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

A. 510(k) Number:

K152846

B. Purpose for Submission:

Addition of Ceftolozane/Tazobactam Antimicrobial Susceptibility Test Disk

C. Measurand:

Ceftolozane/Tazobactam, 30/10µg

D. Type of Test:

Antimicrobial Susceptibility Test Disks

E. Applicant:

Hardy Diagnostics

F. Proprietary and Established Names:

HardyDisk AST Ceftolozane/Tazobactam, (30/10µg) - C/T40

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 AST Ceftolozane/Tazobactam, (30/10µg) - C/T40, for *in vitro* agar diffusion susceptibility testing is indicated when there is a need to determine the susceptibility of bacteria to Ceftolozane/Tazobactam

   The concentration of Ceftolozane/Tazobactam, (30/10µg) - C/T40, has been shown to be active against most of *Pseudomonas aeruginosa* both *in vitro* and in clinical infections.

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   Not Applicable

I. Device Description:

The HardyDisk AST Disks utilize 6-mm diameter white filter paper disks. The disks are prepared by impregnating absorbent paper with a known concentration of 30µg Ceftolozane and 10µg of Tazobactam. The disks are marked with the code C/T40 on both sides. The letters C/T are for the two agents and the number reflects the total content for both agents combined.

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 15µg

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

   K062245

3. Comparison with predicate:

Table 1: Comparison with Predicate Device

Similarities		
Item	Device	Predicate
Test Method	Antimicrobial Susceptibility testing using paper discs impregnated with an antimicrobial agent	Same
Intended Use	Antimicrobial Susceptibility Test Disks are used for *in vitro* susceptibility testing by standardized agar diffusion test procedures.	Same
Methodology	Kirby-Bauer Disk Diffusion Susceptibility Test Protocol. Require 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. Incubate the plate agar side up in a 35 +/- 2 degrees C. incubator for 18-24 hours.	Same
Interpretation	The user will interpret the zone diameters according established interpretive criteria for the drug.	Same
Differences		
Item	Device	Predicate
Product Name	HardyDisk AST Ceftolozane/Tazobactam (30/10µg)- C/T40	HardyDisk Tigecycline

Similarities		
Item	Device	Predicate
Antibiotic	Ceftolozane/Tazobactam	Tigecycline
Concentration	30µg Ceftolozane/10µg Tazobactam	15µg

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

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

CLSI M100-S25, Performance Standards for Antimicrobial Susceptibility Testing; Twenty-Fifth Informational Supplement

L. Test Principle:

The HardyDisk AST Disks is based on the agar diffusion (Kirby-Bauer) methodology. It utilizes dried filter paper disks impregnated with known concentrations of antimicrobial agents that are placed onto the test medium surface. Mueller Hinton agar is recommended for agar diffusion testing of non-fastidious organisms. 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 is streaked with an inoculated swab to obtain an even inoculation. 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 Ceftolozane/Tazobactam disk. The studies evaluated by FDA/CDER at the time of Ceftolozane/Tazobactam approval were used for this review.

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 Interpretative criteria are the same as recommended by the FDA/CDER in the approved pharmaceutical drug package insert.

   For disk diffusion, currently there are interpretative criteria for *Pseudomonas aeruginosa* only, as noted in the Indications for Use statement. There are no disk diffusion interpretative criteria for other groups of organisms. This is consistent with the FDA approved pharmaceutical drug product.

Table 2: FDA Interpretative Criteria for Ceftolozane/Tazobactam

Indications For Use Organism(s)	**Interpretative Criteria**		
	Zone Diameter (mm)		
	R	**I**	**S**
Pseudomonas aeruginosa	≤16	17-20	≥21

N. Proposed Labeling:

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

O. Conclusion:

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