Web site. Content current as of 06 June 2022. https://www.fda.gov/drugs/development-resources/cefiderocol-injection. Last accessed 22 June 2022.
- CLSI. *Performance Standards for Antimicrobial Susceptibility Testing*. 31st ed. CLSI supplement M100. Clinical and Laboratory Institute; 2021.
- CLSI. *Performance Standards for Antimicrobial Susceptibility Testing*. 32nd ed. CLSI supplement M100. Clinical and Laboratory Institute; 2022.
- CLSI. *Performance Standards for Antimicrobial Disk Susceptibility Tests*. 13th ed. CLSI standard M02. Clinical and Laboratory Standards Institute; 2018.
- CLSI. *Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria*. 9th ed. CLSI standard M11. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Reproducibility was conducted at one external site using 15 organisms, tested in triplicate with two disk lots on three separate days using one lot of Mueller Hinton agar (MHA media). Each test was visually read by three independent readers with results masked, resulting in 270 data points for evaluation (15 organisms x 2 disk lots x 1 media lot x 3 days x 3 independent readers = 270 data points).

The reproducibility study included 11 Enterobacterales (1 *Citrobacter koseri*, 1 *Enterobacter cloacae*, 2 *Escherichia coli*, 1 *Klebsiella aerogenes*, 3 *Klebsiella pneumoniae*, 1 *Morganella morganii*, 1 *Proteus mirabilis*, 1 *Proteus vulgaris*, 1 *Serratia marcescens*), 2 *Pseudomonas aeruginosa*, and 1 *Acinetobacter baumannii*. Reproducibility was calculated as the percent of results which were within ±3 mm difference in zone diameter comparing test results with the modal zone diameter value. Summary results between disk lots and across readers are shown in **Table 1** below.

Table 1: Reproducibility Summary

Between Disc Lots			Across Readers			
Lot #1	**Lot #2**	**All Lots**	**Reader #1**	**Reader #2**	**Reader #3**	**All Readers**
100% (135/135)	99.26% (134/135)	99.63% (269/270)[a]	100% (90/90)	100% (90/90)	99% (89/90)	99.63% (269/270)

[a] The combination of Lot #1 and Lot #2 yields the result shown because when the data from these two lots were combined, a new mode was calculated, resulting in only one (1) result falling out of ± 3 mm.

The reproducibility performance between disc lots and across readers is >95% and meets the acceptance criteria.

2. Linearity:

Not applicable.

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3. Analytical Specificity/Interference:

   Not applicable.

4. Assay Reportable Range:

   Not applicable.

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

   Quality Control (QC) Testing:
   The CLSI-recommended quality control (QC) isolates, *Escherichia coli* (ATCC® 25922), and *Pseudomonas aeruginosa* (ATCC® 27853), were tested a sufficient number of times (i.e., a minimum of 20 replicates per lot per reader). One FDA cleared disk lot and two BD disc lots were used. Each test was visually read by three independent readers, resulting in 148 data point (74 data points per lot) and 74 FDA cleared disk data points. The performance is shown in **Table 2** below.

Table 2: Quality Control Performance

QC Organism	Zone Diameter (mm) Range	BD Lot 1[1] (*N*)	BD Lot 2[1] (*N*)	Comparator Disc[2] (*N*)
Escherichia coli ATCC® 25922 Expected Range: 25-31 mm	22			
	23			
	24		2	2
	25	7	11	11
	26	18	12	16
	27	15	13	14
	28	21	21	20
	29	11	14	10
	30	1		
	31			
	32			
	33			
	34			
Pseudomonas aeruginosa ATCC® 27853 Expected Range: 22-31 mm	19			
	20			
	21			
	22			1
	23	2	3	4
	24	10	7	14
	25	23	17	28
	26	32	38	23
	27	6	8	4
	28	1	1	
	29			
	30			
	31			
	32			
	33			
	34			

ATCC = American Type Culture Collection

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[1]Two BD disc lots were tested (Lot A and Lot B).
[2]One comparator disc lot was tested.

The BD disc QC performance is > 95% and is acceptable.

Inoculum Density Check:
Colony counts were conducted for QC, reproducibility isolates, and 9.7% of clinical isolates. All were within the expected range.

6. Detection Limit:

Not applicable.

7. Assay Cut-Off:

Not applicable.

B Comparison Studies:

1.Method Comparison with FDA Cleared Disk:

The BD BBL™ Sensi-Disc™ Cefiderocol 30 µg (FDC30) was compared with an FDA cleared disk of the same antimicrobial, mass/concentration, and content. The study was conducted at one testing site. Three independent operators participated in reading of test results with isolates evenly distributed to mimic testing at multiple sites. Testing was performed with one lot of disk of each test manufacturer (BD and comparator FDA-cleared disc), utilizing MHA media following the method outlined in CLSI M02, M11, and M100.

Clinical:
Clinical testing was performed at one U.S. site with both the BD Cefiderocol disc and the comparator FDA cleared disk using a total of 296 clinical isolates including 207 Enterobacterales (10 *Citrobacter freundii,* 2 *Citrobacter koseri*, 10 isolates of *Enterobacter cloacae*, 30 isolates of *Escherichia coli*, 3 isolates of *Klebsiella aerogenes*, 18 isolates of *Klebsiella oxytoca*, 62 isolates of *Klebsiella pneumoniae*, 17 isolates of *Morganella morganii*, 30 isolates of *Proteus mirabilis*, 2 isolates of *Proteus vulgaris*, 8 isolates of *Providencia rettgeri*, 15 isolates of *Serratia marcescens*), 52 *Pseudomonas aeruginosa,* and 37 *Acinetobacter baumannii* complex.

Challenge:
Challenge testing was performed at one U.S site. A total of 61 challenge isolates were tested which included 49 Enterobacterales (1 *Citrobacter braakii,* 3 *Citrobacter freundii,* 2 *Citrobacter koseri*, 1 *Enterobacter asburiae ,* 3 *Enterobacter cloacae*, 6 *Escherichia*, 3 *Klebsiella aerogenes*, 2 *Klebsiella oxytoca*, 9 *Klebsiella pneumoniae*, 3 *Morganella morganii*, 2 *Proteus mirabilis*, 5 *Proteus vulgaris*, 4 *Providencia rettgeri*, 1 *Providencia stuartii,* 4 *Serratia marcescens*), 5 *Pseudomonas aeruginosa,* and 7 *Acinetobacter baumannii* complex.

Performance results for the total 357 clinical and challenge isolates are shown in **Table 3**.

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Table 3: Overall Performance of the BD BBL™ Sensi-Disc™ Cefiderocol Disc vs. FDA Cleared Disk

	Total	CA#	CA%	S(#)	I(#)	R(#)	VMJ	MAJ	MIN
Enterobacterales Combined									
Clinical	207	207	100%	207	0	0	0	0	0
Challenge	49	45	91.8%	37	10	2	0	0	4
Combined	256	252	98.4%	244	10	2	0	0	4
Pseudomonas aeruginosa									
Clinical	52	51	98.1	51	1	0	0	0	1
Challenge	5	5	100.0	2	2	1	0	0	0
Combined	57	56	98.2	53	3	1	0	0	1
Acinetobacter baumannii complex									
Clinical	37	35	94.6	28	5	4	0	0	2
Challenge	7	7	100.0	2	2	3	0	0	0
Combined	44	42	95.5	30	7	7	0	0	2
Overall									
Clinical	296	293	99.0	286	6	4	0	0	3
Challenge	61	57	93.4	41	14	6	0	0	4
Combined	357	350	98.0	327	20	10	0	0	7

CA – Category Agreement
S – Susceptible isolates
I – Intermediate isolates
R – Resistant isolates
MIN – minor errors
MAJ – major errors
VMJ – very major errors

Category Agreement (CA) is when the BD result interpretation agrees exactly with the comparator HardyDisk result interpretation.

The overall performance of the BD BBL™ Sensi-Disc™ Cefiderocol disc as compared to the FDA cleared disk for Enterobacterales group (**Table 3**) is acceptable with 98.4% CA. There were 4 minor errors and no major or very major errors.

The overall performance of the BD BBL™ Sensi-Disc™ Cefiderocol disc as compared to the FDA cleared disk for *P. aeruginosa* group (**Table 3**) is acceptable with 98.2% CA. There was 1 minor error and no major or very major errors.

The overall performance of the BD BBL™ Sensi-Disc™ Cefiderocol disc as compared to the FDA cleared disk for *Acinetobacter baumannii* group (**Table 3**) is acceptable with 95.5% CA. There were 2 minor errors and no major or very major errors.

As required under 511A(b)(2)(C)(ii)(I) of the Federal Food, Drug and Cosmetic Act, the following statement is included in the 'Warnings and Precautions' section in the device labeling to address testing of non-indicated species:

> *"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 labeling for*

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specific antimicrobial drugs provides the uses for which the antimicrobial drug is approved."

Resistant Isolates:

A total of 357 clinical and challenge isolates were tested when the BD BBL Sensi-Disc was compared to the FDA cleared comparator disk. However, an insufficient number of resistant isolates were available for testing. The following limitation was added in the device labeling:

"The ability of the BD BBL Sensi Disc to detect resistance with the following combination(s) is unknown because an insufficient number of resistant strains were encountered at the time of comparative testing: Cefiderocol (30µg) and Enterobacterales group, P. aeruginosa and Acinetobacter baumannii. If such a strain is encountered, it should be submitted to a reference laboratory for further testing".

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:

The FDA-identified interpretive criteria for Cefiderocol are listed in **Table 4.**

Table 4: Interpretive Categories and Breakpoints for Cefiderocol[1]

	Minimum Inhibitory Concentrations (µg/mL)			**Disk Diffusion (zone diameters in mm)**		
Pathogen	**S**	**I**	**R**	**S**	**I**	**R**
Enterobacteriaceae[2,3]	≤4	8	≥16	≥16	9-15	≤8
Pseudomonas aeruginosa	≤1	2	≥4	≥22	13-21	≤12
Acinetobacter baumannii complex	≤1	2	≥4	≥19	12-18	≤11

[1] According to the **FDA STIC Website**.

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[2] Clinical efficacy was shown for ***Escherichia coli, Klebsiella pneumoniae***, ***Proteus mirabilis***, and ***Enterobacter cloacae*** complex in patients with complicated urinary tract infections (cUTI).
[3] Clinical efficacy was shown for ***Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae*** complex, and ***Serratia marcescens*** in patients with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP).
S = Susceptible
I = Intermediate
R = Resistant

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.