FEB 17 2005

K050002

BIOMÉRIEUX

# 510(k) SUMMARY

## VITEK® 2 Compact

### 510(k) Submission Information:

| | |
|---|---|
| Submitter's Name: | bioMérieux, Inc. |
| Address: | 595 Anglum Road<br>Hazelwood, MO 63042 |
| Contact Person: | Nancy Weaver<br>Staff Regulatory Affairs Specialist |
| Phone Number: | 314 -731-8695 |
| Fax Number: | 314-731-8689 |
| Date of Preparation: | December 30, 2004 |

### B. Device Name:

| | |
|---|---|
| Formal/Trade Name: | VITEK® 2 Compact |
| Classification Name: | Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Device, 21 CFR 866.1645 |
| Common Name: | VITEK 2 Compact System |

### C. Predicate Device:

VITEK® 2 System (N50510/S082)

### D. 510(k) Summary:

VITEK® 2 Compact System is intended to be used with VITEK® 2 AST Cards for the automated quantitative or qualitative susceptibility testing of isolated colonies for most clinically significant aerobic gram-negative bacilli, *Staphylococcus spp.*, *Enterococcus spp.*, *Streptococcus agalactiae* and *S. pneumoniae*. It is intended for use as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents. Antimicrobials presented in VITEK 2 AST Cards are 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 bacterial isolate to be tested is diluted to a standardized concentration in 0.45% saline before being used to rehydrate the antimicrobial medium within the AST card. The cards are filled with a vacuum filling process, sealed and placed into the reader/incubator. The VITEK 2 Compact monitors growth based on attenuation of light measured by an optical scanner 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 antibiotic contained on the VITEK 2 AST Card.

The VITEK 2 Compact demonstrated substantially equivalent performance when compared with the VITEK 2 System. The Premarket Notification (510[k]) presents data in support of VITEK 2 Compact System. External evaluations were conducted with at six external clinical sites. The evaluation included challenge, reproducibility and quality control for both gram-negative and gram-positive organisms. The VITEK 2 Compact demonstrated essential agreement of 99.4% for challenge testing when compared to the VITEK 2. Reproducibility was 100% essential agreement when comparing median results of the VITEK 2 Compact to the VITEK 2 System. Precision dilution differences comparing individual results to the instrument median demonstrated 97.79% essential agreement for the VITEK 2 Compact. Percent in range for quality control was 99.04%.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 17 2005

Ms. Nancy Weaver
Staff Regulatory Affairs Specialist
BioMérieux, Inc.
595 Anglum Road
Hazelwood, MO 63042-2320

Re: k050002
Trade/Device Name: VITEK® 2 Compact
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: December 30, 2004
Received: January 3, 2005

Dear Ms. Weaver:

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 announfcements 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 (240)276-0484. 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/industry/support/index.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): K050002

Device Name: VITEK® 2 Compact

Indications For Use:

The VITEK® 2 Compact is intended to be used for the automated quantitative or qualitative susceptibility testing of isolated colonies for most clinically significant aerobic gram-negative bacilli, *Staphylococcus spp.*, *Enterococcus spp.*, *Streptococcus agalactiae* and *S. pneumoniae.*

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) K050002