

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

A. 510(k) Number:

K143288

B. Purpose for Submission:

Addition of Oritavancin to the Sensititre 18-24 hour MIC susceptibility system for testing non-fastidious Gram positive organisms

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:

Thermo Fisher Scientific

F. Proprietary and Established Names:

Sensititre Susceptibility plates

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[®] MIC and Breakpoint Susceptibility system is an *in vitro* diagnostic product for clinical susceptibility testing of non-fastidious Gram negative isolates, comprising of *Enterobacteriaceae*, *Pseudomonas aeruginosa*, and other non-*Enterobacteriaceae* and of non-fastidious Gram positive isolates, comprising of *Staphylococcus* sp., *Enterococcus* sp., and Beta haemolytic *Streptococci* other than *S. pneumoniae*. The Sensititre[®] ESBL confirmatory test plate is an *in vitro* diagnostic product for detection of ESBLs in clinical isolates of *Klebsiella pneumoniae*, *Klebsiella oxytoca* and *Escherichia coli*. MIC and ESBL plates can either be read manually or automatically on the Sensititre Autoreader[®] / OptiRead[®] and/or ARIS[®]. TREK Diagnostic Systems products have only been validated with TREK manufactured broths.

2. Indication(s) for use:

The Sensititre 18-24 hour MIC or Breakpoint Susceptibility System is an *in vitro* diagnostic product for clinical susceptibility testing of non-fastidious isolates.

This 510 (k) is for the newly approved Oritavancin, in the dilution range of 0.0005-8 µg/mL for testing non-fastidious gram positive organisms on the Sensititre 18-24 hour MIC panel.

The approved primary “Indications for Use” and clinical significance for non-fastidious Gram positive isolates:

Staphylococcus aureus (including methicillin-resistant [MRSA] and methicillin susceptible (MSSA) isolates)

Enterococcus faecalis (vancomycin-susceptible isolates only)

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 for further testing.

The performance of Oritavancin with *S. aureus* and *E. faecalis* was performed using the AIM Autoinoculator. The use of an alternative inoculation system when testing Oritavancin has not been evaluated.

Due to the lack of intermediate and resistant interpretations for Oritavancin, there is a potential very major error rate. There were 3 isolates out of 9 non-susceptible isolates that reported one doubling dilution lower than the reference. Use an alternative testing method prior to reporting results for *Enterococcus faecalis* and *Staphylococcus aureus* with Oritavancin when the Sensititre MIC is 0.12µg/mL (breakpoint) if critical to patient care”.

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. 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):

MicroScan[®] Dried Gram-Negative and Gram Positive MIC/Combo Panels.

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

k010159

3. Comparison with predicate:

Table 1. Comparison of the Sensititre 18-24 h with the Predicate Device

Similarities		
Item	Device	Predicate
Test Panel	Each 96 well plate is precision 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	Antimicrobial agents are precision dosed into 96 wells and combined with culture media in the panel then dried. The bacterial standardized suspension is used to rehydrate the panel.
Intended Use	The Sensititre MIC or Breakpoint Susceptibility system is an in vitro diagnostic product for clinical susceptibility testing.	MicroScan panels are designed for use in determining antimicrobial agent susceptibility for gram positive isolates, gram negative isolates.
Test Organisms	Non-fastidious gram positive isolates from culture	Non-fastidious gram positive and gram negative isolates

Differences		
Item	Device	Predicate
Product Name	Sensititre™ 18-24 hour Susceptibility System <i>S. aureus</i> , <i>E. faecalis</i> Oritavancin	MicroScan®, Dried Gram Negative and Gram-Positive MIC/Combo Panels K010159
Antibiotic/Assay	Oritavancin	Gatifloxacin
Incubation	18-24 hours	16-20 hours
Reading method	Automated OptiRead by detection of fluorescence. Or by reading of growth on the Vizion.	Organism growth read visually or by MicroScan instrumentation
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.	MicroScan®, Dried Gram-Negative and Gram-Positive MIC/Combo panel is inoculated with a standardized organism suspension, incubated in a non-CO2 incubator, and visually read or read by MicroScan instrumentation

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/ucmO71462.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:

Sensititre susceptibility plates are multi-well plastic microtiter plates that contain doubling dilutions of antibacterial agents. Each plate is dosed with antimicrobial agents at appropriate dilutions. Results can be read manually by visual reading of growth or automatically on an Autoreader[®] using fluorescence. The Sensititre Autoreader system utilizes fluorescence technology which 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 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 the substrate already added to the plate. The nonfluorescent substrate is prepared by conjugating a fluorescent compound to the specific enzyme substrates with a bond, which prevents fluorescence (i.e. the fluorophore is quenched in this state). 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 bacterial growth.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

- a. *Precision/Reproducibility:*

A reproducibility study was conducted at three study sites Non-fastidious Gram positive isolates (37) were tested at each site on the Sensititre 18-24 hour Susceptibility System only. Due to insufficient reproducibility isolates tested, based on "Indications for Use" as per the FDA, two studies labeled study 1 and study 2 were included as recommended by the pre-submission (Q141181). Study 1, consisted of 15 gram positive organisms (9 *S. aureus*, 6 *E. faecalis*) and study 2 consisted 22 gram positive organisms (13 *S. aureus*, 9 *E. faecalis*). Testing was performed using Sensititre plates only, read manually and automatically (18-20 hours). *Staphylococcus aureus* (including methicillin-resistant (MRSA) and methicillin-susceptible (MSSA)

isolates), *Enterococcus faecalis* (Vancomycin-susceptible isolates only).

Results were read by the automated read [Study 1 (AutoReader), Study 2 (OptiRead)] and by reading on the Vizion.

Reproducibility was calculated as the percent of results for the combined sites which were within +/- one doubling dilution of the mode MIC value for all sites.

For the sake of reproducibility calculations, off-scale values are handled in two ways; "best case" and "worst case" scenarios. Best case calculation for reproducibility assumes the off-scale result is within one well from the mode MIC value. Worst case calculation for reproducibility assuming the off-scale result is greater than one well from the mode MIC value. There were no off-scale results in this study. So, only one value for overall reproducibility is reported for each reading method.

For reading on the Vizion, the reproducibility in study 1 was 97.7%, and 95.4% in study 2. The overall reproducibility combined in Study 1 and Study 2 (supplemental study) was 96.4% for both *S. aureus* and *E. faecalis*.

For the automated read the AutoReader was utilized in Study 1 with a reproducibility of 97.7% and the OptiRead was utilized in Study 2 with a reproducibility of 95.4% for both *S. aureus* and *E. faecalis*.

The results were acceptable.

b. Linearity/assay reportable range:

Not applicable

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

The FDA (CDER) and CLSI recommended QC isolates were tested on every test occasion with the reference method and the Sensititre. The reference method QC results were in range for every day tested. The Sensititre Susceptibility plate was tested a sufficient number of times to demonstrate that the system can produce QC results in the recommended range.

Quality Control was performed at all sites using the Sensititre Autoinoculator/AIM for inoculation, read by the 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 Non-Fastidious Organisms

ORGANISMS	Oritavancin (µg/mL)	Reference Manual Read	Sensititre- Read Method	
			Optiread	Vizion
<i>S. aureus</i> ATCC 29213 0.015-0.12µg/mL	0.008	0	0	0
	0.015	5% (3/60)	0	0
	0.03	70% (42/60)	1.6% (1/60)	6.6% (4/60)
	0.06	16.6% (10/60)	76.6% (46/60)	78.3% (47/60)
	0.12	8.3%(5/60)	21.6% (13/60)	15% (9/60)
	0.25	0	0	0
<i>E. faecalis</i> ATCC 29212 0.008-0.03µg/mL	0.004	0	0	0
	0.008	65% (39/60)	55% (33/60)	65% (39/60)
	0.015	30% (18/60)	30% (18/60)	21.6% (13/60)
	0.03	5% (3/60)	15% (9/60)	13.3% (8/60)
	0.06	0	0	0

Quality Control (QC) results for the Sensititre Susceptibility System using either reading methods demonstrated that the system could produce the expected quality control results. The QC results with *S. aureus* ATCC 29213 were within the expected range >95% of the time but an upward MIC trend of Sensititre 18-24 hours was observed compared to the reference method. For the Vizion read (the primary method used in the clinical study) almost 70% of the QC reference MIC results are at 0.03µg/mL, while 78.3% of the Sensititre 18-24 hours manual read QC results are at 0.06µg/mL. For the automated read method 76.7% of the QC reference MIC results are at 0.06µg/mL. This MIC trend was addressed by adding a footnote in the labeling.

The QC 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 18-24 hour susceptibility 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.”

The performance of Oritavancin with Gram positive non-fastidious organisms 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 on the automated read (OptiRead) and manually using the Vizion at 18-24 hours.

The device labeling indicates that the 18-24 hour MIC panels Susceptibility System 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 S. aureus and E. faecalis was performed using the AIM Autoinoculator. The use of an alternative inoculation system when testing Oritavancin has not been evaluated.”

For both manual read and automated read, clinical testing was performed on 300 Gram positive isolates (179 *S. aureus* and 121 vancomycin susceptible *Enterococcus faecalis*). All were freshly collected clinical isolates. In addition, testing was

performed on 75 Gram positive stock challenge isolates (40 *S. aureus* and 35 vancomycin susceptible *Enterococcus faecalis*, VSE)

The clinical study included 89 Methicillin Susceptible *Staphylococcus aureus* (MSSA) and 90 Methicillin Resistant *Staphylococcus aureus* (MRSA); the challenge set was comprised of 20 MSSA and 20 MRSA resulting 109 MSSA and 110 MRSA.

The performance evaluations are shown in tables 3-6 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 (OptiRead)

	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	300	292	97.3	292	300	97.3	294	98.0	4	296	N/A	3	2
Challenge	75	75	100	75	75	100	73	97.3	5	70	N/A	2	1
Combined	375	367	97.9	367	375	97.9	367	97.9	9	366	N/A	5	3

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

	EA TOT	EA N	EA%	Eval EA Tot	Eval EAN	Eval EA%	CA N	CA%	No. NS	min ^a	maj ^{a,b}	vmj ^c
MSSA												
Clinical	89	86	96.6	89	86	96.6	86	96.6	2	N/A	2	1
Challenge	20	20	100	20	20	100	19	95	1	N/A	0	1
MRSA												
Clinical	90	89	98.9	90	89	98.9	89	98.9	2	N/A	1	0
Challenge	20	20	100	20	20	100	20	100	0	N/A	0	0
<i>S. aureus</i> (MRSA + MSSA)												
Clinical	179	175	97.8	179	175	97.8	175	97.8	4	N/A	3	1
Challenge	40	40	100	40	40	100	39	97.5	1	N/A	0	1
Combined	219	217	99.1	218	217	99.5	219	100	5	N/A	3	2
<i>Enterococcus faecalis</i> (vancomycin susceptible isolates only)												
Clinical	121	117	96.7	117	121	96.7	119	98.3	0	N/A	2	0
Challenge	35	35	100	35	35	100	34	97.1	4	N/A	0	1
Combined	156	152	97.4	152	156	97.4	153	98.1	4	N/A	2	1

Table 5. Overall Performance of Clinical and Challenge Isolates, Vizion 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	300	293	97.7	293	300	97.7	294	98	4	296	N/A	5	1
Challenge	75	75	100	75	75	100	73	97.3	5	70	N/A	0	1
Combined	375	368	98.1	375	368	98.1	367	97.9	9	366	N/A	5	2

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

	EA TOT	EA N	EA%	Eval EA Tot	Eval EA N	Eval EA%	CA N	CA%	No. NS	min ^a	maj ^{a,b}	vmj ^c
MSSA												
Clinical	89	86	96.6	89	86	96.6	85	95.5	2	N/A	3	1
Challenge	20	20	100	20	20	100	19	95	1	N/A	0	1
MRSA												
Clinical	90	89	98.9	90	89	98.9	90	100	2	N/A	0	0
Challenge	20	20	100	20	20	100	20	100	0	N/A	0	0
S. aureus (MRSA + MSSA)												
Clinical	179	175	97.8	179	175	97.8	175	97.8	4	N/A	3	1
Challenge	40	40	100	40	40	100	39	97.5	1	N/A	0	1
Combined	219	215	98.2	219	215	98.2	214	97.7	5	N/A	3	2
Enterococcus faecalis (vancomycin susceptible only)												
Clinical	121	118	97.5	118	121	97.5	119	98.3	0	N/A	2	0
Challenge	35	35	100	35	35	100	34	97.1	0	N/A	0	0
Combined	156	153	98.1	153	156	98.1	153	98.1	0	N/A	2	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 guidance document, "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA".

EA and CA for all organisms were greater than 90% as shown in Table 7 below.

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

ORGANISMS	Number of isolates tested	% EA	% CA
Optiread			
<i>S. aureus</i>	219	99.1	100
<i>E. faecalis</i>	156	97.4	98.1
Vizion			
<i>S. aureus</i>	219	98.2	97.7
<i>E. faecalis</i>	156	98.1	98.1

For manual reading method in combined clinical and challenge study; there are 8 categorical errors; three of which were *E. faecalis*, five were *S. aureus*.

For the automated read method in combined clinical and challenge study; there are 8 categorical errors; three of which were *E. faecalis* and five were *S. aureus*.

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
OptiRead				
<i>E. faecalis</i>	4	1	25	1
<i>S. aureus</i>	5	2	40	2
Vizion				
<i>E. faecalis</i>	4	1	25	1
<i>S. aureus</i>	5	2	40	2

We observed that there is a high rate of false susceptible in *E. faecalis* and *S. aureus* both Vizion and OptiRead 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 0.12 µg/mL and the reference method is at one double doubling dilution (MIC 0.25 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. aureus* and *E. faecalis* that could otherwise be considered minor errors if an intermediate category existed. Any *S. aureus* and *E. faecalis* isolates that yield MIC results 0.12 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 *S. aureus* and *E. faecalis* was addressed by adding the following limitation in labeling:

“Due to the lack of intermediate and resistant interpretations for Oritavancin, there is a potential very major error rate. There were 3 isolates out of 9 non-susceptible isolates that reported one doubling dilution lower than the reference. Use an alternative testing method prior to reporting results for Enterococcus faecalis and Staphylococcus aureus with Oritavancin when the Sensititre MIC is 0.12µg/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 higher reading trend was observed in the overall performance of *S. aureus* in both manual and automated read methods compared to the CLSI broth micro-dilution method, which raises concerns for potential major errors as summarized in Table 9 and 10 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
MRSA	0	0	8.2% (9/110)	30% (33/110)	60.9% (67/110)	0.9% (1/110)
MSSA	0	0	5.5% (6/109)	27.5% (30/109)	64.2% (70/109)	1.8% (3/109)
Total	0	0	6.8% (15/219)	28.7% (63/219)	62.5% (137/219)	1.8% (4/219)

Table 10. Trending of Results by Vizion 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
MRSA	0	0	7.3% (8/110)	33.6% (37/110)	58.2% (64/110)	0.9% (1/110)
MSSA	0	0	5.5% (6/109)	29.4% (32/109)	62.4% (68/109)	0.9% (3/109)
Total	0	0	6.4% (14/219)	31.5% (69/219)	60.2% (132/219)	1.8% (4/219)

This trending and the potential for occurrence of major errors(s) for Orivancin when testing *S.aureus* was addressed in labeling. This was addressed by adding the following footnote in the interpretation table in labeling:

“Sensititre Oritavancin MIC values for non-fastidious gram positive organisms tended to be one doubling dilution higher in S. aureus Manual and AutoRead compared to reference broth micro-dilution. S. aureus 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 manual and automated read the no growth rate was 0.3% (1/313) MSSA

The growth rate for the manual and automated read 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:

Table 11. FDA Interpretive Criteria for Oritavancin

Organism	Interpretive Criteria (Oritavancin MIC in $\mu\text{g/mL}$)		
	S	I	R
<i>S. aureus</i> (MSSA, MRSA)	≤ 0.12	-	-
<i>E. faecalis</i> (VSE only)	≤ 0.12	-	-

Currently, there are no intermediate or resistance interpretative criteria for Oritavancin

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.