JUL 10 2003

K031410

BIOMÉRIEUX

510(k) SUMMARY

VITEK 2® Gram Positive Linezolid for *Streptococcus pneumoniae*

510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Nancy Weaver, Staff Regulatory Specialist
Phone Number:	314-731-8695
Fax Number:	314-731-8689
Date of Preparation:	April 25, 2003

B. Device Name:

Formal/Trade Name:	VITEK 2® Gram Positive Linezolid for *Streptococcus pneumoniae*
Classification Name:	Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Device, 21 CFR 866.1645
Common Name:	VITEK 2 AST-GP Linezolid for *Streptococcus pneumoniae*

C. Predicate Device: VITEK 2® *Streptococcus pneumoniae* Susceptibility Test for Ceftriaxone (N50510/S135)

D. 510(k) Summary:

The VITEK 2® Gram Positive Linezolid for *Streptococcus pneumoniae* is designed for antimicrobial susceptibility testing of *Streptococcus pneumoniae*. It is intended for use with the VITEK 2® System as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents. The antimicrobial presented in VITEK 2 AST 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) my 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 card. The VITEK 2 automatically fills, seals and places the card into the incubator/reader. 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 antibiotic contained on the card. VITEK 2® Gram Positive Linezolid for *Streptococcus pneumoniae* demonstrated substantially equivalent performance when compared with the NCCLS reference microbroth dilution method, as defined in the FDA DRAFT document "Guidance on Review Criteria for Assessment of Antimicrobial susceptibility Devices", dated March 8, 2000 and 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 2® Gram Positive Linezolid for *Streptococcus pneumoniae.*

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 2 Gram Positive Linezolid for *Streptococcus pneumoniae* by comparing its performance with the NCCLS microbroth dilution reference method. VITEK 2 Gram Positive Linezolid for *Streptococcus pneumoniae* demonstrated acceptable performance of 100.0% overall Category Agreement when compared to the microbroth dilution reference method. Reproducibility and Quality Control demonstrated acceptable results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 10 2003

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

Re: k031410
Trade/Device Name: VITEK 2® Gram Positive Linezolid (1 ug/ml) for Streptococcus pneumoniae
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: April 25, 2003
Received: May 13, 2003

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 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). Other general information on your responsibilities under the Act may be obtained 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,

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K031410

Device Name: VITEK 2® Gram Positive Linezolid (1µg/ml) for *Streptococcus pneumoniae*

Indications for Use:

VITEK 2® Gram Positive Linezolid for *Streptococcus pneumoniae* is designed for antimicrobial susceptibility testing of *Streptococcus pneumoniae.* It is intended for use with the VITEK 2® System as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031410

for prescription use only