



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
ASSAY ONLY**

**I Background Information:**

**A 510(k) Number**

K253105

**B Applicant**

Hardy Diagnostics

**C Proprietary and Established Names**

HardyDisk AST Cefiderocol 30µg (FDC30)

**D Regulatory Information**

Product Code(s)	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:**

In this Traditional 510(k) submission, Hardy Diagnostics seeks the following:

1. To obtain a substantial equivalence determination for cefiderocol antimicrobial susceptibility test disk for testing with an additional organism (*Stenotrophomonas maltophilia*).
2. To 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:**

Cefiderocol 30µg

**C Type of Test:**

Antimicrobial Susceptibility Test Disks

### III Intended Use/Indications for Use:

#### A Intended Use(s):

See Indications for Use below.

#### B Indication(s) for Use:

HardyDisk AST disks are used for semi-quantitative *in vitro* susceptibility testing by the agar diffusion test procedure (Kirby-Bauer) of rapidly growing and certain fastidious bacterial pathogens. Standardized methods for agar diffusion testing have been described for Enterobacterales, *Staphylococcus* spp., *Pseudomonas* spp., *Acinetobacter* spp., *Listeria monocytogenes*, *Enterococcus* spp., and by modified procedures, *Candida* spp., *Haemophilus* spp., *Neisseria gonorrhoeae*, *Neisseria meningitidis* and *Streptococcus* spp., including *Streptococcus pneumoniae*.

Use of HardyDisk AST Cefiderocol 30µg (FDC30) for *in vitro* agar diffusion susceptibility testing is indicated when there is the need to determine the susceptibility of Enterobacterales, *Pseudomonas aeruginosa*, *Acinetobacter baumannii* complex and *Stenotrophomonas maltophilia* to cefiderocol, as recognized by the FDA Susceptibility Test Interpretive Criteria (STIC).

HardyDisk AST Cefiderocol at concentration 30µg demonstrated acceptable performance to determine the zone diameter (mm) of cefiderocol against the following microorganisms:

Enterobacterales (*Citrobacter freundii* complex, *Citrobacter koseri*, *Enterobacter cloacae* complex, *Escherichia coli*, *Klebsiella aerogenes*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Morganella morganii*, *Proteus mirabilis*, *Proteus vulgaris*, *Providencia rettgeri*, and *Serratia marcescens*)

*Pseudomonas aeruginosa*

*Acinetobacter baumannii* complex

*Stenotrophomonas maltophilia*

#### C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

Due to the lack of an interpretive category other than susceptible for cefiderocol with *Stenotrophomonas maltophilia*, the following limitation was included in the device labeling:

*The current absence of resistant isolates for Stenotrophomonas maltophilia precludes defining any results other than “Susceptible”. Isolates yielding results other than “Susceptible” should be submitted to a reference laboratory for further testing.*

#### D Special Instrument Requirements:

Not applicable.

#### IV Device/System Characteristics:

##### A Device Description:

HardyDisk AST Cefiderocol 30µg (FDC30) is a high quality 6 mm diameter white filter paper disk that is impregnated with 30µg cefiderocol. The disks are clearly marked on both sides with FDC30, designating the agent and the drug content. The disks are supplied in plastic cartridges containing 50 disks each. HardyDisk AST Cefiderocol 30µg (FDC30) is intended to be used for *in vitro* agar diffusion susceptibility testing.

##### B Principle of Operation:

The HardyDisk AST Disk is based on the agar diffusion (Kirby-Bauer) methodology. It utilizes dried filter paper disks impregnated with a known concentration of an antimicrobial agent that are placed onto the test medium surface. Three to five similar colonies are transferred to 4-5 mL of a suitable broth medium. The broth is incubated at 35°C for 2-6 hours to develop a turbidity that exceeds or is equivalent to a 0.5 McFarland standard. Alternatively, a direct broth or saline suspension of colonies may be prepared from an overnight culture. The final inoculum density should be equivalent to a 0.5 McFarland turbidity standard. The inoculum density may also be standardized photometrically.

Within 15 minutes of inoculum preparation, the Mueller Hinton agar plate is streaked with an inoculated swab to obtain an even inoculation of organism. Disks are aseptically placed onto the agar surface with a disk dispenser and the disks are pressed down with a sterile needle or forceps to contact the agar surface. Agar plates are incubated in an ambient air incubator at 35±2°C for 16-18 hours.

After incubation, the agar medium is examined for a zone of inhibition around the disks. The zones of inhibition are measured to the nearest millimeter and interpreted by comparison to recognized zone size interpretive criteria for the antimicrobial agent being tested.

#### V Substantial Equivalence Information:

##### A Predicate Device Name(s):

HardyDisk AST Gepotidacin 10µg (GEP10)

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

K241060

##### C Comparison with Predicate(s):

Device & Predicate Device(s):	Device <u>K253105</u>	Predicate <u>K241060</u>
Device Trade Name	HardyDisk AST Cefiderocol 30µg (FDC30)	HardyDisk AST Cefiderocol 30µg (FDC30)
<b>General Device Characteristic Similarities</b>		
Intended Use	Semi-quantitative <i>in vitro</i>	Same

Device & Predicate Device(s):	Device <u>K253105</u>	Predicate <u>K241060</u>
	susceptibility testing by the agar diffusion test procedure (Kirby-Bauer) of rapidly growing and certain fastidious bacterial pathogens.	
Test Method	Antimicrobial susceptibility testing using paper disks impregnated with an antimicrobial agent	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
Inoculum	Prepared from pure isolated colonies to match the turbidity equivalent of a 0.5 McFarland in Tryptic Soy Broth.	Same
Inoculum Method	Dip a sterile swab into the prepared inoculum and streak an appropriate agar plate's surface three times. Add the disks impregnated with the antimicrobial agent to the surface of the plate. The temperature, atmospheric conditions and duration of incubation is dependent on the organism tested.	Same
Reading Method	The user will interpret the zone diameters according to the established interpretive criteria for the drug.	Same
Antimicrobial Agent	Cefiderocol	Same
Concentration	30µg	Same
<b>General Device Characteristic Differences</b>		
Test Organisms	Enterobacterales ( <i>Citrobacter freundii</i> complex, <i>Citrobacter koseri</i> , <i>Enterobacter cloacae</i> complex, <i>Escherichia coli</i> , <i>Klebsiella aerogenes</i> , <i>Klebsiella oxytoca</i> , <i>Klebsiella</i>	Gram-negative bacteria: <i>Escherichia coli</i> <i>Enterobacter cloacae</i> complex

Device & Predicate Device(s):	Device <u>K253105</u>	Predicate <u>K241060</u>
	<p><i>pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Providencia rettgeri, and Serratia marcescens</i>)</p> <p><i>Pseudomonas aeruginosa</i></p> <p><i>Acinetobacter baumannii</i> complex</p> <p><i>Stenotrophomonas maltophilia</i></p>	<p><i>Klebsiella pneumoniae</i></p> <p><i>Proteus mirabilis</i></p> <p><i>Pseudomonas aeruginosa</i></p> <p><i>Acinetobacter baumannii</i> complex</p> <p><i>Serratia marcescens</i></p> <p><i>Citrobacter freundii</i> complex</p> <p><i>Citrobacter koseri</i></p> <p><i>Klebsiella aerogenes</i></p> <p><i>Klebsiella oxytoca</i></p> <p><i>Morganella morganii</i></p> <p><i>Proteus vulgaris</i></p> <p><i>Providencia rettgeri</i></p>

**Predetermined Change Control Plan (PCCP):**

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. 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 Hardy Diagnostics intends to use to evaluate the HardyDisk AST Cefiderocol 30µg (FDC30) when revised breakpoints for cefiderocol are published on the FDA STIC webpage. The PCCP included with the submission indicated that if specific criteria are met, Hardy Diagnostics will update the HardyDisk AST Cefiderocol 30µg (FDC30) device label to include the new breakpoints.

**VI Standards/Guidance Documents Referenced:**

- CLSI M02-14th ed. *Performance Standards for Antimicrobial Disk Susceptibility Tests* (March 2024).
- CLSI M100-35th ed. *Performance Standards for Antimicrobial Susceptibility Testing* (January 2025).

## VII Performance Characteristics (if/when applicable):

The premarket submission for HardyDisk Cefiderocol 30µg (FDC30) included a letter dated December 14, 2023, indicating the right of reference to NDA 209445. Descriptive characteristics were sufficient for the HardyDisk Cefiderocol 30µg (FDC30) disk based on data from microbiology disk studies evaluated by CDER which were used to generate the breakpoints identified by FDA on the susceptibility test interpretive criteria (STIC) webpage. In addition, CDER concurred with the disk QC ranges that were established by CLSI. The disk data used to support this submission included data from testing organisms shown to be active *in vitro* and/or in clinical infections within the spectrum of activity of cefiderocol.

Data obtained from stability, quality control, disk to MIC correlation, and reproducibility (from disk content optimization) studies were generated in accordance with the CDER Clinical/Antimicrobial [guidance](#), *Microbiology Data for Systemic Antibacterial Drugs-Development, Analysis, and Presentation* to ensure precise, accurate, and reproducible results.

For this review, the interpretive criteria are applied to *Stenotrophomonas maltophilia* according to the FDA [STIC](#) website. As required under 511A(2)(2)(B) of the Federal Food, Drug and Cosmetic Act, the following statement is included in the Precautions section of the HardyDisk AST Cefiderocol 30µg package insert:

*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.*

### Non-susceptible Isolates Tested:

Due to the lack of an interpretive category other than susceptible for cefiderocol with *Stenotrophomonas maltophilia*, the following limitation was included in the device labeling:

*The current absence of resistant isolates for Stenotrophomonas maltophilia precludes defining any results other than “Susceptible”. Isolates yielding results other than “Susceptible” should be submitted to a reference laboratory for further testing.*

### A Analytical Performance:

#### 1. Precision/Reproducibility:

Not applicable.

#### 2. Linearity:

Not applicable.

#### 3. Analytical Specificity/Interference:

Not applicable.

4. Detection Limit and Assay Reportable Range:

Not applicable.

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

Not applicable.

6. Assay Cut-Off:

Not applicable.

**B Comparison Studies:**

1. Method Comparison with Predicate Device:

Not applicable.

2. Matrix Comparison:

Not applicable.

**C Clinical Studies:**

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Clinical Cut-Off:

Not applicable.

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

Not applicable.

**D Expected Values/Reference Range:**

Not applicable.

**E Expected Values/Reference Range:**

The FDA-recognized susceptibility interpretive criteria for cefiderocol are listed below in **Table 1**.

**Table 1. FDA-Recognized Disk Diffusion Interpretive Criteria (zone diameter in mm) for Cefiderocol**

Organisms	Interpretive Criteria (mm) <sup>a</sup>		
	Susceptible (S)	Intermediate (I)	Resistant I
Enterobacterales	≥ 16	9 – 15	≤ 8
<i>Pseudomonas aeruginosa</i>	≥ 22	13 – 21	≤ 12
<i>Acinetobacter baumannii</i> complex	≥ 19	12 – 18	≤ 11
<i>Stenotrophomonas maltophilia</i>	≥ 17	-	-

<sup>a</sup> According to the [FDA STIC Webpage, https://www.fda.gov/drugs/development-resources/fda-recognized-antimicrobial-susceptibility-test-interpretive-criteria](https://www.fda.gov/drugs/development-resources/fda-recognized-antimicrobial-susceptibility-test-interpretive-criteria)

## 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.