510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K231988

B Applicant

Thermo Fisher Scientific

C Proprietary and Established Names

Sensititre 20-24-hour *Haemophilus influenzae*/*Streptococcus pneumoniae* MIC or Breakpoint Susceptibility System with Dalbavancin in the dilution range of 0.0005-2µg/ml

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JWY	Class II	21 CFR 866.1640 - Antimicrobial Susceptibility Test Powder	MI - Microbiology
LRG	Class II	21 CFR 866.1640 - Antimicrobial susceptibility test powder	MI - Microbiology
LTT	Class II	21 CFR 866.1640 - Antimicrobial susceptibility test powder	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain clearance for the Sensititre 20-24-hour *Haemophilus influenzae/Streptococcus pneumoniae* MIC or Breakpoint Susceptibility System with Dalbavancin in the dilution range of 0.0005-2µg/ml with updated FDA-recognized breakpoints for *S. pyogenes*, *S. agalactiae* and *S. anginosus* as well as expand claims to include species within the *S. anginosus* group (*S. anginosus*, *S. intermedius* and *S. constellatus*).

Previously obtained QC and reproducibility data are applicable to this reevaluation.

B Measurand:

Dalbavancin in the dilution range 0.0005 to 2 µg/mL

C Type of Test:

Quantitative antimicrobial susceptibility test (AST), growth-based fluorescence

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:
The Sensititre 20-24-hour *Haemophilus influenzae*/*Streptococcus pneumoniae* MIC or Breakpoint Susceptibility System is an *in vitro* diagnostic product for clinical susceptibility testing of fastidious isolates.

This 510(k) is for dalbavancin in the dilution range of 0.0005 - 2µg/ml with new FDA breakpoints for testing fastidious *Streptococcus* spp. on the Sensititre 20 - 24-hour *Haemophilus influenzae*/*Streptococcus pneumoniae* MIC or Breakpoint Susceptibility System.

Dalbavancin has been shown to be active both clinically and *in vitro* against the following organisms according to the FDA drug label:

Streptococcus agalactiae

Streptococcus pyogenes

Streptococcus anginosus group (*S. anginosus*, *S. constellatus* and *S. intermedius*)

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

According to the FDA approved pharmaceutical antimicrobial agent package insert, polysorbate-80 should be used for testing freshly prepared or frozen microtiter trays with Dalbavancin. Dalbavancin on the Sensititre panel has been developed with an alternative method to provide equivalent performance to the reference method that contained polysorbate-80.

The performance of Dalbavancin with *Streptococcu*s spp. was performed using the AIM autoinoculator. The use of an alternative inoculation system when testing Dalbavancin has not been evaluated.

The ability of the Sensititre system to detect resistance or non-susceptibility to antimicrobics as shown below is unknown because an insufficient number of resistant or non-susceptible strains were available at the time of comparative testing. If such a strain is observed, it should be submitted to a reference laboratory.

Sensititre Dalbavancin MIC values for *Streptococcus* species tended to be one doubling dilution higher than the reference method.

D Special Instrument Requirements:

Sensititre AIM for device inoculation
Digital reading device Sensititre Vizion, ARIS/OptiRead (AutoReader)

IV Device/System Characteristics:

A Device Description:

The Sensititre *Haemophilus influenzae*/*Streptococcus pneumoniae* MIC Susceptibility Plate System is a micro-version of the classic broth dilutions method and can provide both qualitative and quantitative susceptibility results in a dried microtiter plate format. Each micro-broth dilution plate is dosed with antimicrobial agents at specific dilutions and then dried. The organism to be tested must be in pure culture and identified as a *Streptococcus* species. A standardized suspension is prepared from colonies and inoculated into the microtiter plate using the Sensititre AutoInoculator/AIM instrument (AutoInoculator). After the indicated hours of incubation, the microtiter plate is examined for growth to determine the MIC either automatically on an ARIS/Autoreader/OptiRead using fluorescence or by visual reading of growth either on the Vizion digital reading device or on a manual viewer.

B Principle of Operation:

The Sensititre *Haemophilus influenzae/Streptococcus pneumoniae* (HP) MIC Susceptibility plates are multi-well plastic microtiter plates that contain doubled dilutions of antibacterial agents. Each plate includes antimicrobial agents at appropriate dilutions. Results can be read using the digital reading device (Vizion) or by use of an automated reader (ARIS/OptiRead).

The digital reading device (Vizion) allows the panel image to be displayed on a touch screen directly from a video camera and allows the user to visually determine MIC results. The Sensititre OptiRead utilizes fluorescence technology to read the microbroth dilution plates after 20 to 24 hours incubation. 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 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 enzymatic action of the bacterial surface enzymes on the bound non-fluorescent substrate cleaves the bond releasing fluorescence. 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 non-fluorescent (fluorogenic) substrate can be added to the inoculum broth which is dispensed into the test plate at the same time as the test organism, or the plates can be prepared with the substrate already added to each micro-well.
Streptococcus spp. plates can either be read automatically on an ARIS/Autoreader/OptiRead using fluorescence or by visual reading of growth either on the Vizion digital reader or on a manual viewer.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Sensititre Susceptibility Plates

B Predicate 510(k) Number(s):
K143381

C Comparison with Predicate(s):

Device & Predicate Device(s):	Device: K231988	Predicate: K143381
Device Trade Name	Sensititre 20-24-hour *Haemophilus influenzae/ Streptococcus pneumoniae* MIC or Breakpoint Susceptibility System with Dalbavancin in the dilution range of 0.0005-2µg/ml	Sensititre *Haemophilus / Streptococcus pneumoniae* (HP) MIC Plates with Dalbavancin at a concentration of 0.0005 - 2µg/ml
General Device Characteristic Similarities		
Indications for Use	The Sensititre 20-24-hour *Haemophilus influenzae/Streptococcus pneumoniae* MIC or Breakpoint Susceptibility System is an *in vitro* diagnostic product for clinical susceptibility testing of fastidious isolates. This 510(k) is for dalbavancin in the dilution range of 0.0005 - 2µg/ml with new FDA breakpoints for testing fastidious *Streptococcus* spp. on the Sensititre 20 - 24-hour *Haemophilus influenzae/Streptococcus pneumoniae* MIC or Breakpoint Susceptibility System. Dalbavancin has been shown to be active both clinically and *in vitro* against the following organisms according to the FDA drug label:	The Sensititre HP MIC Susceptibility plate is an in vitro diagnostic product for clinical susceptibility testing of fastidious isolates. This 510(k) is for the addition of newly approved Dalbavancin for the dilution range of 0.0005–2µg/ml to the Sensititre HP MIC Susceptibility plate for testing *Streptococcus* species. The approved primary "Indications for Use" and clinical significance for *Streptococcus* spp.: *Streptococcus pyogenes* *Streptococcus agalactiae* *Streptococcus anginosus*

	Streptococcus agalactiae *Streptococcus pyogenes* *Streptococcus anginosus* group (*S. anginosus, S. constellatus* and *S. intermedius*)	
Test Panel	96 well plate is dosed with selected antimicrobial agents and substrate for the fluorescent reads, then dried. The bacterial suspension in the appropriate broth is used to rehydrate the plate.	Same
Instrument	Results can be read automatically on an ARIS/ Autoreader/OptiRead using fluorescence or by visual reading of growth either on the Vizion digital device or on a manual viewer.	Same
Reading Method	Fluorescence or organism growth	Same
Incubation Temperature	34-36°C	Same
Incubation Atmosphere	Ambient air	Same
Incubation Time	20-24 hours	Same
Antibiotic and Dilution Range	Dalbavancin 0.0005 - 2µg/ml	Same
General Device Characteristic Differences		
Breakpoints	≤0.25	≤0.12
Indicated Organisms	*Streptococcus pyogenes* *Streptococcus agalactiae* *Streptococcus anginosus* group (*S. anginosus, S. constellatus* and *S. intermedius*)	*Streptococcus pyogenes* *Streptococcus agalactiae* *Streptococcus anginosus*

VI Standards/Guidance Documents Referenced:

M07-A9 Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically; Approved Standard – Ninth Edition, 2012

M100-S33 Performance Standards for Antimicrobial Susceptibility Testing; 33rd Edition, 2023

Guidance for Industry and FDA: Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems, August 28, 2009

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   A reproducibility study of the Sensititre 20-24-hour *Haemophilus influenzae/Streptococcus pneumoniae* MIC or Breakpoint Susceptibility System with Dalbavancin in the dilution range of 0.0005-2µg/ml was previously performed in support of K143381. No additional data were reviewed in the current submission.

   The reproducibility studies for both the Vizion and AutoRead methods demonstrated acceptable performance of 98.7% and 100%, respectively.

2. Linearity:

   Not applicable

3. Analytical Specificity/Interference:

   Not applicable.

4. Assay Reportable Range:

   Not applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Quality Control (QC) testing, growth failure rate, purity check plates, and inoculum density check were previously evaluated during review of K143381 and were determined acceptable. No additional data were reviewed in the current submission.

6. Detection Limit:

   Not applicable.

7. Assay Cut-Off:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

The Sensititre 20-24-hour *Haemophilus influenzae/Streptococcus pneumoniae* MIC or Breakpoint Susceptibility System with Dalbavancin in the dilution range of 0.0005-2µg/ml which was originally cleared in K143381, included indications for *Streptococcus agalactiae*, *Streptococcus pyogenes* and *Streptococcus anginosus* (Viridans Group) read with the Vizion digital reader or using the ARIS/Autoreader/OptiRead (AutoReader) and compared to the CLSI broth microdilution reference method.

The performance of the Sensititre 20-24-hour *Haemophilus influenzae/Streptococcus pneumoniae* MIC or Breakpoint Susceptibility System with Dalbavancin in the dilution range of 0.0005-2µg/ml with *S. agalactiae*, *S. pyogenes* and *S. anginosus* group (*S. anginosus, S. constellatus* and *S. intermedius*) using revised criteria currently recognized by FDA was evaluated in the current submission using the original data obtained in support of K143381.

Since there was no change in the design or the dilution range of the Sensititre 20-24-hour *Haemophilus influenzae/Streptococcus pneumoniae* MIC or Breakpoint Susceptibility System with Dalbavancin, the performance evaluation was achieved via re-analysis of the MIC data of the original 510(k) submission (K143381). For this review, the current Dalbavancin interpretive criteria are applied to *S. agalacitae*, *S. pyogenes* and *S. anginosus* group (*S. anginosus, S. constellatus* and *S. intermedius*) according to the FDA STIC webpage.

Results obtained with the Thermo Fisher Sensititre dried MIC susceptibility panels with Dalbavancin were compared to results obtained using the reference frozen broth microdilution panel (which was prepared in the original studies according to CLSI M07-A9 guidelines and included 0.002% polysorbate-80). Sensititre panels were prepared using an alternative method that was developed to provide comparable results to the reference method containing polysorbate-80.

The following footnote was added to the Performance Information insert of the device labeling: *According to the FDA approved pharmaceutical antimicrobial agent package insert, polysorbate-80 should be used for testing freshly prepared or frozen microtiter trays with Dalbavancin. Dalbavancin on the Sensititre panel has been developed with an alternative method to provide equivalent performance to the reference method that contained polysorbate-80.*

All isolates were tested using the same 13 two-fold dilutions of Dalbavancin in both the Sensititre and reference panels. Dilutions tested were appropriate for the interpretive breakpoints established for the drug.

Test inocula were standardized using a spectrophotometric method; Sensititre panels were inoculated using the Autoinoculator and incubated at 34 to 36°C. Sensititre panels were read using the both the Vizion and the AutoRead methods. Reference panels were inoculated as outlined in the CLSI M07-A9 document and were read manually.

The device labeling indicates that the *Haemophilus influenzae/Streptococcus pneumoniae* MIC panels can be manually inoculated. However, this procedural option was not utilized for testing either the clinical isolates or the challenge isolates. Therefore, the following limitation was added to the device package insert: "*The performance of Dalbavancin with*

Streptococcus spp. was performed using the AIM autoinoculator. The use of an alternative inoculation system when testing Dalbavancin has not been evaluated."

Data from a total of 418 (clinical and challenge) *Streptococcus* spp. isolates that were tested using the AutoRead Method was reanalyzed using the current breakpoints in this submission. The isolates included 358 clinical isolates and 60 challenge isolates.
Results of the re-analyzed 418 *Streptococcus* spp. clinical and challenge isolates (including 189 *Streptococcus pyogenes* (Group A Beta-Hemolytic streptococci), 184 *Streptococcus agalactiae* (Group B Beta-Hemolytic streptococci) and 45 *Streptococcus anginosus* group are summarized in **Table 1.** There were no non-susceptible isolates tested based on the revised breakpoints and the potential very major error rate could not be determined.

Based on the lack of non-susceptible isolates, the following statement was applied to Dalbavancin testing in the device package insert: *The ability of the Sensititre system to detect resistance or non-susceptibility to antimicrobics as shown below is unknown because an insufficient number of resistant or non-susceptible strains were available at the time of comparative testing. If such a strain is observed, it should be submitted to a reference laboratory.*

Data from a total of 424 (clinical and challenge) *Streptococcus* spp. isolates that were tested using the Vizion digital reader was reanalyzed using the current breakpoints in this submission. The isolates included 364 clinical isolates and 60 challenge isolates. Results of the re-analyzed 424 *Streptococcus* spp. clinical and challenge isolates (including 189 *Streptococcus pyogenes* (Group A Beta-Hemolytic streptococci), 190 *Streptococcus agalactiae* (Group B Beta-Hemolytic streptococci) and 45 *Streptococcus anginosus* are summarized in **Table 2.**

Table 1: Performance of Clinical and Challenge Isolates by Species, AutoRead Method

	Total	#EA	%EA	Eval EA Total	Eval EA #	Eval EA %	#CA	%CA	#NS	#S	min[a]	maj[a,b]	vmj[a]
***S. pyogenes* and *S. agalactiae* (Beta-Hemolytic streptococci) ≤0.25 (S)**													
Clinical	323	311	96.3	323	311	96.3	323	100.0	0	323	N/A	0	N/A
Challenge	50	46	92.0	50	46	92.0	49	98.0	0	50	N/A	1	N/A
Combined	373	357	**95.7**	373	357	**95.7**	372	**99.7**	0	373	N/A	1	N/A
***S. anginosus* group[c] (Viridans) ≤0.25 (S)**													
Clinical	35	35	100.0	35	35	100.0	35	100.0	0	35	N/A	0	N/A
Challenge	10	10	100.0	10	10	100.0	10	100.0	0	10	N/A	0	N/A
Combined	45	45	**100.0**	45	45	**100.0**	45	**100.0**	0	45	N/A	0	N/A
All *Streptococcus* species													
Clinical	358	346	96.6	358	346	96.6	358	100.0	0	358	N/A	0	N/A
Challenge	60	56	93.3	60	56	93.3	59	98.3	0	60	N/A	1	N/A
Combined	418	402	**96.2**	418	402	**96.2**	417	**99.8**	0	418	N/A	1	N/A

N/A, Not applicable

[a]There are no intermediate or resistant interpretive criteria for Dalbavancin. The current absence of resistant isolates precludes defining any results other than "susceptible."

[b]These isolates would be considered potential major errors (a non-susceptible result obtained for a susceptible organism)

[c]Including the following species: *S. anginosus* (28), *S. constellatus* (9), *S. intermedius* (8).

EA – Essential Agreement
CA – Category Agreement
EVAL – Evaluable isolates
NS – Non-susceptible
maj – major discrepancies
vmj – very major discrepancies
min – minor discrepancies
S – Susceptible

Table 2: Performance of Clinical and Challenge Isolates by Species, Vizion

	Total	#EA	%EA	Eval EA Total	Eval EA #	Eval EA %	#CA	%CA	#NS	#S	min[a]	maj[a,b]	vmj[a]
***S. pyogenes* and *S. agalactiae* (Beta-Hemolytic streptococci) ≤0.25 (S)**													
Clinical	329	317	96.4	329	317	96.4	328	99.7	0	329	N/A	1	N/A
Challenge	50	46	92.0	50	46	92.0	49	98.0	0	50	N/A	1	N/A
Combined	379	363	**95.8**	379	363	**95.8**	377	**99.5**	0	379	N/A	2	N/A
***S. anginosus* group[c] (Viridans) ≤0.25 (S)**													
Clinical	35	35	100.0	35	35	100.0	35	100.0	0	35	N/A	0	N/A
Challenge	10	10	100.0	10	10	100.0	10	100.0	0	10	N/A	0	N/A
Combined	45	45	**100.0**	45	45	100.0	45	**100.0**	0	45	N/A	0	N/A
All *Streptococcus* species													
Clinical	364	352	96.7	364	352	96.7	363	99.7	0	364	N/A	1	N/A
Challenge	60	56	93.3	60	56	93.3	59	98.3	0	60	N/A	1	N/A
Combined	424	408	**96.2**	424	408	**96.2**	422	**99.5**	0	424	N/A	2	N/A

N/A, Not applicable
[a]There are no intermediate or resistant interpretive criteria for Dalbavancin. The current absence of resistant isolates precludes defining any results other than "susceptible."
[b]These isolates would be considered potential major errors (a non-susceptible result obtained for a susceptible organism)
[c]Including the following species: *S. anginosus* (28), *S. constellatus* (9), *S. intermedius* (8).

EA – Essential Agreement
CA – Category Agreement
EVAL – Evaluable isolates
NS – Non-susceptible
maj – major discrepancies
vmj – very major discrepancies
min – minor discrepancies
S – Susceptible

When applying the new breakpoint of ≤0.25 (S), the overall performance of *Streptococcus* spp. using the Autoread method demonstrated an EA of 96.2% and a CA of 99.8%. When evaluating Beta-Hemolytic streptococci (*S. pyogenes* and *S. agalactiae*), performance was acceptable with an EA of 95.7% and a CA of 99.7%. There was one potential major error (0.54%) for *S. agalactiae.* With *S. anginosus* group isolates, the combined EA and CA was 100%. The performance based on combined clinical and challenge data was acceptable. The overall performance when using the AutoRead method is shown in Table 1.

When applying the new breakpoint of ≤0.25 (S), the overall performance of *Streptococcus* spp. using the Vizion digital reader demonstrated an EA of 96.2% and a CA of 99.5%. When evaluating Beta-Hemolytic streptococci (*S. pyogenes* and *S. agalactiae*), performance was acceptable with an EA of 95.8% and a CA of 99.5%. There were two potential major errors (1.05%) for *S. agalactiae.* With *S. anginosus* group isolates, the combined EA and CA was 100%. The performance based on combined clinical and challenge data was acceptable. The overall performance when using the Vizion digital reader is shown in Table 2.

MIC Trending
An analysis of trending was conducted using the combined clinical and challenge data for each organism group. This trending calculation considers MIC values that are determined to be one or more doubling dilutions lower or higher compared to the reference method regardless of whether the device MIC values are on-scale. Results that are not clearly determined to be at least one dilution lower, at least one dilution higher or in exact agreement with the CLSI reference method are not considered in the trending analysis. Trending results were stratified by species to assess species-related trends. Species for which the difference between the percentage of isolates with higher or lower readings was ≥ 30 with a statistically significant confidence interval were considered to show evidence of trending.

The data demonstrated that there was an upward trend in the MIC of the Sensititre panel compared to the reference method. Re-analysis of the trending of results for the AutoRead Method indicated that 77.1% of isolates gave Sensititre results that were ≥ 1 MIC doubling dilution higher than the MIC determined using the reference method (containing 0.002% polysorbate-80) (Table 3). For the Vizion Read Method, re-analysis of the results indicated that 79.5% of isolates Sensititre results that were ≥ 1 MIC doubling dilution higher than the MIC determined using the reference method. For most isolates, the higher MIC reading did not result in a change in the categorical interpretation (susceptible vs. non-susceptible).

The following statement is included in the device package insert as a footnote to the interpretation table: "*Sensititre Dalbavancin MIC values for Streptococcus species tended to be one doubling dilution higher than the reference method"*.

The performance of the Sensititre panel for determination of MIC values for Dalbavancin was determined to be acceptable.

Table 3: Trending Re-analysis for *Streptococcus* spp. with Vizion and ARIS/Autoreader/OptiRead

Read Method	Organism	Total Evaluable for Trending	≥ 1 Dilution Lower No. (%)	Exact No. (%)	≥ 1 Dilution Higher No. (%)	Percent Difference (CI)	Trending Noted
Vizion	*S. pyogenes*	189	6 (3.2)	33 (17.5)	150 (79.4)	76.2	Yes High
	S. agalactiae	190	0 (0.0)	32 (16.8)	158 (83.2)	83.2	Yes High
	S. anginosus group	45	0 (0.0)	16 (35.6)	29 (64.4)	64.4	Yes High
Autoread	*S. pyogenes*	189	5 (2.6)	33 (17.5)	151 (79.9)	77.3	Yes High
	S. agalactiae	184	0 (0.0)	39 (21.2)	145 (78.8)	78.8	Yes High
	S. anginosus group	45	1 (2.2)	13 (28.9)	31 (68.9)	66.7	Yes High

Testing/Reporting MICs for Non-indicated Species. For this review, the interpretive criteria are applied to the organisms/organism groups according to the FDA STIC website. As required under 511A(2)(2)(B) of the Federal Food, Drug and Cosmetic Act, the following statement is included in the Warnings and Precautions section of the device labeling to address testing and reporting of non-indicated species:

> *The safety and efficacy of antimicrobial drugs, for which antimicrobial susceptibility is tested by this AST device, may or may not have been established in adequate and well controlled clinical trials for treating clinical infections due to microorganisms outside of those found in the indications and usage in the drug label. The clinical significance of susceptibility information in those instances is unknown. The approved labeling for*

specific antimicrobial drugs provides the uses for which the antimicrobial drug is approved.

2. Matrix Comparison:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The FDA and CLSI susceptibility interpretive criteria for Dalbavancin are listed in Table 4.

Table 4: FDA Recognized Interpretive Criteria for Dalbavancin

	Minimum Inhibitory Concentrations (µg/mL)[a]		
Organisms	**S**	**I**	**R**
Streptococcus spp. *β*-Hemolytic Group[b]	≤0.25	-	-
Streptococcus spp. Viridans Group[c]	≤0.25	-	-

S = Susceptible; I = Intermediate; R = Resistant
[a]FDA-Recognized Antimicrobial Susceptibility Test Interpretative Criteria Website https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm410971.htm
[b]Report only on *S. pyogenes*, *S. agalactiae* and *S. dysgalactiae*
[c]Report only on *S. anginosus* group (includes *S. anginosus*, *S. intermedius* and *S. constellatus*)

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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

To support the implementation of changes to FDA-recognized susceptibility test interpretive criteria (i.e., breakpoints), this submission included the breakpoint change protocol that was reviewed and accepted by FDA during review of K231988. This protocol addresses future revisions to device labeling in response to breakpoint changes that are recognized on the FDA STIC webpage (https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm410971.htm). The protocol outlined the specific procedures and acceptance criteria that Thermo Fisher intends to use to evaluate the Sensititre 20-24-hour *Haemophilus influenzae/Streptococcus pneumoniae* MIC or Breakpoint Susceptibility System with Dalbavancin in the dilution range of 0.0005-2µg/ml when revised breakpoints for dalbavancin are published on the FDA STIC webpage. The breakpoint change protocol included in K231988 indicated that if specific criteria are met, Thermo Fisher will update the dalbavancin device label to include (1) the new breakpoints, (2) an updated performance section after re-evaluation of data in this premarket notification with the new breakpoints, and (3) any new limitations as determined by their evaluation.