

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

A. 510(k) Number:

k073558

B. Purpose for Submission:

To add Cefoxitin screen on the Sensititre® 18 – 24 hour MIC or Breakpoint (BP) panel for testing *Staphylococcus aureus*

C. Measurand:

Cefoxitin 6 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:

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 will include cefoxitin screen at a concentration of 6 µg/mL for testing *Staphylococcus aureus* 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:

Similarities		
Item	Device	Predicate
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

Differences		
Item	Device	Predicate
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-S17) “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 19 *S. aureus* isolates. These were tested one time at each of the three sites on each reading method. This demonstrated >95% reproducibility using either the automated read method or the manual read method.

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 29213, and *S. aureus* ATCC BAA-976 were tested daily with acceptable results as shown in the table below. Quality control was also performed at all sites using both manual and autoread methods. The Sensititre® results demonstrated that the system can produce QC results in the recommended range for both manual and automated read methods.

Quality Control Table

ORGANISM	Results	Sensititre® Autoread	Sensititre® manual	Reference
<i>S. aureus</i>	Neg	60	60	60
ATCC 29213	Pos			
Expected Result : Neg				
<i>S. aureus</i>	Neg			
BAA-976	Pos	60	60	60
Expected Result: Pos				

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

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* isolates at three sites which included fresh and stock clinical isolates, a set of challenge organisms, and Centers for Disease Control (CDC) study isolates. Two read methods (manual and automated) were evaluated. The comparison resulted in the following performance evaluations as reflected below.

Summary Table for (**Manual Read Method**)

	Total	#S	#R	CA	%CA	maj	vmj
Clinical and Challenge	177	75	102	176	99.4	0	1
CDC	30	13	17	30	100	0	0

Summary Table for (**Auto Read Method**)

	Total	#S	#R	CA	%CA	maj	vmj
Clinical and Challenge	177	74	103	175	98.9	0	2
CDC	30	13	17	30	100	0	0

CA-Category Agreement

maj-major discrepancies

vmj-very major discrepancies

CA is when the interpretation of the reference method agrees exactly with the interpretation of the VITEK®2 results.

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:

S. aureus – growth or no growth

N. Proposed Labeling:

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

O. Conclusion:

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