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

A. 510(k) Number:

K172621

B. Purpose for Submission:

Addition of Meropenem/Vaborbactam Antimicrobial Susceptibility Test Disk

C. Measurand:

Meropenem/Vaborbactam, 20/10 µg

D. Type of Test:

Antimicrobial Susceptibility Test Disks

E. Applicant:

Hardy Diagnostics

F. Proprietary and Established Names:

HardyDisk Meropenem/Vaborbactam 20/10 µg (MEV30)

G. Regulatory Information:

1. Regulation section:

   21 CFR 866.1620 Antimicrobial Susceptibility Test Disc

2. Classification:

   Class II

3. Product code:

   JTN – Susceptibility Test Disc, Antimicrobial

4. Panel:

   83, Microbiology

H. Intended Use:

1. Intended use(s):

   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 *Enterobacteriaceae*, *Staphylococcus* spp., *Pseudomonas* spp., *Acinetobacter* spp., *Listeria monocytogenes*, *Enterococcus* spp., and by modified procedures, *Haemophilus* spp., *Neisseria gonorrhoeae*, *N. meningitidis* and *Streptococcus* spp., including *Streptococcus pneumoniae*.

2. Indication(s) for use:

   Use of HardyDisk Meropenem/Vaborbactam 20/10 µg (MEV30) for *in vitro* agar diffusion susceptibility testing is indicated when there is need to determine the susceptibility of bacteria to Meropenem/Vaborbactam.

   Meropenem/Vaborbactam has been shown to be active against susceptible isolates of the following microorganisms both *in vitro* and in clinical infections:
   Enterobacter cloacae species complex
   Escherichia coli
   Klebsiella pneumoniae

   Meropenem/Vaborbactam has been shown to be active *in vitro* against susceptible isolates of the following microorganisms:
   Citrobacter freundii
   Citrobacter koseri
   Enterobacter aerogenes
   Klebsiella oxytoca
   Morganella morganii
   Proteus mirabilis
   Providencia spp.
   Pseudomonas aeruginosa
   Serratia marcescens

   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 *Enterobacteriaceae*, *Staphylococcus* spp., *Pseudomonas* spp., *Acinetobacter* spp., *Listeria monocytogenes*, *Enterococcus* spp., and by modified procedures, *Haemophilus* spp., *Neisseria gonorrhoeae*, *N. meningitidis* and *Streptococcus* spp., including *Streptococcus pneumoniae*.

3. Special conditions for use statement(s):

   For prescription use only.

   The following footnote was added to the labeling:

   > *K. pneumoniae ATCC 1705 and K. pneumoniae ATCC BAA-2814 are included for the QC of the vaborbactam activity. Routine testing of meropenem/vaborbactam should include P. aeruginosa ATCC 27853 and K. pneumoniae ATCC BAA-2814.*

4. Special instrument requirements:

   N/A

I. Device Description:

HardyDisk AST Disks utilize 6-mm diameter white filter paper disks. The disks are prepared by impregnating absorbent paper with a known concentration of 20 µg Meropenem and 10 µg Vaborbactam. The disks are marked with the code MEV30 on both sides.
HardyDisk AST Disks are supplied in plastic cartridges containing 50 disks each. They are also packaged as one cartridge per vial with desiccant or five cartridges per vial with desiccant.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   HardyDisk Tigecycline 15 µg

2. Predicate 510(k) number(s):

   K062245

3. Comparison with predicate:

Table 1. Comparison with the Predicate

Similarities		
Item	**Device K172621 HardyDisk Meropenem/Vaborbactam 20/10 µg**	**Predicate K062245 HardyDisk Tigecycline 15 µg**
Test Method	Antimicrobial Susceptibility Testing using paper disks impregnated with an antimicrobial agent	Same

Similarities		
Item	**Device K172621 HardyDisk Meropenem/Vaborbactam 20/10 µg**	**Predicate K062245 HardyDisk Tigecycline 15 µg**
Intended Use	Antimicrobial susceptibility Test Disks are used for *in vitro* susceptibility test by standardized agar diffusion test procedures	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
Inoculation 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. Incubate the agar plate agar side up in a 35 ± 2°C incubator for 16-18 hours.	Same
Reading Method	The user will interpret the zone diameters according established interpretive criteria for the drug.	Same

Differences		
Item	Device	Predicate
Product Name	HardyDisk Meropenem/Vaborbactam 20/10 µg (MEV30)	HardyDisk Tigecycline
Antimicrobial Agent	Meropenem/Vaborbactam	Tigecycline
Concentration	20/10 µg	15 µg

K. Standard/Guidance Document Referenced (if applicable):

CLSI M02-A12, Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard- Twelfth Edition

CLSI M100-S27, Performance Standards for Antimicrobial Susceptibility Testing; Twenty-Seventh Informational Supplement

L. Test Principle:

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. Mueller Hinton agar is recommended for agar diffusion testing of non-fastidious organisms and Mueller Hinton with 5% Sheep Blood for *Streptococcus* spp. 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 make contact with the agar surface. Agar plates are incubated in an ambient air incubator at 35±2°C for 16 - 18 hours. Fastidious organisms are tested using appropriate media incubated in an atmosphere enriched with 5% CO_2, as recommended in the CLSI M02 approved standard document.

After incubation the agar medium is examined for zone of inhibition around the disks. The zones of inhibition are measured to the nearest millimeter and compared against recognized zone size ranges for the antimicrobial agent being tested.

M. Performance Characteristics (if/when applicable):

Descriptive characteristics were sufficient for this disk because the drug studies evaluated by CDER generated the breakpoints and quality control (QC) expected ranges used for review of this device.

1. Analytical performance:

   a. *Precision/Reproducibility:*

      Not applicable

   b. *Linearity/assay reportable range:*

      Not applicable

   c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

      Not applicable

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The interpretive criteria, QC isolates and expected ranges are the same as recommended by FDA/CDER in the approved pharmaceutical drug package insert. The interpretive criteria are shown in Table 2.

Table 2. FDA Breakpoints for Meropenem/Vaborbactam

Indications For Use Organism(s)	Interpretative Criteria Zone Diameter (mm)		
	R	I	S
Enterobacteriaceae	≤13	14-16	≥17

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR 21 CFR Part 809.10.

O. Conclusion:

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