

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

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

k073653

**B. Purpose for Submission:**

To add the Dtest to the Sensititre® 18 – 24 hour MIC or Breakpoint (BP) panel for testing *Staphylococcus* spp.

**C. Measurand:**

Clindamycin 0.5, 1.5 µg/mL

Erythromycin 4, 8 µg/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 hour MIC or BP 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):

The Sensititre® 18 – 24 hour MIC or Breakpoint Susceptibility System is an *in vitro* diagnostic product for clinical susceptibility testing of non-fastidious Gram positive isolates comprising of *Staphylococci*, *Enterococci*, and beta hemolytic *Streptococci* other than *S. pneumoniae*.

2. Indication(s) for use:

This 510k is indicated for the addition of Dtest (Dtest well 1 contains 4 µg/mL erythromycin and 0.5 µg/mL clindamycin; Dtest well 2 contains 8 µg/mL erythromycin and 1.5 µg/mL clindamycin) for testing *Staphylococcus* spp. on the Sensititre® 18 – 24 hour MIC or BP panel.

3. Special conditions for use statement(s):

Prescription use

4. Special instrument requirements:

Not applicable

**I. Device Description:**

The Sensititre® MIC or BP Susceptibility system is a microversion of the classic broth dilution methods and can provide both qualitative and quantitative susceptibility results. Each microdilution plate is dosed with antimicrobial agents at appropriate dilutions then dried. After inoculation, plates are sealed with an adhesive seal, incubated at 34 -36°C for 18 – 24 hours and examined for bacterial growth.

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 MIC and MIC/ID Panels

2. Predicate K number(s):

K033119

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 gram negative and gram positive organisms.	same
Inoculum	Prepared from colonies using the direct inoculation method	Prepared from colonies using the direct inoculation method
Inoculation method	Direct equated to a 0.5 McFarland	Direct equated to a 0.5 McFarland

<b>Differences</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Type panel	Dried antibiotics	100 µl/well frozen
Incubation	18-24 hours	16-24 hours
Technology	Fluorescence detection of growth	Turbidity detection of growth
Reading method	Visual growth and Auto read by instrumentation	Turbidity detection of growth

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

“Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test Systems; Guidance for Industry and FDA”; CLSI M7 (M100-S18) “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 by monitoring the activity of specific surface enzymes produced by the test organism. Growth is determined by generating a fluorescent product from a non-fluorescent (fluorogenic) substrate. The non-fluorescent substrate is prepared by conjugating a fluorescent compound to the specific enzyme substrates with a bond which prevents fluorescence. The fluorophore is then said to be quenched. The substrate can be added to the inoculum broth and dispensed into the test plates at the same time as the test organism or the plates can be prepared with substrate already added to the plate. Enzymatic action of the bacterial surface enzymes on the specific substrates cleave this bond releasing the fluorophore which is now capable of fluorescing. 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.

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

1. Analytical performance:

a. *Precision/Reproducibility:*

Reproducibility testing was performed on ten *Staphylococcus aureus*, and five Coagulase Negative *Staphylococcus* isolates using either the automated read method or the manual read method. Acceptable reproducibility was demonstrated with only category agreement (Negative, Positive) since that is all that is detected.

b. *Linearity/assay reportable range:*

Not applicable

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

The CLSI recommended Quality Control (QC) isolates, *S. aureus* ATCC BAA-976 and *S. aureus* ATCC BAA-977 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 demonstrated that the system can produce QC results in the recommended range for both the manual method of reading and the automated read method.

Quality Control Table for DTEST

<b>ORGANISM</b>	<b>Conc ug/mL (Ery/Cli)</b>	<b>Sensititre® Autoread</b>	<b>Sensititre® manual</b>	<b>Reference</b>
<i>S. aureus</i> BAA-976 Expected Range : Neg	4/0.5 Neg	64	60	63
	8/1.5 Neg	64	60	63
	Pos			
<i>S. aureus</i> BAA-977 Expected Range : Pos	4/0.5 Neg	1	1	0
	8/1.5 Neg	1	1	0
	4/0.5 Pos	57	58	60
	8/1.5 Pos	57	58	60

A nephelometer was used at each site to standardize the inoculum and it was

calibrated each time it was used. Colony counts were also performed at each site to demonstrate that colony counts were in the expected range in most occasions.

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:*

The CLSI recommended broth dilution reference panel was prepared according to the CLSI recommendation. Clinical testing was performed on 207 *S. aureus* and 200 coagulase negative *Staphylococcus* spp. isolates at three external sites which included fresh and stock clinical isolates, a set of challenge organisms, and CDC study isolates.

Sensititre Dtest uses two wells to detect inducible clindamycin resistance. Growth in either or both wells indicates the presence of inducible clindamycin resistance. These isolates would be reported as clindamycin resistant. No growth in both wells will be reported as negative for inducible resistance.

The comparison resulted in the following performance evaluations as reflected below.

Summary Table for (Manual Read Method)

	<b>Total</b>	<b>CA</b>	<b>CA%</b>	<b># Neg</b>	<b># Pos</b>	<b>maj</b>	<b>vmj</b>
<i>S. aureus</i>	207	207	100	92	115	0	0
<b>Coagulase-negative</b> <i>Staphylococcus</i>	200	200	200	95	105	0	0

Summary Table for (Auto Read Method)

	<b>Total</b>	<b>CA</b>	<b>CA%</b>	<b># Neg</b>	<b># Pos</b>	<b>maj</b>	<b>vmj</b>
<i>S. aureus</i>	207	207	100	92	115	0	0
<b>Coagulase-negative</b> <i>Staphylococcus</i>	197	195	98.9	91	106	0	2

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:

*Staphylococcus* species – Growth (inducible clindamycin resistance)

No growth (no inducible clindamycin resistance)

**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.