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

A. 510(k) Number:
K060621

B. Purpose for Submission:
Submission of the antibiotic ertapenem at concentrations of 0.002 - 16 µg/mL for Gram Negative organisms and at concentrations of 0.015-64µg/mL for Gram Positive organisms to the Sensititre 18-24 hour MIC panels.

C. Measurand:
Ertapenem at 0.002 - 16 µg/mL and at 0.015-64µg/mL

D. Type of Test:
Quantitative Antimicrobial Susceptibility Test (AST) growth based fluorescence

E. Applicant:
TREK Diagnostic Systems, Inc.

F. Proprietary and Established Names:
Sensititre® 18-24 hours Susceptibility Plates

G. Regulatory Information:

1. Regulation section:
   866.1640 Antimicrobial Susceptibility Test Powder
2. Classification:
   Class II
3. Product Code:
   JWY-manual readings of AST testing of >16 hour incubation
   LRG- Automated readings of AST of >16 hour incubation
4. Panel:
   83 Microbiology

H. Intended Use:

1. Intended use(s):
   For the addition of Ertapenem at concentrations of 0.002 - 16 µg/mL for *Enterobacteriaceae,* (Gram Negative organisms), and at concentrations of 0.015-64µg/mL for Methicillin susceptible *Staphylococcus species,* and *Beta hemolytic Streptococcus,* (Gram Positive organisms) to the Sensititre 18-24 hour MIC panels for testing gram positive and gram negative isolates.

The Sensititre® 18-24 hour MIC Susceptibility system is an *in vitro* diagnostic product for clinical susceptibility testing of Gram negative and Gram positive organisms.

2. Indication(s) for use:
   Addition of the antibiotic ertapenem at concentrations of 0.002 - 16 µg/mL for Gram Negative organisms and at concentrations of 0.015-64µg/mL for Gram Positive organisms to the Sensititre® 18-24 hour MIC panels.
3. Special condition for use statement(s):
   The ability of the Sensititre® 18-24 hour susceptibility system to detect resistance with: *Streptococcus spp* and Ertapenem is unknown because these strains have not yet been detected and should be retested. If the non-susceptible result is confirmed the strain should be sent to a reference laboratory for further testing.

   Prescription Use Only

4. Special instrument Requirements:
   Not Applicable

I. Device Description:

Sensititre® MIC Susceptibility plate MIC panels are multi-well plastic microtitre plates, precision dosed with dried, stabilized antimicrobics. This is a modification of the classic broth dilution methods and can provide both qualitative and quantitative susceptibility results in a dried plate format. Inoculum is prepared in Mueller-Hinton broth for testing gram negative and gram positive organisms. After inoculation, plates are sealed with an adhesive seal, incubated at 34-36°C for 18-24 hours and the contents of the wells are examined for bacterial growth.

The AST results may be read automatically using the Sensititre® Autoreader® or Sensititre® ARIS® or manually using the Sensititre manual viewer or SensiTouch®.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Pasco Laboratories, Inc. MIC and MIC/ID panels
2. Predicate K number(s):
   K041776
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended use	an *in vitro* diagnostic product for clinical susceptibility testing of indicated organisms	an *in vitro* diagnostic product for clinical susceptibility testing of indicated organisms
Inoculum	Prepared from colonies	Prepared from colonies

	using the direct inoculation method	using the direct inoculation method
Inoculation method	Direct equated to a 0.5 McFarland	Direct equated to a 0.5 McFarland
	Differences	
Item	**Device**	**Predicate**
Antibiotic	Ertapenem	Different antibiotic and concentrations
Type panel	antimicrobial agent serially diluted then dried	frozen
Technology	Fluorescence detection of growth for automated reading, growth for manual read method.	Visual growth

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

"Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA"; Clinical and Laboratory Standards Institute (CLSI) M7 (M100-S16) "Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard."

L. Test Principle:

The Sensititre® Autoread System utilizes fluorescence technology to read 18-24 hour plates. The technology involves the detection of bacterial growth which is determined by generating a fluorescent product form a non-fluorescent substrate. The non-fluorescent substrate is prepared by conjugating a fluorescent compound to the specific enzyme substrates with a bond which prevents fluorescence. The substrate is added to the inoculum broth and dispensed into the test plates at the same time as the test organism. The amount of fluorescence detected is directly related to the activity of bacterial growth. The MIC is determined by observing the lowest dilution of antimicrobial agent that inhibits growth of the organism.

Alternatively, after incubation for 18-24 hours, the Sensititre viewer enables the user to read the panel manually for growth based on turbidity, haziness, or a deposit of cells at the bottom of a well. The MIC is recorded as the lowest concentration of antimicrobic that inhibits visible growth. The growth control well should be read first. If the growth control well does not exhibit growth, the test is considered invalid.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. ***Precision/Reproducibility***

Testing was performed using the Sensititre 18-24 hour Susceptibility System. The 25 gram negative and 25 gram positive isolate study described in the guidance document was used. (25 organisms tested 1 time at 3 sites). The study demonstrated >95% reproducibility

using either the automated read method or the manual method of reading.

b. Linearity/assay reportable range:
Not applicable

c. Traceability, Stability, Expected values (controls, calibrators, or method)
The CLSI recommended QC isolates were tested daily with acceptable results with the reference method. Quality control was also performed at all sites using both the manual read method and the Autoread® method. The Sensititre® results demonstrate that the system can produce QC results in the recommended range for both the manual method of reading and the automated read method.

ORGANISM	**Conc ug/mL**	**Reference**	**Sensititre® Autoread**	**Sensititre® manual**
S. aureus ATCC 29213 Range 0.06-0.25 ug/ml	<0.06	0	0	0
	0.06	0	0	0
	0.12	48	38	43
	0.25	12	22	17
	>0.25	0	0	0
Total		60	60	60
Enterococcus faecalis ATCC 29212 Range 4-16 ug/ml	<4	0	3	0
	4	0	5	1
	8	56	52	59
	16	4	0	0
	>16	0	0	0
Total		60	60	60
E. coli ATCC 25922 Range 0.004-0.016 ug/ml	≤0.004	1	0	0
	0.004	27	0	0
	0.008	32	60	55
	0.016		0	5
	>0.016		0	0
Total		60	60	60
P. aeruginosa ATCC 27853 Range 2-8 ug/ml	<2			
	2	12	3	13
	4	42	51	40
	8	5	6	7
	>8	1		
Total		60	60	60

Pseudomonas aeruginosa and *Enterococcus faecalis* were tested for QC purposes only.

Nephelometer was used at each site to standardize the inoculum and it was calibrated each time it was switched on. Colony counts were performed with a range of 8.6×10^5-1.1×10^5.

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:
Broth reference panels prepared according to the recommendations of the CLSI were used to compare to the Sensititre® panel results. Testing was performed at 3 sites and included fresh and stock clinical isolates and a set of challenge organisms. The following are the comparative results for the gram positive panels for the automated read method only for the organisms indicated for use:

Gram Positive isolates= Methicillin Susceptible Staph species (MSSS), Beta hemolytic Streptococci

Gpos	total	EA	%EA Total	Total evaluable	EA of evaluable	%EA eval	CA	%CA	#R	min	maj	vmj
Clinical	**120**	**120**	**100**	**107**	**107**	**100**	**120**	**100**	**0**	**0**	**0**	**0**
Challenge	**22**	**21**	**95.4**	**22**	**21**	**95.4**	**21**	**95.4**	**0**	**0**	**1**	**0**
Combined	**142**	**141**	**99.3**	**129**	**128**	**99.2**	**141**	**95**	**0**	**0**	**1**	**0**

The following are the comparative results for the gram negative panels for the automated read method only:

Gneg=Enterobacteriaeae

Gneg	total	EA	%EA Total	Total evaluable	EA of evaluable	%EA eval	CA	%CA	#R	min	maj	vmj
Clinical	**245**	**242**	**98.8**	**245**	**242**	**98.8**	**245**	**100**	**0**	**0**	**0**	**0**
Challenge	**58**	**57**	**98.3**	**57**	**56**	**98.2**	**58**	**100**	**0**	**0**	**0**	**0**
Combined	**303**	**299**	**98.7**	**302**	**298**	**98.7**	**303**	**100**	**0**	**0**	**0**	**0**

EA-Essential Agreement
CA-Category Agreement
R-resistant isolates
maj-major discrepancies
vmj-very major discrepancies
min- minor discrepancies

Essential agreement (EA) is when the Sensititre 18-24 hour MIC panel results agree with the reference test panel results exactly or within one doubling dilution of the reference method. Category agreement (CA) is when the Sensititre 18-24 hour MIC panel interpretative results, Sensitive, Intermediate, and Resistant (SIR) agrees exactly

with the reference panel result interpretation. Evaluable (Eval) are results that are within the test range and are on scale.

The test device had a growth rate of >95% and the performance data are acceptable.

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:
   MSSS= <=2 (S), 4 (I), >=8 (R)
   *Beta hemolytic *Strep spp.* (BHS) = ≤1 (S)
   Enterobacteriaceae = <=2 (S), 4 (I), >=8 (R)

   *The ability of the Sensititre® 18-24 hour susceptibility system to detect resistance with: *Streptococcus spp* and Ertapenem is unknown because these strains have not yet been detected and should be retested. If the non-susceptible result is confirmed the strain should be sent to a reference laboratory for further testing.

   The expected value range, interpretative criteria and QC are the same as recommended in CLSI and FDA.

N. Labeling

The expected value range, interpretive criteria and QC for ertapenem utilized in the gram negative panels and in the gram positive panels are included in the package insert. The labeling conforms to the requirements of 21 CRF Part 809.10.

O. Conclusion:

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