DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 8 2001

Mr. Ross Mulder
BioMerieux Vitek, Inc.
595 Anglum Drive
Hazelwood, MO 63042-2395

Re: Reclassification Order:
Docket No. 97P-0313
Reclassification of the Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Devices

Dear Mr. Mulder:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for reclassification of the Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Device that is intended for use in determining, in less than 16 hours, the antimicrobial susceptibility of nonfastidious aerobic and/or facultative anaerobic bacteria to legally marketed antimicrobial agents. FDA concludes that this device and substantially equivalent devices of this generic type, should be reclassified from class III into class II. This order, therefore, reclassifies the Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Device, and substantially equivalent devices of this generic type into class II under the generic name Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Device, effective immediately. This order also identifies the special controls applicable to the device as the FDA guidance document "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems" (FDA guidance document). You do not need to submit a premarket notification submission (510(k)) for your Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Device as described in your reclassification petition.

FDA identifies this generic type of device, the subject of this reclassification, as follows: A Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Device is a device intended to determine, in less than 16 hours, the antimicrobial susceptibility of nonfastidious aerobic and/or facultative anaerobic bacteria to legally marketed antimicrobial agents.

The device is an automated short-term incubation (less than 16 hours) antimicrobial susceptibility system. Pure cultures of rapidly growing aerobic non-fastidious Gram positive and Gram negative organisms are standardized for correct inoculum density and used to inoculate the various concentrations of antimicrobial agents. After a short inoculation period, less than 16 hours, a determination of susceptible, intermediate, or resistant can be made with the use of computer-assisted extrapolations or non-visual assessments of bacterial growth. Test results are used as an aid for the physician in making therapeutic decisions involving the administration of antimicrobial drugs.

In accordance with section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) the device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act (21 U.S.C. 360c(f)(2)), as amended by the FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807).

As you know, on July 2, 1997, FDA filed your petition requesting reclassification of the Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Device from class III into class II. The petition was submitted under section 513(f)(2) of the act, now section 513(f)(3) of the act, as amended by the FDAMA, and 21 CFR 860.134 of the agency's regulations. In accordance with section 513(f)(1) of the act, the Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Devices were automatically classified into class III because the Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Devices were not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and had not been found substantially equivalent to a device placed in commercial distribution after May 28, 1976, which was subsequently reclassified into class II or class I. In order to reclassify the Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Devices intended to determine, in less than 16 hours, the antimicrobial susceptibility of nonfastidious aerobic and/or facultative anaerobic bacteria to legally marketed antimicrobial agents into class II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of safety and effectiveness of the device for its intended use.

Pursuant to 21 CFR 860.125 and 860.134, FDA consulted with the Microbiology Devices Panel (the Panel). The Panel unanimously recommended that the Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Devices intended to determine, in less than 16 hours, the antimicrobial susceptibility of nonfastidious aerobic and/or facultative anaerobic bacteria to legally marketed antimicrobial agents be reclassified from class III into class II because the Panel believes that special controls will provide reasonable assurance of the safety and effectiveness of the device. This recommendation was based on the information and data contained in the reclassification petition, on the summary and analysis of the data as set forth in the petition, on information presented during the open public hearing and open committee discussions of the meeting held on February 13, 1998, and on the Panel member's own personal knowledge of, and clinical experience with, the device.

The report and recommendation of the Panel were published in the Federal Register of March 8, 2000, 65FR 12268, Vol. 65, No. 46 (enclosed) and interested persons were invited to comment by June 7, 2000. FDA received six comments in response to the notice of panel recommendation. None of the comments objected to the reclassification of Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Devices from class III into class II.

FDA agrees with the Panel's recommendation to reclassify Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Devices from class III into class II with the following identified special control: the FDA guidance document entitled "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems." This decision is based on the administrative record that consists of the reclassification petition, the transcript and minutes of the February 13, 1998 meeting of the Panel, the Panel member's individual data sheets containing their recommendations, and all other information identified in this letter.

After review of the information submitted in the petition, other information, and consultation with the Panel regarding the reclassification petition, FDA has determined that Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Devices intended for determining, in less than 16 hours, the antimicrobial susceptibility of nonfastidious aerobic and/or facultative anaerobic bacteria to legally marketed antimicrobial agents as described and identified herein can be reclassified from class III into class II with the establishment of special controls. The Agency identified special controls following the panel's recommendations because of past experience with the short-term incubation systems' inability to detect new mechanisms of resistance as they develop with use of antimicrobial agents. FDA believes that class II with special controls provides reasonable assurance of the safety and effectiveness of the device.

After considering the information discussed by the Panel during the reclassification proceedings, the published literature, data in PMA applications available to FDA under section 520(h)(4) of the act, as amended by FDAMA, and the Medical Device Reports, FDA believes the following risk is associated with the use of the antimicrobial susceptibility systems intended for the in vitro quantitative or qualitative determination of antimicrobial susceptibility of rapidly growing aerobic non-fastidious Gram positive and Gram negative organisms isolated from clinical specimens, where resistant or susceptible determinations are made in less than 16 hours. The failure of the device to perform its intended use may result in the administration of an inappropriate antimicrobial agent to a patient. When an antimicrobial agent result is erroneously reported to the clinician as "susceptible" and in reality is "resistant," the patient may be treated inappropriately and inadvertently subjected to an exacerbation of the infection, drug reaction, an extended hospital stay, collateral infections, or possibly death. When an antimicrobial agent result is erroneously reported to the clinician as "resistant" and in reality is "susceptible", the appropriate treatment may be delayed with a similar potential of severe sequelae.

The device is subject to the general control sections of the act and any special controls identified under section 513(a)(1)(B) of the act (21 U.S.C. 360c(a)(1)(B)), including any performance standards promulgated under section 514 of the act (21 U.S.C. 360d). Thus, persons who intend

to market this device must submit to FDA a premarket notification submission containing information on the Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Devices they intend to market prior to marketing the device.

A notice announcing this reclassification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

If you have any questions concerning this reclassification order, please contact Freddie Poole or Sally Selepak at 301-594-2096.

Sincerely yours,

Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure