

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
DEVICE ONLY TEMPLATE**

**A. 510(k) Number:**

K080019

**B. Purpose for Submission:**

To obtain a substantial equivalent determination for the Doripenem 10µg HardyDisk™

**C. Measurand:**

Susceptibility to Doripenem 10µg

**D. Type of Test:**

Semi-quantitative Antimicrobial Susceptibility Test Disc

**E. Applicant:**

Hardy Diagnostics

**F. Proprietary and Established Names:**

HardyDisk™ Doripenem 10µg

**G. Regulatory Information:**

1. Regulation section:

866.1620 Antimicrobial Susceptibility Test Disc

2. Classification:

II

3. Product code:

JTN – Susceptibility Test Disc, Antimicrobial

4. Panel:

83 Microbiology

## H. Intended Use:

1. Intended use(s):

HardyDisk™ Antimicrobial Susceptibility Test 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 procedure, *Haemophilus* spp., *Neisseria gonorrhoeae*, *N. meningitidis*, and *Streptococcus* spp., including *Streptococcus pneumoniae*.

2. Indication(s) for use:

Use of HardyDisk™ Doripenem 10µg for *in vitro* agar diffusion susceptibility testing is indicated when there is a need to determine the susceptibility of bacteria to Doripenem. The concentration of Doripenem 10µg has been shown to be active against most isolates of the following microorganisms:

Both *in vitro* and in clinical infections:

*Acinetobacter baumannii*, *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Streptococcus constellatus*, *Streptococcus intermedius*.

3. Special conditions for use statement(s):

The current absence of resistant isolates precludes defining any results other than “Susceptible”. Isolates yielding MIC or disk diffusion results suggestive of “Nonsusceptible” should be subjected to additional testing.

For prescription use only.

4. Special instrument requirements:

None

## I. Device Description:

The HardyDisk™ Doripenem 10µg utilizes 6-mm disks prepared by impregnating absorbent paper with a known concentration of Doripenem. Disks are marked on both sides with letters (DOC) and numbers (10) designating the agent and the drug content. HardyDisk™ are furnished in cartridges containing 50 disks each.

## J. Substantial Equivalence Information:

1. Predicate device name(s):

HardyDisk™ Tigecycline

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

K062245

3. Comparison with predicate:

<b>Similarities</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Intended Use	An <i>in vitro</i> diagnostic product for clinical susceptibility testing of aerobic gram positive and gram negative bacteria	same
Inoculum	Prepared from colonies using the direct inoculation method or growth method	same
Inoculation method	Directly equated to a 0.5 McFarland turbidity standard	same

<b>Difference</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Antibiotic	Doripenem	Tigecycline

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

CLSI M2-A9 “Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard.” CLSI M100-S17, “Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard”. The Center for Drug Evaluation and Review (CDER) pharmaceutical approved package insert, developed during clinical trial studies, was used for Interpretive Criteria and Quality Control (QC) Expected Ranges.

**L. Test Principle:**

HardyDisk™ utilizes dried filter paper disks impregnated with known concentrations of antimicrobial agents that are placed onto the test medium surface. The standard method of testing is the Kirby-Bauer method. The recommended test medium is cation-adjusted Mueller-Hinton agar supplemented with the appropriate concentration of calcium. Four to five colonies are transferred to 5 ml of a suitable broth medium. The broth is incubated at 35-37° C for 2 to 8 hours until a light to moderate turbidity develops. Alternately, a direct broth or saline suspension of colonies may be prepared from an 18-24 hour agar plate 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 is streaked to obtain an even inoculation. Disks are aseptically placed onto the agar surface with a disk dispenser or sterile forceps to ensure contact with the test surface. Plates are incubated in an ambient air incubator at 35-37° C. Fastidious organisms (*Streptococcus species*) are tested using appropriate media incubated in a CO<sub>2</sub> enriched atmosphere, as recommended in the CLSI M7 Approved Standard document. After incubation the media is examined, and zones of inhibition around the disks are measured and compared against recognized zone size ranges for the antimicrobial agent being tested.

**M. Performance Characteristics (if/when applicable):**

Descriptive characteristics are sufficient for susceptibility test discs, because the drug manufacturer performed several clinical outcome studies enrolling 2117 patients, which were evaluated by CDER to grant approval of doripenem. These studies generated the Interpretive Criteria and QC Expected Ranges which the susceptibility tests disc manufactures use for interpretation of results also. No additional *in vitro* diagnostic clinical studies are therefore required.

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 required—CDER reviewed data from a multi-center double-blinded study of 946 adults with complicated intra-abdominal infections and 1171 adults with complicated urinary tract infections to determine not only drug efficacy, but also interpretative criteria and quality control ranges.

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 in millimeters:

*Pseudomonas aeruginosa*  $\geq 24\text{mm}$  (S)\*

*Acinetobacter baumannii*  $\geq 17\text{mm}$  (S)\*

*Streptococcus anginosus* group  $\geq 24\text{mm}$  (S)\*

*Enterobacteriaceae*  $\geq 23\text{ mm}$  (S) \*

\* The current absence of resistant isolates precludes defining any results other than “Susceptible”. Isolates yielding MIC or disk diffusion results suggestive of “Nonsusceptible” should be subjected to additional testing.

**N. Proposed Labeling:**

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

**O. Conclusion:**

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

