

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

A. 510(k) Number:

k070262

B. Purpose for Submission:

Addition of Ertapenem Antimicrobial Susceptibility Test Disc

C. Measurand:

Ertapenem 10 µg/mL

D. Type of Test:

Semi-quantitative Antimicrobial Susceptibility Test Disc

E. Applicant:

Oxoid Limited

F. Proprietary and Established Names:

Ertapenem Antimicrobial Susceptibility Test Disc

G. Regulatory Information:

1. Regulation section:

21 CFR 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):

Oxoid Antimicrobial Susceptibility Test Discs are used in the agar diffusion test method for *in vitro* susceptibility testing. This semi-quantitative method is for use with rapidly growing organisms including *Enterobacteriaceae*, *Staphylococcus* spp., *Pseudomonas* spp., *Acinetobacter* spp., *Listeria monocytogenes* and some *streptococci*, and by modified procedures, *Haemophilus influenzae*, *Neisseria gonorrhoeae*, and *Streptococcus pneumoniae*.

2. Indication(s) for use:

Ertapenem antimicrobial susceptibility test disc is indicated for *Staphylococcus aureus* (methicillin susceptible isolates only), *Streptococcus agalactiae*, *Streptococcus pyogenes*, *Escherichia coli*, *Klebsiella pneumoniae*, *Moraxella catarrhalis*, *Proteus mirabilis*, and by modified procedures *Streptococcus pneumoniae* (penicillin susceptible isolates only), and *Haemophilus influenzae* (Beta-lactamase negative isolates only).

3. Special conditions for use statement(s):

For prescription use only

The ability of Ertapenem to detect resistance with *Haemophilus* spp., *Streptococcus pneumoniae*, and *Streptococcus* spp. Other than *S. pneumoniae* is unknown because these strains have not yet been detected and should be retested. If a non-susceptible result is obtained, the strain should be sent to a reference laboratory for further testing.

4. Special instrument requirements:

Not Applicable

I. Device Description:

Ertapenem Antimicrobial Susceptibility Test Discs are 6 mm discs prepared by impregnating high quality absorbent paper with accurately determined amounts of Ertapenem. The Disc is clearly marked on both sides with the code ETP10, which designates the agent, Ertapenem, and the drug content. Discs are supplied in cartridges containing 50 discs each. Cartridges are individually sealed together with a desiccant capsule in a foil covered see-through blister pack.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Remel Antimicrobial Susceptibility Test Discs, Meropenem 10 µg/mL

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

K964421

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
1. Intended Use	an <i>in vitro</i> diagnostic product for clinical susceptibility testing of most bacteria	same
2. Inoculum	prepared from colonies	same

Similarities		
Item	Device	Predicate
	using the direct inoculation method	
3. Inoculum Method	Direct equated to a 0.5 McFarland turbidity standard	same
4. Antibiotic concentration	10 µg/mL	same

Differences		
Item	Device	Predicate
1. Antimicrobial	Ertapenem	Meropenem

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

CLSI M7 (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:

The Ertapenem Antimicrobial Susceptibility Test Disc utilizes a dried filter paper disc 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. Four to five colonies are transferred to 5ml of a suitable broth medium. The broth is either incubated at 35-37 °C for 2 to 8 hours until a light to moderate turbidity develops. Alternatively, 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 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. Discs are aseptically placed onto the agar surface with an antibiotic dispenser or sterile forceps to ensure contact with the test surface. Plates are incubated in a regular air incubator at 35-37° C and not incubated in a CO2 enriched atmosphere with the exception of *Haemophilus influenzae*, *Neisseria gonorrhoeae*, and some *Streptococcus pneumoniae*. After incubation, the media is examined and zones of inhibition around the discs are measured 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 disc, because the drug studies that CDER evaluated generated the Interpretive Criteria 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:

Susceptibility Interpretive Criteria for Ertapenem			
Pathogen	Disk Diffusion Zone Diameter (mm)		
	S	I	R
<i>Enterobacteriaceae</i> and <i>Staphylococcus</i> spp.	≥ 19	16–18	≤ 15
<i>Haemophilus</i> spp.	≥ 19	*	*
<i>Streptococcus pneumoniae</i>	≥ 19	*	*
<i>Streptococcus</i> spp. other than <i>Streptococcus pneumoniae</i>	≥ 19	*	*

*The current absence of data in resistant isolates precludes defining any results other than "Susceptible". Isolates yielding MIC results suggestive of a "Nonsusceptible" category should be submitted to a reference laboratory for further testing.

N. Proposed Labeling:

The Interpretative criteria, QC isolates and expected ranges are the same as recommended by the FDA/CDER in the approved pharmaceutical package insert. All values will be included in the device package insert.

O. Conclusion:

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