K043230

DEC 3 0 2004

BIOMÉRIEUX

510(k) SUMMARY

VITEK® Gram Negative Ertapenem

510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Jolyn Tenllado Regulatory Affairs Specialist
Phone Number:	314 -731-8386
Fax Number:	314-731-8689
Date of Preparation:	November 17, 2004

B. Device Name:

Formal/Trade Name:	VITEK® Gram Negative Ertapenem (≤0.5 – ≥8 μg/ml)
Classification Name:	Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Device, 21 CFR 866.1645
Common Name:	VITEK GNS Ertapenem

C. Predicate Device:

VITEK Gram Negative Susceptibility (GNS) Card for Gatifloxacin (K032711)

D. 510(k) Summary:

VITEK® Gram Negative Ertapenem is designed for antimicrobial susceptibility testing of *Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii, Citrobacter koseri, Enterobacter aerogenes, Enterobacter cloacae, Klebsiella oxytoca* (excluding ESBL producing strains), *Morganella morganii, Proteus mirabilis, Proteus vulgaris* and *Serratia marcescens.* It is intended for use with the VITEK® System as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents. The antimicrobial presented in VITEK GNS Cards is in concentrations equivalent by efficacy to standard method concentrations in mcg/ml. The VITEK GNS Cards are essentially miniaturized versions of the doubling dilution technique for determining the minimum inhibitory concentration (MIC) microdilution methodology.

calculated once a predetermined growth threshold is reached, and a report is generated that contains the MIC result and the interpretive category result.

VITEK Gram Negative Ertapenem demonstrated substantially equivalent performance when compared with the NCCLS reference agar dilution method, as defined in the FDA Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA. Issued Feb. 5, 2003.

The Premarket Notification (510[k]) presents data in support of VITEK Gram Negative Ertapenem. An external evaluation was conducted with fresh and stock clinical isolates and stock challenge strains. The external evaluations were designed to confirm the acceptability of VITEK Gram Negative Ertapenem by comparing its performance with the NCCLS agar dilution reference method. VITEK Gram Negative Ertapenem demonstrated acceptable performance of 98.7% overall Category Agreement when compared to the agar dilution reference method. Reproducibility and Quality Control demonstrated acceptable results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 3 0 2004

Ms. Jolyn Tenllado
Regulatory Affairs Specialist
BioMérieux, Inc.
595 Anglum Road
Hazelwood, MO 63042-2320

Re: k043230
Trade/Device Name: VITEK® Gram Negative Ertapenem (≤0.5 - ≥8 µg/ml)
Regulation Number: 21 CFR 866.1645
Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Devices
Regulatory Class: Class II
Product Code: LON
Dated: November 17, 2004
Received: November 22, 2004

Dear Ms. Tenllado:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

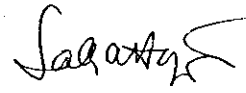
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k043230

Device Name: VITEK® Gram Negative Ertapenem (≤ 0.5 – ≥ 8 μg/ml)

Indications For Use:

The VITEK® Gram Negative Susceptibility Test is intended to be used with the VITEK® System for the automated quantitative or qualitative susceptibility testing of isolated colonies for the most clinically significant aerobic gram-negative bacilli, *Staphylococcus spp.*, *Enterococcus spp.*, *Streptococcus agalactiae*, and *S. pneumoniae*. VITEK® Gram Negative Ertapenem is designed for antimicrobial susceptibility testing of *Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii, Citrobacter koseri, Enterobacter aerogenes, Enterobacter cloacae, Klebsiella oxytoca* (excluding ESBL producing strains), *Morganella morganii, Proteus mirabilis, Proteus vulgaris* and *Serratia marcescens*. VITEK Gram Negative Ertapenem is for qualitative testing only. It is intended for use with the VITEK System as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k043230