

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

A. 510(k) Number:

K143526

B. Purpose for Submission:

Addition of Oritavancin to the Sensititre HP MIC susceptibility plate for testing *Streptococcus* species

C. Measurand:

Oritavancin in the dilution range of 0.0005-8 µg/mL

D. Type of Test:

Quantitative Antimicrobial Susceptibility Test (AST), growth based fluorescence.

E. Applicant:

ThermoFisher Scientific

F. Proprietary and Established Names:

Sensititre Haemophilus influenza/Streptococcus pneumoniae MIC Susceptibility Plate

G. Regulatory Information:

1. Regulation section:

21 CFR 866.1640 Antimicrobial Susceptibility Test Powder

2. Classification:

Class II

3. Product code(s):

JWY – Manual Antimicrobial Susceptibility Test Systems

LRG – Instrument for Auto Reader & Interpretation of overnight susceptible systems

LTT – Panels, Test, Susceptibility, Antimicrobial

4. Panel:

83 - Microbiology

H. Intended Use:

1. Intended use(s):

The Sensititre *Haemophilus influenzae*/*Streptococcus pneumoniae* plates are *in vitro* diagnostic products for clinical susceptibility testing of *Haemophilus influenzae*, *Streptococcus pneumoniae* and *Streptococcus* species.

2. Indication(s) for use:

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 newly approved Oritavancin in the dilution range of 0.0005-8µg/mL to the Sensititre HP MIC Susceptibility plate for testing *Streptococcus* spp.

The approved primary “Indications for Use” and clinical significance for *Streptococcus* spp. is for the following species:

Streptococcus pyogenes

Streptococcus agalactiae

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

3. Special conditions for use statement(s):

Prescription use only

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

4. Special instrument requirements:

The Sensititre Autoinoculator/AIM

The Sensititre Optiread System

The Sensititre Vizion

I. Device Description:

Each plate is dosed with antimicrobial agents at appropriate dilutions. Results can be read manually by visual reading of growth or automatically on an ARIS[®] / Autoreader[®] / OptiRead[®] using fluorescence. The Sensititre Autoreader/OptiRead[®] system utilizes fluorescence technology. 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 plates are prepared with the substrate already added to the plate. Enzymatic action of the bacterial surface enzymes on the specific substrates cleaves this bond releasing the fluorophore, which is now capable of fluorescence. The amount of fluorescence detected is directly related to the activity of the bacterial surface enzymes and, therefore, to the bacterial growth.

J. Substantial Equivalence Information:

1. Predicate device name(s):

MICroSTREP plus Panel

2. Predicate 510(k) number(s):

K021184

3. Comparison with predicate:

Table 1. Comparison with the Predicate Device

Similarities		
Item	Device	Predicate
Intended Use	The Sensititre Haemophilus influenzae/Streptococcus pneumoniae (HP) MIC Susceptibility plate is an <i>in vitro</i> diagnostic product for clinical susceptibility testing of Haemophilus influenzae: <i>Streptococcus pneumoniae</i> and <i>Streptococcus</i> species.	MICroSTREP plus panel is designed for use for <i>in vitro</i> for clinical susceptibility testing of <i>Streptococcus</i> including <i>Streptococcus pneumoniae</i> .
Test Panel	Each 96 well plate is precision dosed with selected antimicrobial agents and substrate for the fluorescent reads, then dried. The bacterial	Antimicrobial agents are precision dosed into 96 wells and combined with culture media in the panel then dried. The bacterial standardized suspension is

Similarities		
Item	Device	Predicate
	suspension in the appropriate broth is used to rehydrate the plate	used to rehydrate the panel.
Test Organisms	<i>Streptococcus</i> spp.	Same
Incubation	20-24 hours	Same
Specimen	Isolated colonies from pure culture	Same
Incubation Temperature	34-36° C	Same

Differences		
Item	Device	Predicate
Product Name	Sensititre Haemophilus/ <i>Streptococcus</i> pneumoniae (HP) MIC Susceptibility Plates	MICroSTREP plus panel k021184
Instrumentation	Each plate is dosed with antimicrobial agents at appropriate dilutions and inoculated with standardized organism suspension. Results can be read automatically on ARIS®/Autoreader®/OptiRead® using fluorescence or manually on the Vizion or a manual viewer, by visual reading of growth.	The MICroSTREP plus panel is inoculated with a standardized organism suspension, incubated in a non-CO2 incubator, and visually read.
Antibiotic/Assay	Oritavancin	Clindamycin
Reading method	Fluorescence	Organism growth

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

1. Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071462.pdf>
2. Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically, Approved Standard-9th Edition, Document M07-A9
3. Performance Standards for Antimicrobial Susceptibility Testing - 24th Informational Supplement, M100-S24 (QC parameters only)

L. Test Principle:

The Sensititre 20-24 hour *Haemophilus influenzae*/*Streptococcus pneumoniae* MIC Susceptibility plates are multi-well plastic microtiter plates that contain doubling dilution of antibacterial agents. Each plate includes antimicrobial agents at appropriate dilutions. Results can be read manually by visual reading of growth or automatically on an AutoReader via fluorescence.

The Sensititre AutoReader /OptiRead System utilize fluorescence technology to read the micro-broth 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 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 enzymatic action of the bacterial surface enzymes on the bound non-fluorescent substrate cleaves the bond releasing the 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 pneumoniae and *Streptococcus* spp. plates can either be read manually or automatically on the AutoReader /ARIS/OptiRead. *Haemophilus influenzae* can only be read on the Vizion or manual viewer.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

A reproducibility study was conducted at three study sites using 24 *Streptococcus* spp consisting of 1 *S. anginosus*, 1 *S. dysgalactiae*, 10 *S. pyogenes*, and 12 *S. agalactiae*. The Sensititre plates were inoculated by the Sensititre Autoinoculator/AIM. The organisms were tested one time at each of three sites for each reading method (Vizion for manual, OptiRead for automated read). The mode MIC value was determined and the reproducibility was calculated based on MICs falling within ± 1 dilution of the mode MIC value. The reproducibility was 97.2% for the manual (Vizion) and 95.8% for the automated (Optiread) reading methods. The testing resulted in overall reproducibility results of greater than 95% for both Manual and Automated read methods. The results were acceptable.

b. *Linearity/assay reportable range:*

Not applicable

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

The organism recommended by both the FDA (CDER) and the CLSI, *S. pneumoniae* ATCC 49619 was tested against Oritavancin. Quality control was performed at all sites using the Sensititre Autoinoculator/AIM for inoculation, read by the manual (i.e. Vizion) and the automated (i.e. OptiRead) read methods. Table 2 below represents the frequency of the results and all results were in acceptable range.

Table 2. Summary of Quality Control Results for Oritavancin for Fastidious Organisms

ORGANISMS	Oritavancin (µg/mL)	Reference Manual Read	Sensititre- Read Method	
			Optiread	Manual (Vizion)
<i>S. pneumoniae</i> ATCC 49619 0.004-0.015 µg/mL	0.0005	0	0	0
	0.001	25% (15/60)	63.3% (38/60)	65%(39/60)
	0.002	65% (39/60)	30%(18/60)	30%(18/60)
	0.004	10%(6/60)	6.6%(4/60)	5%(3/60)
	0.008	0	0	0

Quality Control results for the Sensititre Susceptibility System using either reading methods demonstrated that the system could produce the expected quality control results. The quality control (QC) results with *S. pneumoniae* ATCC 49619 were within the expected range >95% of the time but a downward MIC trend of Sensititre Susceptibility System was observed compared to the reference method. For the manual read (the primary method used in the clinical study) almost 65% of the QC reference MIC results are at 0.002µg/mL, while 65% of the Sensititre Susceptibility System manual read QC results are at 0.001µg/mL. For the Automated reading method 63.3% of the QC MIC results are at 0.001µg/mL. This MIC trend was addressed by adding a footnote in the labeling.

The quality control results are acceptable.

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:*

Performance was established through a clinical study which was conducted at three sites. Studies have been conducted with the Sensititre dried susceptibility plates containing Oritavancin to test susceptibility Gram positive isolates (Sensititre *Streptococcus* spp. HP MIC plate). The CLSI microdilution reference methods with 0.002% Polysorbate 80 containing the same antimicrobial in the same dilutions were used for a comparison and evaluation of performance. 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 Oritavancin. Oritavancin 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 Oritavancin in both the Sensititre and reference panels. Dilutions tested were appropriate for the interpretive breakpoints established for the drug.

The performance of Oritavancin with *Streptococcus* spp was performed using the Aim autoinoculator. The inoculum was prepared using the Sensititre Nephelometer which was calibrated at the start of each test. Plates were inoculated and incubated at 35° C. The reading was done automatically on the Optiread and manually using the Vizion at 20-24 hours.

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 sponsor was asked to include a limitation in the device package insert stating the following:

“The performance of Oritavancin with Streptococcus spp. was performed using the AIM autoinoculator. The use of an alternative inoculation system when testing Oritavancin has not been evaluated.”

For the manual read, clinical testing was performed on 411 *Streptococcus* spp (165 *Streptococcus pyogenes*, 165 *Streptococcus agalactiae* and 44 *Streptococcus anginosus* and 37 *Streptococcus dysgalactiae*).

For the Auto Read, clinical testing was performed on 410 *Streptococcus* spp. (164 *Streptococcus pyogenes*, 165 *Streptococcus agalactiae*, 44 *Streptococcus anginosus* and 37 *Streptococcus dysgalactiae*). All were freshly collected clinical isolates; no stock isolates were tested during the clinical studies.

In addition, testing was performed on 65 *Streptococcus* spp. stock challenge isolates (25 *Streptococcus pyogenes*, 25 *Streptococcus agalactiae*, 10 *Streptococcus anginosus* and 5 *Streptococcus dysgalactiae*) for both automated and manual Read. The performance evaluations are shown in table 3-7 below.

Footnotes for Tables 3-6:

^a There are no intermediate or resistant interpretive criteria for Oritavancin. The current absence of resistant isolates precludes defining any results other than “Susceptible.”

^b The number of potential major errors.

^c These isolates would be considered potential very major errors (i.e. false susceptible)

Table 3. Overall Performance of Clinical and Challenge Isolates, Automated Read Method

	Tot	No. EA	EA %	Eval Tot	No. Eval EA	Eval EA %	No. CA	CA %	No. NS	No. S	min ^a	maj ^{a,b}	vmj ^c
Clinical	410	385	93.9	401	376	93.8	395	96.3	29	381	N/A	5	10
Challenge	65	65	100	65	65	100	58	89.2	5	60	N/A	4	3
Combined	475	450	94.7	466	441	94.6	453	95.4	34	441	N/A	9	13

Table 4. Trek Oritavancin Performance of Clinical and Challenge Isolates by Species, Automated Read (Optiread)

	TOT	EA N	EA %	Eval Tot	Eval EA N	Eval EA %	CA N	CA %	No. NS	min ^a	maj ^{a,b}	vmj ^c
<i>Streptococcus pyogenes</i>												
Clinical	164	156	95.1	164	156	95.1	153	93.3	12	N/A	5	6
Challenge	25	25	100	25	25	100	22	88	2	N/A	1	2
Combined	189	181	95.8	189	181	95.8	175	92.6	14	N/A	6	8
<i>Streptococcus agalactiae</i>												
Clinical	165	152	92.1	165	152	92.1	165	100	3	N/A	0	0
Challenge	25	25	100	25	25	100	23	92	1	N/A	1	1
Combined	190	177	93.2	190	177	93.2	188	98.9	4	N/A	1	1
<i>Streptococcus dysgalactiae</i>												
Clinical	37	36	97.3	34	33	97.05	33	89.2	12	N/A	0	4
Challenge	5	5	100	5	5	100	4	80	2	N/A	1	0
Combined	42	41	97.6	39	38	97.4	37	88.1	14	N/A	1	4
<i>Streptococcus anginosus</i> grp (<i>S. anginosus</i> , <i>S. intermedius</i> , and <i>S. constellatus</i>)												
Clinical	44	41	93.2	36	39	92.3	44	100	2	N/A	0	0
Challenge	10	10	100	10	10	100	9	90	0	N/A	1	0
Combined	54	51	94.4	46	49	93.9	53	98.1	2	N/A	1	0

Table 5. Overall Performance of Clinical and Challenge Isolates, Manual Read Method

	Tot	EA N	EA %	Eval EA Tot	Eval EA N	Eval EA %	CA N	CA %	No. NS	No. S	min ^a	maj ^{a,b}	vmj ^c
Clinical	411	385	93.7	403	377	93.5	397	96.6	29	382	N/A	4	10
Challenge	65	64	98.5	65	64	98.5	58	89.2	5	60	N/A	4	3
Combined	476	449	94.3	468	441	94.2	455	95.6	34	442	N/A	8	13

Table 6. Trek Oritavancin Performance of Clinical and Challenge Isolates by Species, Manual Read (Vizion)

	TOT	EA N	EA %	Eval Tot	Eval EA N	Eval EA %	CA N	CA %	No. NS	min ^a	maj ^{a,b}	vmj ^c
<i>Streptococcus pyogenes</i>												
Clinical	165	154	93.3	165	154	93.3	155	93.9	12	N/A	4	6
Challenge	25	24	96	25	24	96	22	88	2	N/A	1	2
Combined	190	178	93.7	190	178	93.7	177	93.2	14	N/A	5	8
<i>Streptococcus dysgalactiae</i>												
Clinical	37	36	97.3	32	33	97.0	33	89.2	12	N/A	0	4
Challenge	5	5	100	5	5	100	4	80	2	N/A	1	0
Combined	42	41	97.6	37	38	97.4	37	88.1	14	N/A	1	4
<i>Streptococcus agalactiae</i>												
Clinical	165	154	93.3	165	154	93.3	165	100	3	N/A	0	0
Challenge	25	25	100	25	25	100	23	92	1	N/A	1	1
Combined	190	179	94.2	190	179	94.2	188	98.9	4	N/A	1	1
<i>Streptococcus anginosus group (S. anginosus, S. intermedius, and S. constellatus)</i>												
Clinical	44	41	93.2	37	40	92.5	44	100	2	N/A	0	0
Challenge	10	10	100	10	10	100	9	90	0	N/A	1	0
Combined	54	51	94.4	47	50	94	53	98.1	2	N/A	1	0

EA-Essential Agreement CA-Category Agreement NS-not susceptible

Essential agreement (EA) is when the Sensititre panels agree with the reference test panel results exactly or within one doubling dilution of the reference method. Category agreement (CA) is when the Sensititre panel result interpretation agrees exactly with the reference panel result interpretation. Evaluable EA is when the MIC result is on scale for both the Sensititre and the reference and have on-scale EA.

The EA% is acceptable when compared to the reference method as described in the FDA AST Special Controls Guidance.

EA and CA for all organisms were greater than 90% as shown in Table 7 below. In accordance with the FDA AST Special Controls Guidance, the CA of *S. dysgalactiae* of 88.1% was considered acceptable because of very good EA of the evaluable test results of 97.4%.

Table 7. Performance of Sensititre Panels Read on the Optiread and on the Vizion

ORGANISMS	Number of isolates tested	% EA	% CA
Automated Read Method-Optiread			
<i>S. agalactiae</i>	190	93.2	98.9
<i>S. pyogenes</i>	189	95.8	92.6
<i>S. dysgalactiae</i>	42	97.6	88.1
<i>S. anginosus</i>	54	94.4	98.1
Manual Read Method-Vizion			
<i>S. agalactiae</i>	190	94.2	98.9
<i>S. pyogenes</i>	190	93.7	93.2
<i>S. dysgalactiae</i>	42	97.6	88.1
<i>S. anginosus</i>	54	94.4	98.1

For manual reading method, the combined data from clinical and challenge study demonstrated that there were 21 categorical errors; 13 of which were *S. pyogenes*, two of which were *S. agalactiae*, five of which were *S. dysgalactiae*, and one was *S. anginosus*.

For the automated reading method, the combined data from clinical and challenge study demonstrated that there were 22 categorical errors; two of which were *S. agalactiae*, 14 were *S. pyogenes*, five were *S. dysgalactiae*, and one was *S. anginosus*.

Currently, there are no intermediate or resistance interpretative criteria for Oritavancin. The data was analyzed for major (maj) and very major (vmj) errors only, considering any false susceptible as vmj error and any false non-susceptible as maj error. An analysis was conducted to calculate the vmj error (i.e. false susceptible) as described in Table 8 below.

Table 8. Analysis of False Susceptible Results

Organism	Total # of NS by reference method	# vmj (false susceptible)	% of false susceptible	# within EA
Manual Read				
<i>S. agalactiae</i>	4	1	25	1
<i>S. pyogenes</i>	14	8	57.2	6
<i>S. dysgalactiae</i>	14	4	28.6	4
<i>S. anginosus</i>	2	0	0	NA
Total	34	13	38.2	11
AutoRead				
<i>S. agalactiae</i>	4	1	25	1
<i>S. pyogenes</i>	14	8	57.2	7
<i>S. dysgalactiae</i>	14	4	28.6	4
<i>S. anginosus</i>	2	0	0	NA
Total	34	13	38.2	11

We observed that there is a high rate of false susceptible in *S. agalactiae*, *S. pyogenes* and *S. dysgalactiae* by both manual and automated reading methods. Using the data provided by the sponsor in the diagonal table format recommended in the AST Guidance, the majority of the vmj error (i.e. false susceptible) were observed when the Sensititre MIC is at 0.25 µg/mL and the reference method is at one double doubling dilution (MIC 0.5 µg/mL). Due to the lack of an intermediate interpretation for this drug, there is a high potential for occurrence of very major error for *S. agalactiae*, *S. pyogenes* and *S. dysgalactiae* that could otherwise be considered minor

errors if an intermediate category existed. Any *Streptococcus* isolates that yield MIC results 0.25 µg/mL for Oritavancin should be submitted to a reference laboratory for additional testing.

The potential for occurrence of vmj error(s) for Oritavancin when testing *Streptococcus* spp was addressed by adding the following limitation in labeling:

“Due to the lack of an intermediate and resistant interpretations for Oritavancin, there is a potential very major error rate. There were 13 isolates out of 34 non susceptible isolates that reported one doubling dilution lower than the reference. Use an alternative testing method prior to reporting results for Streptococcus spp. with Oritavancin when the Sensititre MIC is 0.25µg/mL (breakpoint) if critical to patient care”.

MIC Trend Analysis:

Using the data provided by the sponsor in the diagonal table format recommended in the AST Guidance, an analysis was conducted to check for trending in MIC values.

A lower reading trend was observed in the overall performance of *Streptococcus* spp in both manual and automated reading methods compared to the CLSI broth micro-dilution method, which raises concerns for potential very major errors as summarized in Table 9 below.

Table 9. Trending of Results by Automated Read Method in Combined Clinical and Challenge Study

Organism	Difference in MIC as Compared to the CLSI Reference Method					
	-3	-2	-1	0	+1	+2
<i>S. agalactiae</i>	0.52% (1/190)	6.31% (12/190)	64.21% (122/190)	23.15% (44/190)	5.78% (11/190)	0
<i>S. pyogenes</i>	1% (2/189)	2.1% (4/189)	52.4% (99/189)	25.4% (48/189)	17.9% (34/189)	1% (2/189)
<i>S. anginosus</i>	3.7% (2/54)	1.9% (1/54)	57.4% (31/54)	27.7% (15/54)	9.3% (5/54)	NA
<i>S. dysgalactiae</i>	0	2.4% (1/42)	50% (21/42)	33.3% (14/42)	14.3% (6/42)	0
Total	5 (1.2%)	18 (4.2%)	273 (63%)	121 (27.9%)	56 (12.9%)	2 (0.5%)

Table 10. Trending of Results by Manual Method in Combined Clinical and Challenge Study

Organism	Difference in MIC as Compared to the CLSI Reference Method					
	-3	-2	-1	0	+1	+2
<i>S. agalactiae</i>	1	5.3 (10/190)	63.15 (120/190)	22.63 (43/190)	8.42 (16/190)	0
<i>S. pyogenes</i>	4	3.68 (7/190)	54.21 (103/190)	24.73 (47/190)	14.73 (28/190)	0.52 (1/190)
<i>S. dysgalactiae</i>	0	2.4 (1/42)	57.14 (24/42)	30.95 (13/42)	9.52 (4/42)	0
<i>S. anginosus</i>	3.7 (2/54)	1.85 (1/54)	57.4 (31/54)	31.48 (17/54)	5.55 (3/54)	0

Total	7 (1.5%)	19 (4.0%)	278 (58.4%)	120 (25.2%)	51 (10.7%)	1 (0.2%)
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This trending and the potential for occurrence of very major errors(s) for Oritavancin when testing *Streptococcus spp* was also addressed in labeling. This was addressed by adding the following footnote in the interpretation table in labeling:

“Sensititre Oritavancin MIC values for fastidious gram positive organisms tended to be one doubling dilution lower in Streptococcus spp Manual and AutoRead compared to reference broth micro-dilution”.

“Streptococcus spp with an interpretation of non-susceptible for Oritavancin is uncommon in most institutions or may result from technical errors. Verify AST if this phenotype has not been previously encountered from this patient or institution”.

Growth Rate:

In the Automated Read the no growth rate was 0.5% (2/410) *S. pyogenes* and *S. dysgalactiae*.

In the Manal Read the no growth rate was 0.2 % (1/411) *S. dysgalactiae*.

The growth rate for the manual and automated reading methods was greater than 90%; this meets the acceptance criteria of $\leq 10\%$ non-growth of organisms tested.

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:

The FDA interpretative criteria were used to evaluate all performance data:

Table 11. FDA Interpretive Criteria for Oritavancin

Organism	Interpretive Criteria (Oritavancin MIC in µg/mL)		
	S	I	R
<i>Streptococcus agalactiae</i> , <i>Streptococcus pyogenes</i> , <i>Streptococcus anginosus</i> <i>Streptococcus dysgalactiae</i>	≤0.25	-	-

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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