510(k) SUMMARY

VITEK® 2 AST-GN Meropenem/Vaborbactam

510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Esther Hernandez Regulatory Affairs Specialist
Phone Number:	314 -731-8841
Fax Number:	314-731-8689
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B. Device Name:

Formal/Trade Name:	VITEK® 2 AST- Gram Negative Meropenem/ Vaborbactam (≤0.5/8 – ≥ 64/8 µg/mL)
Classification Name:	21 CFR 866.1645 Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System Product Code LON
Common Name:	VITEK® 2 AST-GN Meropenem/Vaborbactam

C. Predicate Device: VITEK® 2 AST-GN Amikacin (K172731)

D. 510(k) Summary:

VITEK® 2 AST-Gram Negative Meropenem/Vaborbactam 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 Meropenem/Vaborbactam is a quantitative test. Meropenem/Vaborbactam 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:
Enterobacter cloacae complex
Escherichia coli
Klebsiella pneumoniae

In vitro data available but clinical significance unknown:
Citrobacter freundii
Citrobacter koseri
Klebsiella (Enterobacter) aerogenes
Klebsiella oxytoca
Morganella morganii
Proteus mirabilis
Providencia spp.
Serratia marcescens

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.

The antimicrobial presented in VITEK® 2 AST-GN Cards is in concentrations equivalent by efficacy to standard method concentrations in mcg/ml. The VITEK® 2 AST Cards are essentially miniaturized versions of the doubling dilution technique for determining the minimum inhibitory concentration (MIC) microdilution methodology.

The isolate to be tested is diluted to a standardized concentration in 0.45 - 0.50% saline before being used to rehydrate the antimicrobial medium within the card. The VITEK® 2 automatically fills, seals and places the card into the incubator/reader. The VITEK® 2 Compact has a manual filling and sealing operation. The VITEK® 2 monitors the growth of each well in the card over a defined period of time (up to 18 hours). 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 Meropenem/Vaborbactam demonstrated substantially equivalent performance when compared with the CLSI broth microdilution reference method, as defined in the FDA Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA (Issued August 28, 2009).

The Premarket Notification (510[k]) presents data in support of VITEK® 2 AST-GN Meropenem/Vaborbactam. An external evaluation was conducted with fresh and stock clinical isolates, as well as a set of challenge strains. The external evaluations were designed to confirm the acceptability of VITEK® 2 AST-GN Meropenem/Vaborbactam by comparing its performance with the CLSI broth microdilution reference method incubated at 16-20 hours. The data is representative of performance on both the VITEK® 2 and VITEK® 2 Compact instrument platforms. VITEK® 2 AST-GN Meropenem/Vaborbactam demonstrated acceptable performance of 98.2% overall Essential Agreement and 98.7% overall Category Agreement with the reference method. Reproducibility and Quality Control demonstrated acceptable results.