510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K260842

B Applicant

Hardy Diagnostics

C Proprietary and Established Names

HardyDisk AST Gepotidacin 10µg (GEP10)

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 the gepotidacin antimicrobial susceptibility test disk for testing with an additional organism (*Neisseria gonorrhoeae*).
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:

Gepotidacin 10µg

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 Gepotidacin 10µg (GEP10) for *in vitro* agar diffusion susceptibility testing is indicated when there is the need to determine the susceptibility of Enterobacterales, *Staphylococcus saprophyticus*, *Enterococcus faecalis*, and *Neisseria gonorrhoeae* to gepotidacin, as recognized by the FDA Susceptibility Test Interpretive Criteria (STIC).

HardyDisk AST Gepotidacin at concentration 10µg demonstrated acceptable performance to determine the zone diameter (mm) of gepotidacin against the following microorganisms:

Enterobacterales (*Citrobacter freundii* complex*, Escherichia coli, Klebsiella pneumoniae, Citrobacter koseri, Klebsiella aerogenes, Klebsiella oxytoca/Raoultella ornithinolytica, Morganella morganii, Proteus mirabilis, Providencia rettgeri*)

Enterococcus faecalis

Staphylococcus saprophyticus

Neisseria gonorrhoeae

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

Not applicable.

IV Device/System Characteristics:

A Device Description:

HardyDisk AST Gepotidacin 10µg (GEP10) is a high quality 6 mm diameter white filter paper disk that is impregnated with 10µg gepotidacin. The disks are clearly marked on both sides with GEP10, designating the agent and the drug concentration. The disks are supplied in plastic cartridges containing 50 disks each. HardyDisk AST Gepotidacin 10µg (GEP10) 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):

K250956

C Comparison with Predicate(s):

Device & Predicate Device(s):	Device K260842	Predicate K250956
Device Trade Name	HardyDisk AST Gepotidacin 10µg (GEP10)	HardyDisk AST Gepotidacin 10µg (GEP10)
General Device Characteristic Similarities		
Intended Use	Semi-quantitative *in vitro* susceptibility testing by the agar diffusion test procedure (Kirby-Bauer) of rapidly growing and certain fastidious bacterial pathogens.	Same
Test Method	Antimicrobial susceptibility testing using paper disks impregnated with an	Same

Device & Predicate Device(s):	Device K260842	Predicate K250956
	antimicrobial agent	
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	Gepotidacin	Same
Concentration	10µg	Same
General Device Characteristic Differences		
Test Organisms	Enterobacterales (*Citrobacter freundii* complex*, Escherichia coli, Klebsiella pneumoniae, Citrobacter koseri, Klebsiella aerogenes, Klebsiella oxytoca/Raoultella ornithinolytica, Morganella morganii, Proteus mirabilis, Providencia rettgeri*) *Enterococcus faecalis* *Staphylococcus saprophyticus*	Enterobacterales (*Citrobacter freundii* complex*, Escherichia coli, Klebsiella pneumoniae, Citrobacter koseri, Klebsiella aerogenes, Klebsiella oxytoca/Raoultella ornithinolytica, Morganella morganii, Proteus mirabilis, Providencia rettgeri*) *Enterococcus faecalis* *Staphylococcus saprophyticus*

Device & Predicate Device(s):	Device K260842	Predicate K250956
	Neisseria gonorrhoeae	

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 (FDA-Recognized Antimicrobial Susceptibility Test Interpretive Criteria). The PCCP outlined the specific procedures and acceptance criteria that Hardy Diagnostics intends to use to evaluate the HardyDisk AST Gepotidacin 10µg (GEP10) when revised breakpoints for gepotidacin 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 Gepotidacin 10µg (GEP10) 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 AST Gepotidacin 10µg (GEP10) included a letter dated October 7, 2024, indicating the right of reference to NDA 218230. Descriptive characteristics regarding *Neisseria gonorrhoeae* testing were sufficient for the HardyDisk AST Gepotidacin 10µg (GEP10) 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 gepotidacin.

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 *Neisseria gonorrhoeae* 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 Gepotidacin 10µg (GEP10) 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.

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 gepotidacin are listed below in **Table 1**.

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

Organisms	Interpretive Criteria (mm)[a]		
	Susceptible (S)	Intermediate (I)	Resistant I
Neisseria gonorrhoeae	≥ 28	23 – 27	≤ 22

[a] FDA STIC Webpage, 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.