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

A. 510(k) Number:
   k040619
B. Purpose for Submission
   Addition of clindamycin to the Sensititre® Haemophilus/Streptococcus pneumoniae (HP) MIC Plates
C. Analyte:
   Clindamycin (0.016 - 8 ug/mL) AST
D. Type of Test:
   Quantitative Antimicrobial Susceptibility Test (AST) growth based fluorescence
E. Applicant:
   TREK Diagnostic Systems, Inc.
F. Proprietary and Established Names:
   Sensititre® Haemophilus/Streptococcus pneumoniae (HP) MIC Plates
G. Regulatory Information:
   1. <u>Regulation section:</u>
      866.1640 Antimicrobial Susceptibility Test Powder
   2. <u>Classification:</u>
      II
   3. <u>Product Code:</u>
      JWY-manual readings of AST testing of >16 hour incubation
      LRG-Automated readings of AST of >16 hour incubation.
   4. <u>Panel:</u>
      83 Microbiology

H. Intended Use:
   1. <u>Intended use(s):</u>
      The Sensititre® Haemophilus/Streptococcus pneumoniae (HP) MIC plates are *in vitro* diagnostic product for clinical susceptibility testing of *Haemophilus influenzae, Streptococcus pneumoniae* and other fastidious organisms.

   2. <u>Indication(s) for use:</u>
      This will include clindamycin in the dilution range of 0.016 - 8 ug/mL to the Sensititre® Haemophilus/Streptococcus pneumoniae (HP) MIC susceptibility plate for testing *Streptococcus pneumoniae* isolates.

   3. <u>Special condition for use statement(s):</u>
      Not routinely reported on isolates from the urinary tract

      Prescription use only

4. Special instrument Requirements:
   Automated readings are performed on the Sensititre® AutoReader or ARIS®.

I. Device Description:
Sensititre® Haemophilus/Streptococcus pneumoniae (HP) Susceptibility plates are multi-well plastic microtitre plates, precision dosed with dried, stabilized antimicrobics. This is a microversion of the classic broth dilution methods and can provide both qualitative and quantitative susceptibility results. Inoculum is prepared in 2 – 5% lysed horse blood. After inoculation, plates are sealed with an adhesive seal, incubated at 34 -36°C for 20 – 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):
   MicroScan® MICroSTREP *plus*™ Panel
2. Predicate K number(s):
   K021037
3. Comparison with predicate:

Item	Device	Predicate
Similarities		
Intended use	an *in vitro* diagnostic product for clinical susceptibility testing of *Haemophilus influenzae, Streptococcus pneumoniae* and other fastidious organisms.	an *in vitro* diagnostic product for clinical susceptibility testing of streptococci including *Streptococcus pneumoniae.*
Type panel	Dried antibiotics	Same
Inoculation method	Direct equated to a 0.5 McFarland	Same
Results	Report results as minimum inhibitory concentration (MIC) and categorical interpretation (SIR)	Same
Differences		
Reading method	Visual growth and Auto read by instrumentation	Visual growth only
Technology	Fluorescence detection of growth	Growth based

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

"Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA"; NCCLS M7 (M100-S14) "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.

The manual reading is based solely in visualization of growth as turbidity.

M. Performance Characteristics (if/when applicable):
1. Analytical performance:
    a. *Precision/Reproducibility:*
       Reproducibility testing was performed on 25 gram-positive isolates appropriate for testing with clindamycin. These were tested 1 time at each of the three sites on each reading method. This demonstrated >95% reproducibility using either the automated read method or the manual method of reading.
    b. *Linearity/assay reportable range:*
       Not applicable
    c. *Traceability (controls, calibrators, or method):*
       The recommended QC isolate was 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.

ORGANISM	Conc ug/mL	Reference	Sensititre® Autoread	Sensititre® manual
S. pneumoniae ATCC 49619 Expected Range 0.03 – 0.12 ug/ml	<0.06	65	65	65

Nephelometer was used at each site to standardize the inoculum and it was calibrated each time it was switched on. 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:*
Broth reference panels prepared according to the recommendations of the NCCLS standards 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 manual read method.

	EA Tot	EA N	EA %	Eval EA Tot	Eval EA N	Eval EA %	CA N	CA %	#R	min	maj	vmj
Clinical	309	305	98.7	231	227	98.3	308	99.7	76	1	0	0
Challenge	53	53	100.0	40	40	100.0	53	100.0	14	0	0	0
Combined	362	358	98.9	271	267	98.5	361	99.7	90	1	0	0

The following are the comparative results for the Automated Read method.

	EA Tot	EA N	EA %	Eval EA Tot	Eval EA N	Eval EA %	CA N	CA %	#R	min	maj	vmj
Clinical	309	305	98.7	228	224	98.2	309	100.0	76	0	0	0
Challenge	53	53	100.0	40	40	100.0	53	100.0	14	0	0	0
Combined	362	358	98.9	268	264	98.5	362	100.0	90	0	0	0

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

EA is when there is agreement between the reference method and the Sensititre panel within plus or minus one serial two-fold dilution of antibiotic. Category agreement (CA) is when the Sensititre® panel result interpretation agrees exactly with the reference panel result interpretation. The %EA is acceptable when compared to the reference method as described in the FDA guidance document, "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA".

Autoread results were very similar to the manual readings with no observable trending. There was one min error for the manual read method which was in essential agreement. No vmj errors and maj errors were encountered in the study.

The overall EA% of 99.4 and CA% of 99.9 for the manual read and overall EA% of 99.4 and CA% of 100.0 for the Autoread methods were both very good.

The percent no growth in the manual reading method was 0% and the Autoread method was 0%.

  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:
 ≤ 0.25 (S), 0.5 (I), ≥ 1 (R)
 The Interpretative criteria, QC isolates and the expected ranges are the same as recommended by the NCCLS. All values will be included in the package insert.

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