**510(k) SUMMARY**

**VITEK® 2 AST-GN Minocycline**

**510(k) Submission Information:**

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| Submitter's Name: | bioMérieux, Inc. |
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| Date of Preparation: | December 19, 2018 |

**B. Device Name:**

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| Formal/Trade Name: | VITEK® 2 AST- GN Minocycline (≤ 0.5 – ≥ 32 µg/mL) |
| Classification Name: | 21 CFR 866.1645<br>Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System<br>Product Code LON |
| Common Name: | VITEK® 2 AST-GN Minocycline |

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

**D. 510(k) Summary:**

VITEK® 2 AST-Gram Negative Minocycline 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 Minocycline is a quantitative test. Minocycline has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial.

<u>Active *in vitro* and in clinical infections:</u>
*Acinetobacter* spp.

*Klebsiella* (Enterobacter) *aerogenes*
*Escherichia coli*
*Klebsiella* spp.

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 Minocycline 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 Minocycline. 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 Minocycline by comparing its performance with the CLSI broth microdilution reference method incubated at 16-20 hours (20-24 hours for *Acinetobacter* species). The data is representative of performance on both the VITEK® 2 and VITEK® 2 Compact instrument platforms. VITEK® 2 AST-GN Minocycline demonstrated acceptable performance of 97.0% overall Essential Agreement and 93.7% overall Category Agreement with the reference method. Reproducibility and Quality Control demonstrated acceptable results.