510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K260281

B Applicant

bioMérieux, Inc.

C Proprietary and Established Names

VITEK 2 AST-*Streptococcus* Cefuroxime (≤0.125 - ≥8 µg/mL)

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LON	Class II	21 CFR 866.1645 - Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System	MI - Microbiology
LTT	Class II	21 CFR 866.1640 - Antimicrobial susceptibility test powder	MI - Microbiology
LTW	Class II	21 CFR 866.1640 - Antimicrobial susceptibility test powder	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain a substantial equivalence determination for the VITEK 2 AST-*Streptococcus* Cefuroxime (≤0.125 - ≥8 µg/mL) assay for testing of *Streptococcus pneumoniae* on the VITEK 2, VITEK 2 Compact, and VITEK COMPACT PRO Antimicrobial Susceptibility Test (AST) Systems.

B Measurand:

Cefuroxime ≤0.125 - ≥8 µg/mL

C Type of Test:

Automated quantitative or qualitative antimicrobial susceptibility test

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

VITEK 2 AST-*Streptococcus* Cefuroxime (≤0.125 - ≥8) is designed for antimicrobial susceptibility testing of *Streptococcus* species and is intended for use with the VITEK 2 Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents.

VITEK 2 AST-*Streptococcus* Cefuroxime (≤0.125 - ≥8) is a quantitative test. Testing is indicated for *Streptococcus pneumoniae* as recognized by the FDA Susceptibility Test Interpretive Criteria (STIC).

VITEK 2 AST-*Streptococcus* Cefuroxime (≤0.125 - ≥8) has demonstrated acceptable performance with the following organism:

Streptococcus pneumoniae

The VITEK 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of *Streptococcus pneumoniae*, beta-hemolytic *Streptococcus* and Viridans *Streptococcus* to antimicrobial agents when used as instructed.

C Special Conditions for Use Statement(s):

Rx – For Prescription Use Only

Due to the occurrence of very major errors, perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination:
Cefuroxime (cxm01n): *S. pneumoniae* when the VITEK2 MIC is 0.5 µg/mL (based on parenteral breakpoints)

D Special Instrument Requirements:

VITEK 2 Systems (i.e., VITEK 2, VITEK 2 Compact, and VITEK COMPACT PRO), Software version 10.1 or newer

IV Device/System Characteristics:

A 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 which contains 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.

VITEK 2 AST cards are intended to be used with VITEK 2 System instruments (VITEK 2, VITEK 2 Compact, and VITEK COMPACT PRO). The VITEK 2 System is a fully automated instrument that integrates sample preparation, incubation, and optical measurement for microbial identification and antimicrobial susceptibility testing (AST).

The VITEK 2 System will automatically (or allow operator to manually) dilute the organism 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 and VITEK COMPACT PRO have 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. The analysis program determines when a well demonstrates growth based on attenuation of light measured by an optical scanner. The data are used to determine the MIC values for the antimicrobial 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-ST Cefuroxime has the following concentrations in the card: 0.25, 0.5, 1 and 2 µg/mL (equivalent standard method concentration by efficacy in µg/mL). The MIC result range for the VITEK 2 AST-ST Cefuroxime test is ≤0.125 - ≥8 µg/mL.

B Principle of Operation:

The VITEK 2 AST cards use an abbreviated doubling dilution series of antimicrobial to establish the MIC. Each VITEK 2 AST card contains 64 wells—one “growth” control well contains nutrient medium only, and the remaining wells contain premeasured antimicrobials in nutrient media.

The VITEK 2 System instruments (VITEK 2, VITEK 2 Compact, and VITEK COMPACT PRO) utilize automated growth-based detection using attenuation of light measured by an optical scanner. The optics in the VITEK 2 Systems use visible light to directly measure organism growth within each of the 64 micro-wells. Transmittance optics is based on an initial light reading of a well before significant growth has begun. Every 15 minutes throughout the incubation cycle (defined period of time based on the VITEK 2 AST card), light transmittance readings of each well determine organism growth by the amount of light that is prevented from passing through the well. At the completion of the incubation period, the MIC values and their associated interpretive category results for each antimicrobial on the test card are displayed in an automatically generated report.

V Substantial Equivalence Information:

A Predicate Device Name(s):

VITEK 2 AST-*Streptococcus* Penicillin (≤0.06 - ≥8 µg/mL)

B Predicate 510(k) Number(s):

K232201

C Comparison with Predicate(s):

Device & Predicate Device(s):	Device: K260281	Predicate: K232201
Device Trade Name	VITEK 2 AST-*Streptococcus* Cefuroxime (≤0.125 - ≥8 µg/mL)	VITEK 2 AST-*Streptococcus* Penicillin (≤0.06 - ≥8 µg/mL)
General Device Characteristic Similarities		
Indications For Use	VITEK 2 AST-*Streptococcus* Cefuroxime (≤0.125 - ≥8) is designed for antimicrobial susceptibility testing of *Streptococcus* species and is intended for use with the VITEK 2 Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents. VITEK 2 AST-*Streptococcus* Cefuroxime (≤0.125 - ≥8) is a quantitative test. Testing is indicated for *Streptococcus pneumoniae* as recognized by the FDA Susceptibility Test Interpretive Criteria (STIC). VITEK 2 AST-*Streptococcus* Cefuroxime (≤0.125 - ≥8) has demonstrated acceptable performance with the following organism: *Streptococcus pneumoniae* The VITEK 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of *Streptococcus pneumoniae*, beta-hemolytic *Streptococcus*	VITEK 2 *Streptococcus* Penicillin is designed for antimicrobial susceptibility testing of *Streptococcus* species 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 *Streptococcus* Penicillin is a quantitative test. Penicillin has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial. Active both *in vitro* and in clinical infections: Beta hemolytic streptococci groups C and G *Streptococcus pyogenes* *Streptococcus agalactiae* *Streptococcus* viridans group *Streptococcus pneumoniae* The VITEK 2 Streptococcus Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of *Streptococcus pneumoniae*, beta-hemolytic *Streptococcus*, and Viridans *Streptococcus* to antimicrobial agents when used as instructed.

	and Viridans *Streptococcus* to antimicrobial agents when used as instructed.	
Test Methodology	Automated quantitative antimicrobial susceptibility test for use with the VITEK 2 Systems to determine the *in vitro* susceptibility of microorganisms	Same
Inoculum	Saline suspension of organism	Same
Test Card	VITEK 2 *Streptococcus* Susceptibility Test Card	Same
General Device Characteristic Differences		
Antimicrobial Agent	Cefuroxime	Penicillin
Antimicrobial Concentrations	0.25, 0.5, 1, 2 µg/mL	0.06, 0.12, 0.5, 2 µg/mL
Instrument	VITEK 2, VITEK 2 Compact, and VITEK COMPACT PRO Systems	VITEK 2 and VITEK 2 Compact Systems
Analysis Algorithm	Growth Pattern Analysis	Discriminant Analysis
Base Broth	Modified ST1	ST4
Tested Species	*Streptococcus pneumoniae*	Beta hemolytic Streptococci groups C and G *Streptococcus pyogenes* *Streptococcus agalactiae* *Streptococcus viridans* group *Streptococcus pneumoniae*

Predetermined Change Control Plan (PCCP):

To support the implementation of changes to FDA-recognized susceptibility test interpretive criteria (i.e., breakpoints), this submission included a predetermined change control plan (PCCP) with a breakpoint change protocol that was reviewed and accepted by FDA in submission K250274 cleared on April 30, 2025. 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 bioMérieux intends to use to evaluate the VITEK 2 AST-*Streptococcus* Cefuroxime when revised breakpoints for cefuroxime are published on the FDA STIC webpage. The breakpoint change protocol included with the submission indicated that if specific criteria are met, bioMérieux will update the VITEK 2 AST-*Streptococcus* Cefuroxime 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.

VI Standards/Guidance Documents Referenced:

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

CLSI M07 12th Edition, Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically (May 2024)

CLSI M100 35th ed. Performance Standards for Antimicrobial Susceptibility Testing (January 2025)

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Reproducibility testing for the VITEK 2 AST-*Streptococcus* Cefuroxime was conducted at three external sites using a panel of ten *S. pneumoniae* isolates consistent with the indications for use. Each isolate was tested in triplicate, using separate inoculum for each and tested over three days for a total of 270 data points. The inocula were prepared using both the auto-dilution and manual dilution methods for testing with the VITEK 2 and the manual dilution method for testing with the VITEK 2 Compact.

The COMPACT PRO did not obtain premarket clearance until after the closure of the external study sites; therefore, reproducibility for the COMPACT PRO was assessed with separate inocula prepared from ten isolates and tested at one internal site with three instruments and three operators for a total of 270 data points. Additionally, due to the similarities between the two Compact systems, the VITEK 2 Compact reproducibility performance was leveraged to support the VITEK COMPACT PRO. Taken together, this was considered acceptable.

For analysis of the data, the mode of MIC values was determined for each isolate and the reproducibility was calculated based on the number of MIC values that fell within ± one doubling dilution of the mode MIC value. Both best-case and worst-case scenarios were analyzed per FDA Class II Special Controls Guidance. The majority of data points were on-scale and within ± one doubling dilution agreement as compared to the mode MIC.

The reproducibility performance is shown in **Table 1**. For the VITEK COMPACT PRO, the worst-case scenario reproducibility was 80% due to two isolates with off-scale modes, which were previously on-scale for cefuroxime when tested two years prior with the VITEK 2 and VITEK 2 Compact. Additional testing was performed with the manual dilution method with the VITEK 2 and VITEK COMPACT PRO. Results were off-scale for both instruments, indicating that results were likely due to isolate variability and not reproducibility issues with the instruments. Taken together, the results are acceptable.

Table 1. Reproducibility Performance of VITEK 2 AST-*Streptococcus* Cefuroxime

	VITEK 2		**VITEK 2 Compact**	**VITEK COMPACT PRO**
	Auto-Dilution	**Manual Dilution**	**Manual Dilution**	**Manual Dilution**
Best-Case	98.1%	98.5%	98.1%	94.1%
Worst-Case	94.4%	95.9%	100%	80.0%

2. Linearity:

   Not applicable.

3. Analytical Specificity/Interference:

   Not applicable.

4. Detection Limit and Assay Reportable Range:

   Not applicable.

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

   Quality Control (QC) Testing:
   The CLSI recommended QC strain *Streptococcus pneumoniae* ATCC 49619 was tested a sufficient number of times (i.e., at least 20/site) at each testing site using the VITEK 2 AST-*Streptococcus* Cefuroxime and Broth Microdilution (BMD) reference method. Both the automatic dilution and manual dilution methods were used for the VITEK 2 and the manual dilution method was used for the VITEK 2 Compact and VITEK COMPACT PRO. The results are summarized in **Table 2** below. Both the auto-dilution and manual dilution methods for VITEK 2 and the manual dilution methods for VITEK 2 Compact and VITEK COMPACT PRO QC results were within the expected range >95% of the time.

   Table 2. Quality Control Results for VITEK 2 AST-*Streptococcus* Cefuroxime

Organism	VITEK 2 Result Range (µg/mL)	BMD Result Range (µg/mL)	VITEK 2 Auto Dilution	BMD	VITEK 2 Manual Dilution	BMD	VITEK 2 Compact Manual Dilution	BMD	VITEK COMPACT PRO Manual Dilution	BMD
Streptococcus pneumoniae ATCC 49619 Expected Results: 0.25-1 µg/mL		≤0.0625		1						
	0.125	0.125	2	4		2		2		
	0.25	0.25	34	179	7	88	8	88	1	22
	0.5	0.5	153	5	83		82		21	
	1	1								
	2	2								
	4	4								
	8	8								
		16								
		≥32								

   Two ancillary QC organisms, *Staphylococcus aureus* ATCC 29213 and *Escherichia coli* ATCC 25922, were tested throughout comparative testing by the BMD reference method only to ensure further quality control of the BMD panels. QC results for the BMD reference method were within the expected result range 100% (125/125) of the time for *S. aureus* ATCC 29213 and 99.2% (123/124) of the time for *E. coli* ATCC 25922.

Inoculum Density Control:
The DensiCHEK Plus was used to standardize the inoculum to a 0.5 McFarland standard. The instrument was standardized daily with all results recorded at each site. Calibration values were within the expected range.

Purity Check:
A purity check of all organisms was performed on the dilution tube used to prepare the VITEK 2 card inoculum. Only those cultures that were pure were evaluated in the study.

Device Failure:
During the performance of the comparative study, there were zero (0) device failures with the VITEK 2 System instruments.

Growth Failure Rate:
A total of 353 clinical and challenge isolates were tested by VITEK 2 AST-ST Cefuroxime. No growth failures were recorded, and all 353 isolates had VITEK 2 AST results available.

6. Assay Cut-Off:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Testing of cefuroxime was performed at three external sites and one internal site. Results obtained with VITEK 2 AST-*Streptococcus* Cefuroxime were compared to results obtained with the CLSI broth microdilution reference panel. The MIC result range for the VITEK 2 AST-*Streptococcus* Cefuroxime is ≤0.125 - ≥8 µg/mL for *S. pneumoniae*. The testing conditions for the reference method consisted of the following:

- Medium: 2.5% to 5% LHB-supplemented CAMHB
- Inoculum: Direct colony suspension
- Incubation: 35ºC; 20-24 hours

The VITEK 2 cards were inoculated with test organisms using the auto-dilution method (VITEK 2) and using the manual dilution method (VITEK 2, VITEK 2 Compact, VITEK COMPACT PRO). All test inocula used for the VITEK 2 AST cards and the reference method were standardized using the DensiCHEK instruments. A total of 303 *S. pneumoniae* clinical isolates were evaluated using auto-dilution and VITEK 2. Of these isolates, 38.3% were contemporary isolates (tested within six months of isolation) and 61.7% were stock isolates (no specific time from isolation).

A total of 50 *S. pneumoniae* challenge isolates were evaluated at one external site (VITEK 2 and VITEK 2 Compact) or one internal site (VITEK COMPACT PRO).

Clinical and Challenge Data – VITEK 2 Auto-Dilution
The results obtained using the auto-dilution method of the VITEK 2 from the 353 total isolates (303 clinical isolates and 50 challenge isolates) are summarized in **Table 3**.

Table 3. Performance of All Clinical and Challenge Isolates for Cefuroxime: VITEK 2 Auto-Dilution

	Total	#EA	%EA	Eval EA Total	Eval EA #	Eval EA %	#CA	%CA	#R	#S	min	maj	vmj
***Streptococcus pneumoniae* Parenteral Breakpoints ≤0.5 (S), 1 (I), ≥2 (R)**													
Clinical	303	287	94.7	52	36	69.2	296	97.7	62	239	2	0	5
Challenge	50	50	100	22	22	100	49	98	41	8	1	0	0
Combined	353	337	95.5	74	58	78.4	345	97.7	103	247	3	0	5
***Streptococcus pneumoniae* Oral Breakpoints ≤1 (S), 2 (I), ≥4 (R)**													
Clinical	303	287	94.7	52	36	69.2	290	95.7	56	241	12	0	1
Challenge	50	50	100	22	22	100	47	94	39	9	3	0	0
Combined	353	337	95.5	74	58	78.4	337	95.5	95	250	15	0	1

EA – Essential Agreement
CA – Category Agreement
Eval – Evaluable isolates
R – Resistant
min – Minor Discrepancies
maj – Major Discrepancies
vmj – Very Major Discrepancies
S – Susceptible

Essential agreement (EA) occurs when the result of the reference method and that of the VITEK 2 AST 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 VITEK 2 AST card or results in which an off-scale result is at least two doubling dilutions from the on-scale result. Category agreement occurs when the interpretation of the result of the reference method agrees exactly with the interpretation of the VITEK 2 AST card.

For testing *S. pneumoniae* with the auto-dilution method of the VITEK 2, the EA was acceptable at 95.5% (**Table 3**). Using the parenteral breakpoints for *S. pneumoniae* with the auto-dilution method of the VITEK 2, the CA was acceptable at 97.7% and there were three minor errors, zero major errors, and five very major errors (4.9%). The very major error rate was not acceptable. To address the unacceptable very major error rate, the following limitation was included in the device labeling:

Due to the occurrence of very major errors, perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination: Cefuroxime (cxm01n): S. pneumoniae when the VITEK2 MIC is 0.5 µg/mL (based on parenteral breakpoints)

Using the oral breakpoints for *S. pneumoniae* with the auto-dilution method of the VITEK 2, the CA was acceptable at 95.5% and there were 15 minor errors, zero major errors, and one very major error (1.1%).

Challenge Data –VITEK 2, VITEK 2 Compact, and VITEK COMPACT PRO Manual Dilution

The 50 challenge isolates were also evaluated at one external site with the manual dilution option of the VITEK 2 and VITEK 2 Compact Systems, and one internal site with the VITEK COMPACT PRO (summarized in **Table 4**).

Table 4. Performance of Challenge Isolates for Cefuroxime: VITEK 2, VITEK 2 Compact and VITEK COMPACT PRO Manual Dilution

VITEK 2 Systems	Total	#EA	%EA	Eval Total	Eval EA #	Eval EA %	#CA	%CA	#R	#S	min	maj	vmj
***Streptococcus pneumoniae* Parenteral Breakpoints ≤0.5 (S), 1 (I), ≥2 (R)**													
VITEK 2	50	50	100	22	22	100	49	98	41	8	1	0	0
VITEK 2 Compact	50	50	100	22	22	100	49	98	41	8	1	0	0
VITEK COMPACT PRO	50	50	100	13	13	100	49	98	41	8	1	0	0
***Streptococcus pneumoniae* Oral Breakpoints ≤1 (S), 2 (I), ≥4 (R)**													
VITEK 2	50	50	100	22	22	100	47	94	39	9	3	0	0
VITEK 2 Compact	50	50	100	22	22	100	47	94	39	9	3	0	0
VITEK COMPACT PRO	50	50	100	13	13	100	47	94	39	9	3	0	0

EA – Essential Agreement
CA – Category Agreement
Eval – Evaluable isolates
R – Resistant
min – Minor Discrepancies
maj – Major Discrepancies
vmj – Very Major Discrepancies
S – Susceptible

Essential agreement (EA) occurs when the result of the reference method and that of the VITEK 2 AST 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 VITEK 2 AST card or results in which an off-scale result is at least two doubling dilutions from the on-scale result. Category agreement occurs when the interpretation of the result of the reference method agrees exactly with the interpretation of the VITEK 2 AST card.

For testing *S. pneumoniae* with the manual dilution method of the VITEK 2, the EA was acceptable at 100%. Similarly, the EA was acceptable at 100% with the manual dilution method of both the VITEK 2 Compact and the VITEK COMPACT PRO.

Using parenteral breakpoints, the overall performance of the VITEK 2 AST-*Streptococcus* Cefuroxime when testing *S. pneumoniae* with the manual dilution method was acceptable with a CA of 98.0%, and one minor error and no major or very major errors. Similarly, the CA was acceptable at 98.0% and one minor error and no major or very major errors with the manual dilution method of both the VITEK 2 Compact and the VITEK COMPACT PRO.

Using oral breakpoints, the overall performance of the VITEK 2 AST-*Streptococcus* Cefuroxime when testing *S. pneumoniae* with the manual dilution method was acceptable with a CA of 94.0%, and three minor errors and no major or very major errors. Similarly, the CA was acceptable at 94.0% and three minor errors and no major or very major errors with the manual dilution of both the VITEK 2 Compact and the VITEK COMPACT PRO.

MIC Trending

A trending analysis was conducted using the combined data (clinical and/or challenge) obtained for *Streptococcus pneumoniae*. This trending calculation takes into account MIC values that are determined to be one or more doubling dilutions lower or higher than the reference method irrespective of whether the device MIC values are on-scale or not.

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 shows higher or lower MIC values compared to the reference is addressed in the labeling.

Table 5. Trending for *Streptococcus pneumoniae* with Cefuroxime and the VITEK 2 Systems

Organism	Inoculation/ Read Method	Total Evaluable for Trending	≥ 1 Dilution lower No. (%)	Exact No. (%)	≥ 1 Dilution Higher No. (%)	Percent Difference (CI)	Trending Noted
Streptococcus pneumoniae	Auto/ VITEK 2	110	68 (61.8)	32	10, (9.1)	-53% (-62%, -41%)	Yes
	Manual/ VITEK 2	25	8 (32.0)	13	4, (16.0)	-16% (-38%, 8%)	No
	Manual/ VITEK 2 Compact	24	7 (29.2)	14	3, (12.5)	-17% (-38%, 7%)	No
	Manual/ VITEK COMPACT PRO	21	4 (19.1)	8	9, (42.9)	24% (-4%, 47%)	No

A trend toward lower MIC values was observed for *S. pneumoniae* when compared to the CLSI broth microdilution reference method, as summarized in **Table 5**. The following statement is included as a footnote to the performance table in the device labeling to address the observed trending:

VITEK 2 AST-Streptococcus Cefuroxime MIC values tended to be in exact agreement or at least one doubling dilution lower when testing Streptococcus pneumoniae by VITEK 2 auto-dilution method compared to the CLSI reference broth microdilution method.

Testing/Reporting MICs for Species Not Listed in the Indications for Use

For this review, the interpretive criteria are applied to the organisms/organism groups according to the FDA STIC website. As required under 511A(b)(2)(C)(ii)(I) of the Federal Food, Drug and Cosmetic Act, the following statement was added to the package insert to address testing and reporting of species not listed in the Indications for Use:

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.

2. Matrix Comparison:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Clinical Cut-Off:

Not applicable.

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

Not applicable.

D Expected Values/Reference Range:

Table 6. FDA-Approved or Recognized Interpretive Criteria

Organism	Minimum Inhibitory Concentrations (µg/mL)[a]		
	Susceptible	**Intermediate**	**Resistant**
Streptococcus pneumoniae	Parenteral Breakpoints		
	≤0.5	1	≥2
	Oral Breakpoints [b]		
	≤1	2	≥4

[a] According to FDA STIC Webpage, https://www.fda.gov/drugs/development-resources/fda-recognized-antimicrobial-susceptibility-test-interpretive-criteria

[b] Interpretations for oral cefuroxime may be reported for isolates other than those from CSF

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.