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

A. 510(k) Number:

K183415

B. Purpose for Submission:

To obtain a substantial equivalence determination for imipenem at concentrations of 0.25 – 16 µg/mL for susceptibility testing of gram-negative aerobic organisms on the VITEK 2 and VITEK 2 Compact Antimicrobial Susceptibility Test (AST) Systems.

C. Measurand:

Imipenem 0.25 – 16 µg/mL

D. Type of Test:

Automated quantitative antimicrobial susceptibility (AST)

E. Applicant:

bioMérieux, Inc.

F. Proprietary and Established Names:

VITEK 2 AST-Gram Negative Imipenem (≤0.25 - ≥16 µg/mL)

G. Regulatory Information:

1. Regulation section:

   21 CFR 866.1645 Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System

2. Classification:

   Class II

3. Product code:

   LON – Fully automated short-term incubation cycle antimicrobial susceptibility system

LTW – Susceptibility Test Cards, Automated

LTT – Panels, Test, Susceptibility, Automated

4. Panel:

83 Microbiology

H. Intended Use:

1. Intended use(s):

The VITEK 2 Gram-negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.

2. Indication(s) for use:

VITEK 2 AST-Gram Negative Imipenem is designed for antimicrobial susceptibility testing of Gram negative bacilli and is intended for use with the VITEK 2 and VITEK 2 Compact Systems as a laboratory aid in the determination of in vitro susceptibility to antimicrobial agents. VITEK 2 AST Gram Negative Imipenem is a quantitative test. Imipenem has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial.

Active in vitro and in clinical infections:
Acinetobacter spp.
Citrobacter spp.
Enterobacter cloacae/E. cloacae complex
Escherichia coli
Klebsiella spp.
Pseudomonas aeruginosa

The VITEK 2 Gram-negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.

3. Special conditions for use statement(s):

Prescription use only

Limitations

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combinations:
Imipenem (ipm05n): Klebsiella (*Enterobacter*) *aerogenes, Proteus species, Providencia species, Morganella species and Serratia species.*

4. Special instrument requirements:

VITEK 2 and VITEK 2 Compact Systems

I. Device Description:

The VITEK® 2 AST card is a miniaturized, abbreviated and automated version of the doubling dilution technique for determining the minimum inhibitory concentration (MIC). Each VITEK® 2 AST card contains 64 wells. A control well(s) which contain only nutrient medium is resident on all cards. The remaining wells contain premeasured portions of antimicrobials combined with the nutrient media. The isolate to be tested is diluted to a standardized concentration with 0.45% to 0.50% saline before being used to rehydrate the antimicrobial medium within the card. The VITEK 2 System will automatically dilute the bacterial suspension to prepare an inoculum for susceptibility cards. Then the VITEK® 2 will fill, seal and place the card into the incubator/reader. The VITEK 2 Compact has a manual filling, sealing and loading operation. The VITEK 2 Systems monitor the growth of each well in the card over a defined period of time (up to 24 hours for *Streptococcus* species). The analysis program determines when a well demonstrates growth based on attenuation of light measured by an optical scanner. This data is used to determine the minimum inhibitory concentration or MIC values for the anti-microbial agent. At the completion of the incubation cycle, a report is generated that contains the MIC value along with the interpretive category result for each antimicrobial contained on the card.

VITEK 2 AST-GN Imipenem has the following concentrations in the card: 0.5, 2, 8, and 16 µg/mL (equivalent standard method concentration by efficacy in µg/mL).

The MIC result range for VITEK 2 AST-GN Imipenem on the VITEK 2 card is ≤ 0.25 - ≥ 16 µg/mL for *Enterobacteriaceae* and ≤ 0.5 - ≥ 16 µg/mL for *Acinetobacter* spp. and *P. aeruginosa.*

J. Substantial Equivalence Information:

1. Predicate device name(s):

VITEK 2 AST-GN Amikacin

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

K172731

3. Comparison with predicate:

Table 1. Comparison with the Predicate Device

Similarities		
Item	**Device K183425 VITEK 2 AST-GN Imipenem**	**Predicate K172731 VITEK 2 AST-GN Amikacin**
Intended Use	VITEK 2 AST-Gram Negative Imipenem is designed for antimicrobial susceptibility testing of Gram negative bacilli and is intended for use with the VITEK 2 and VITEK 2 Compact Systems as a laboratory aid in the determination of in vitro susceptibility to antimicrobial agents. VITEK 2 AST Gram Negative Imipenem is a quantitative test. Imipenem has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial. Active in vitro and in clinical infections: *Acinetobacter* spp. *Citrobacter* spp. *Enterobacter cloacae*/*E. cloacae* complex *Escherichia coli* *Klebsiella* spp. *Pseudomonas aeruginosa*	VITEK 2 AST Gram Negative Amikacin is designed for antimicrobial susceptibility testing of Gram negative bacilli and is intended for use with the VITEK 2 and VITEK 2 Compact Systems as a laboratory aid in the determination of in vitro susceptibility to antimicrobial agents. VITEK 2 AST Gram Negative Amikacin is a quantitative test. Amikacin has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial. Active in vitro and in clinical infections: *Pseudomonas* spp. *Escherichia coli* *Proteus mirabilis* *Klebsiella* spp. *Enterobacter* spp. *Serratia* spp. *Acinetobacter* species *(*excluding *A. baumannii* Complex) In vitro data available but clinical significance is unknown: *Citrobacter freundii*
Test Methodology	Automated quantitative	Same

Similarities		
Item	**Device K183425 VITEK 2 AST-GN Imipenem**	**Predicate K172731 VITEK 2 AST-GN Amikacin**
	antimicrobial susceptibility test for use with the VITEK 2 and VITEK 2 Compact Systems to determine the in vitro susceptibility of Gram negative bacilli	
Inoculum	Saline suspension of organism	Same
Test Card	VITEK 2 Gram Negative Susceptibility Test Card	Same
Instrument	VITEK 2 and VITEK 2 Compact	Same
Analysis Algorithm	Growth Pattern Analysis	Same

Differences		
Item	**Device K183425 VITEK 2 AST-GN Imipenem**	**Predicate K172731 VITEK 2 AST-GN Amikacin**
Antimicrobial Agent	Imipenem	Amikacin
Antimicrobial Concentrations	0.5, 2, 8, 16	2, 4, 16, 48

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

CLSI Document M07-A10, Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically; Approved Standard – Tenth Edition, Vol. 35, No. 2; January, 2015.

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

L. Test Principle:

The VITEK® 2 and VITEK® 2 Compact Systems utilize automated growth-based detection using attenuation of light measured by an optical scanner. The optics used in the systems use visible light to directly measure organism growth. Transmittance optics are based on an initial light reading of a well before significant growth has begun. Periodic light transmittance samplings of the same well measure organism growth by how much light is prevented from going through the well. The VITEK 2 System monitors the growth of each well in the card over a defined period of time. An interpretive call is made between 4 and 16

hours for a "rapid" read but may be extended to 18 hours in some instances. At the completion of the incubation cycle, a report is generated that contains the MIC value along with the interpretive category result for each antibiotic on the card.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

A reproducibility study was performed at three external sites using a panel comprised of 10 isolates from indicated species: *P. aeruginosa* (three isolates) and *K. pneumoniae* (seven isolates). All isolates were tested in triplicate at each of the testing sites with each inoculation method and with the VITEK 2 and the VITEK 2 Compact. The mode MIC was determined and the reproducibility was calculated based on MIC values falling within ± 1 dilution of the mode MIC value. Reproducibility was greater than 95% for all inoculation and read methods and was considered to be acceptable.

b. Linearity/assay reportable range:

N/A

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

Quality control strains recommended by the CLSI were tested with imipenem at four sites. The QC organisms tested were *E. coli* ATCC 25922 and *P. aeruginosa* ATCC 27853. The QC strains were tested a minimum of 20 time per site and inoculated using both the automated dilution and manual dilution for VITEK 2 and using manual dilution for the VITEK 2 Compact. Testing with *E. coli* ATCC 25922 provided off scale results with the VITEK 2 card as the acceptable range for this strain is at or lower than the lowest dilution on the card. The sponsor included the following footnote to the *E. coli* ATCC 25922 expected range in the device labeling QC table:

> *FDA/CLSI Broth Microdilution expected QC range = 0.06 – 0.25 µg/mL. Does not include the full recommended dilution range for QC testing with this organism.*

As an additional check of the reference method, two gram positive organisms were tested throughout the study at each clinical site. Isolates tested were *E. faecalis* ATCC 29212 and *S. aureus* ATCC 29213. All results were within the expected range.

The results demonstrate that the VITEK 2 can provide quality control results within the recommended ranges for all inoculation methods > 95% of the time (Table 2).

Table 2. Quality Control Results for Imipenem with VITEK 2 (Automated and Manual Dilution) and VITEK 2 Compact (Manual Dilution)

Organism	Conc. (µg/mL)	VITEK 2 Automatic Dilution		VITEK 2 Manual Dilution		VITEK 2 Compact Manual Dilution	
		Test	Ref.[a]	Test	Ref.	Test	Ref.
E. coli ATCC 25922 0.06 – 0.25	0.125	-	46	-	42	-	42
	0.25[b]	115	68	90	48	90	48
	0.5	0	1				
	1						
	2						
	4						
	8						
	≥16						
P. aeruginosa ATCC 27853 1-4 µg/mL	≤0.25						
	0.5						
	1		5		3		3
	2	116	96	92	79	92	79
	4		15		10		10
	8						
	≥16						

[a] Reference panel
[b] Lowest dilution of imipenem on the VITEK 2 GN card

Inoculum Density Check. The inoculum density was monitored using the DensiCHEK Plus instrument. The DensiCHEK Plus was standardized weekly with all results recorded and in expected range.

Purity Check: A purity check of all organisms was performed at the time of VITEK2 card inoculation. Only results obtained with pure cultures were evaluated.

Growth Failure Rate: One clinical isolate of *P. aeruginosa* failed to grow in the VITEK 2 AST card.

d. Detection limit:

N/A

e. Analytical specificity:

N/A

f. Assay cut-off:

N/A

2. Comparison studies:

a. Method comparison with predicate device:

Testing of imipenem on the VITEK AST gram-negative card was performed at three external sites and one internal site. Results obtained with the VITEK 2 AST-Gram Negative card were compared to results obtained with the CLSI broth microdilution reference panel using direct colony suspension inoculation. Reference panels were incubated at 35° C for 16 to 20 hours for *Enterobacteriaceae* and *P. aeruginosa* and 20 to 24 hours for *Acinetobacter* spp.

Test inocula for VITEK 2 AST were standardized using the DensiCHEK Plus instrument. The DensiCHEK instrument was calibrated within specified intervals; all recorded calibration values were within acceptable parameters. VITEK 2 AST – Gram Negative cards were inoculated using automatic dilution (for reading on the VITEK 2 instrument) or using a manual dilution method (for reading on the VITEK 2 instrument or on the VITEK 2 COMPACT instrument).

A total of 385 clinical isolates were evaluated, 379 of these were from indicated species. A total of 239 (61.9%) isolates were fresh or recent isolates (tested within one year of isolation from clinical specimens); 146 (37.8%) were stock. Clinical isolates included: *Acinetobacter* spp. (36 isolates), *P. aeruginosa* (122 isolates), *E. coli* (97 isolates), *Citrobacter* spp. (13 isolates), *Enterobacter cloacae*/*E. cloacae* complex (32 isolates), *Klebsiella* spp. (79 isolates). An additional six isolates of non-indicated species were tested. One clinical isolate of *P. aeruginosa* failed to grow in the VITEK 2 AST-GN card.

A total of 218 challenge isolates were tested at one clinical site using both automatic and manual dilution methods for the VITEK 2 System and manual dilution for the VITEK 2 Compact System. Challenge isolates tested included: *Acinetobacter* spp. (23 isolates), *P. aeruginosa* (55 isolates), *E. coli* (6 isolates), *Citrobacter* spp. (1 isolate), *Enterobacter cloacae*/*E. cloacae* complex (18 isolates), *Klebsiella* spp. (115 isolates).

For the VITEK 2 with automatic dilution, the MIC results obtained with clinical and challenge isolates of *Enterobacteriaceae* demonstrated an EA of 96.2% and CA of 97.0%, EA of 98.3% and CA of 98.3% for *Acinetobacter* spp. and EA of 94.4% and CA of 91.0% for *P. aeruginosa*. For all organism groups combined the MIC results demonstrated an EA of 95.9% and CA of 95.4%. The majority of errors for all organisms were minor errors. There were 100 resistant *P. aeruginosa* isolates by the reference method; the VITEK 2 with automatic dilution showed a very major error rate of 2.0% for this organism, which is considered acceptable. The EA of evaluable results was low for all organism groups (88.1%, 83.3% and 88.9% for

Enterobacteriaceae, *Acinetobacter* spp. and *P. aeruginosa*, respectively); the low EA of evaluable results for *Acinetobacter* spp. was due to the large number of isolates showing MICs ≥16 for the reference method and the test device (Table 3).

For VITEK 2 with manual dilution the MIC results obtained with challenge isolates demonstrated an EA of 98.6% and CA of 97.9% for *Enterobacteriaceae*, EA and CA of 95.7% for *Acinetobacter* spp., and EA of 96.4% and CA of 94.5% for *P. aeruginosa*. The EA of evaluable results for *Acinetobacter* spp. was 80.0% due to the majority of isolates (20/23) having MICs ≥16 for both the reference method and test device resulting in a low number of evaluable results. (Table 4).

For VITEK 2 Compact with manual dilution, the MIC results obtained with challenge isolates demonstrated an EA of 99.3% and CA of 97.9% for *Enterobacteriaceae*, EA and CA of 95.7% for *Acinetobacter* spp., and EA of 96.4% and CA of 94.5% for *P. aeruginosa*. The EA of evaluable results for *Acinetobacter* spp. was 80.0% due to the majority of isolates (20/23) having MICs ≥16 for both the reference method and test device (Table 5).

The sponsor included the following limitation in the device labeling to address testing for species for which no performance data was provided for FDA review in this submission:

> *Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combinations: Imipenem (ipm05n): Klebsiella* (*Enterobacter*) *aerogenes, Proteus species, Providencia species, Morganella species and Serratia species.*

Table 3. Performance of Imipenem, VITEK 2 Automatic Dilution, Clinical and Challenge Isolates

Organism Type	Tot	No. EA	EA %	Eval EA Tot	No. Eval EA	Eval EA %	No. CA	CA %	No. R	No. S	min	maj	vmj
***Enterobacteriaceae* (*Citrobacter* spp., *E. cloacae/E. cloacae* complex, *E. coli*, *Klebsiella* spp.)**													
Clinical	227	215	94.7%	54	42	77.8%	219	96.5%	8	212	8	0	0
Challenge	140	138	98.6%	55	54	98.2%	137	97.9%	120	24	3	0	0
Combined	367	353	96.2%	109	96	88.1%	356	97.0%	128	236	11	0	0
Acinetobacter spp.													
Clinical	36	36	100.0%	1	1	100.0%	36	100.0%	19	17	0	0	0
Challenge	23	22	95.7%	5	4	80.0%	22	95.7%	20	3	1	0	0
Combined	59	58	98.3%	6	5	83.3%	58	98.3%	39	20	1	0	0
P. aeruginosa													
Clinical	122	114	93.4%	68	60	88.2%	109	89.3%	61	51	11	0	2
Challenge	55	53	96.4%	22	20	90.9%	52	94.5%	39	15	3	0	0
Combined	177	167	94.4%	90	80	88.9%	161	91.0%	100	66	14	0	2
All organisms													
Clinical	385	365	94.8%	123	103	83.7%	364	94.5%	88	280	19	0	2
Challenge	218	213	97.7%	82	78	95.1%	211	96.8%	179	42	7	0	0
Combined	603	578	95.9%	205	181	88.3%	575	95.4%	267	322	26	0	2

EA – Essential Agreement (± 1 dilution)
CA – Category Agreement
EVAL – Evaluable isolates
R – Resistant isolates
min – minor discrepancies
maj – major discrepancies
vmj – very major discrepancies

Essential agreement (EA) occurs when the result of the reference method and that of the VITEK card are within plus or minus one serial two-fold dilution of the antibiotic. Evaluable results are those that are on scale for both the reference method and the VITEK card. Category agreement (CA) occurs when the interpretation of the result of the reference method agrees exactly with the interpretation provided by the VITEK card.

Table 4. Performance of Imipenem, VITEK 2, Manual Dilution, Challenge Isolates

Organism Type	Tot	No. EA	EA %	Eval EA Tot	No. Eval EA	Eval EA %	No. CA	CA %	No. R	No. S	min	maj	vmj
***Enterobacteriaceae* (*Citrobacter* spp., *E. cloacae/E. cloacae* complex, *E. coli, Klebsiella* spp.)**													
Challenge	140	138	98.6%	51	50	98.0%	137	97.9%	120	20	3	0	0
***Acinetobacter* spp.**													
Challenge	23	22	95.7%	5	4	80.0%	22	95.7%	20	3	1	0	0
P. aeruginosa													
Challenge	55	53	96.4%	23	21	91.3%	52	94.5%	39	15	2	0	0

Table 5. Performance of Imipenem, VITEK 2, Compact, Challenge Isolates

Organism Type	Tot	No. EA	EA %	Eval EA Tot	No. Eval EA	Eval EA %	No. CA	CA %	No. R	No. S	min	maj	vmj
***Enterobacteriaceae* (*Citrobacter* spp., *E. cloacae/E. cloacae* complex, *E. coli, Klebsiella* spp.)**													
Challenge	140	139	99.3%	64	63	98.4%	137	97.9%	120	19	3	0	0
***Acinetobacter* spp.**													
Challenge	23	22	95.7%	5	4	80.0%	22	95.7%	20	3	1	0	0
P. aeruginosa													
Challenge	55	53	96.4%	22	20	90.9%	52	94.5%	39	15	3	0	0

To address testing of non-indicated species the sponsor included the following statement in the Precautions section of the device labeling:

> *Per the FDA-Recognized Susceptibility Test Interpretive Criteria website, 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.*

Device failure: During the clinical study two episodes of device failure occurred; both were resolved with an instrument restart. Isolates being processed at the time of device failure were discarded and retested.

Resistance Mechanisms. Challenge isolates of *P. aeruginosa* and *Enterobacteriaceae* harboring the following resistance mechanisms were evaluated: KPC, OXA, IMP, VIM, SPM, modified OprD, VEB, CARB-3, TEM, PDC, GES, PER, NDM, OmpK, OmpC, ACT/MIR, IMI, VEB-1B, and SHV.

MIC Trending

An analysis of trending was conducted using the combined clinical and challenge data for each organism group. This trending calculation takes into account MIC values that are determined to be one or more doubling dilutions lower or higher compared to the reference method irrespective of whether the device MIC values are on-scale or not. Results that are not clearly 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 are shown in Table 6; results were stratified by species to determine if species-related trends were observed. Species for which the difference between the percentage of isolates with higher vs. lower readings was ≥30 and for which the confidence interval was determined to be statistically significant were considered to show evidence of trending. Trending that provides higher or lower MIC values compared to the reference is addressed in labeling.

A trend toward higher MIC readings was observed for E. coli with the autodilution inoculation method on VITEK 2, and for *E. cloacae/E. cloacae* complex with all dilution methods on VITEK 2 and VITEK 2 Compact. A trend toward lower MIC readings was observed for *Klebsiella* spp. for manual dilution with VITEK 2 and VITEK 2 Compact (Table 6). The sponsor included the following footnote to the performance table to address the trending observed for imipenem.

> *Overall, MIC values for Enterobacteriaceae were within one dilution of the CLSI reference broth microdilution method. However, imipenem MIC values tended to be in exact agreement or at least one dilution higher when testing E. coli with autodilution, E. cloacae/E. cloacae complex with manual dilution and autodilution and at least one dilution lower when testing Klebsiella spp. with manual dilution as compared to the CLSI reference broth microdilution*

Table 6. MIC Trending for all Dilution and Read Methods

Inoculation/ Read Method	Organism	Total Evaluable for Trending	≥ 1 Dilution lower No. (%)	Exact No. (%)	≥ 1 Dilution Higher No. (%)	Percent Difference (CI)	Trending Noted
Autodilution/ VITEK 2	*Acinetobacter spp.*	6	0	4 (66.7)	1 (33.3)	33.3 (-12.3-70.0)	Yes[a]
	Citrobacter spp.	8	2 (25.0)	4 (50.0)	2 (25.0)	0	No
	E. cloacae/E. cloacae complex	40	1 (2.5)	21	18 (45.0)	42.5 (24.8-57.8)	Yes
	E. coli	10	2 (20.0)	1 (10.0)	7 (70.0)	50.0 (6.7-74.0)	Yes
	Klebsiella spp.	50	16 (32.0)	22 (44.0)	12 (24.0)	-8.0	No
	Enterobacteriaceae	108	21 (19.44)	48 (44.4)	39 36.1)	16.7	No
	P. aeruginosa	90	26 (28.9)	36 (40.0)	28 (31.1)	2.2	No
Manual Dilution VITEK 2	*Acinetobacter spp.*	5	1 (20.0)	2 (40.0)	2 (40.0)	20.0	No
	Citrobacter spp.	0	-	-	-	-	-
	E. cloacae/E. cloacae complex	13	0	6 (46.2)	7 (53.9)	53.9 (20.2-76.8)	Yes
	E. coli	3	0	1 (33.3)0	2 (66.7)	66.7 (-5.9-93.9)	Yes[a]
	Klebsiella spp.	36	16 (44.4)	16 (44.4)	4 (11.1)	-33.3 (-50.7 - -12.8)	Yes
	Enterobacteriaceae	52	16 (30.8)	23 (44.2)	13 (25.0)	-5.8	No
	P. aeruginosa	23	6 (26.1)	10 (43.5)	7 (30.4)	4.5	No
Manual Dilution Compact	*Acinetobacter spp.*	5	1 (20.0)	3 (60.0)	1 (20.0)	0	No
	Citrobacter spp.	0	-	-	-	-	-
	E. cloacae/E. cloacae complex	15	0	7 (46.7)	8 (53.3)	53.3 (22.4-75.2)	Yes
	E. coli	3	0	1 (33.3)	2 (66.7)	66.7 (-5.9-93.9)	Yes[a]
	Klebsiella spp.	46	20 (43.5)	22 (47.8)	4 (8.7)	-34.8 (-5.0- -17.1)	Yes
	Enterobacteriaceae	64	20 (31.2)	30 (46.9)	14 (21.9)	-9.4	No
	P. aeruginosa	22	6 (27.3)	9 (40.9)	7 (31.8)	4.6	No

[a] Not statistically significant

b. Matrix comparison:

N/A

3. Clinical studies:

a. Clinical Sensitivity:

N/A

b. Clinical specificity:

N/A

c. Other clinical supportive data (when a. and b. are not applicable):

N/A

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

Table 7. Interpretive Categories for Imipenem (FDA STIC Webpage and CLSI M100)

Organism	Interpretive Categories for Imipenem MIC (µg/mL)[a]		
	S	I	R
Enterobacteriaceae	**≤ 1**	**2**	**≥ 4**
P. aeruginosa	**≤ 2**	**4**	**≥ 8**
Acinetobacter spp.	**≤ 2**	**4**	**≥ 8**

[a] FDA STIC Webpage https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm410971.htm

N. Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device

O. Conclusion:

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