DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center- W066-G609
Silver Spring, MD 20993-0002

January 28, 2014

bioMérieux, Inc.
C/O Nancy Weaver, Associate Director, Regulatory Affairs
595 Anglum Rd
Hazelwood, MO 63042-2320

Re: K124067- Order Granting the Request for *De Novo* Classification
Vitek ®MS
Evaluation of Automatic Class III Designation- *De Novo* Request
Regulation Number: 21 CFR 866.3361
Regulation Name: Mass spectrometer system for clinical use for the identification of microorganisms
Regulatory Classification: Class II
Product Code: PEX
Dated: December 12, 2012
Received: January 3, 2013

Dear Ms. Weaver:

This letter corrects the letter dated August 21, 2013.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the Vitek®MS. The intended use of the Vitek®MS is:

> VITEK®MS is a mass spectrometer system using matrix-assisted laser desorption/ ionization - time of flight (MALDI-TOF) for the identification of microorganisms cultured from human specimens.
>
> The VITEK®MS is a qualitative *in vitro* diagnostic device indicated for use in conjunction with other clinical and laboratory findings to aid in the diagnosis of bacterial and yeast infections.
>
> List of claimed organisms:

Abiotrophia defectiva	*Candida pelliculosa*
Achromobacter denitrificans[1]	*Candida rugosa*
Achromobacter xylosoxidans[1]	*Candida tropicalis*
Acinetobacter baumannii complex	*Candida utilis*
Acinetobacter haemolyticus	*Candida zeylanoides*
Acinetobacter junii	*Chryseobacterium indologenes*
Acinetobacter lwoffii	*Citrobacter amalonaticus*
Actinomyces meyeri	*Citrobacter braaki* [3]
Actinomyces neuii	*Citrobacter freundii*[3]
Actinomyces odontolyticus	*Citrobacter koseri*
Aerococcus viridans	*Citrobacter youngae*[3]
Aeromonas hydrophila/caviae[2]	*Clostridium clostridioforme*
Aeromonas sobria[2]	*Clostridium difficile*
Aggregatibacter actinomycetemcomitans	*Clostridium perfringens*
Aggregatibacter aphrophilus	*Clostridium ramosum*
Aggregatibacter segnis	*Corynebacterium jeikeium*
Alcaligenes faecalis ssp faecalis	*Cronobacter sakazakii*
Bacteroides caccae	*Cryptococcus neoformans*
Bacteroides fragilis	*Edwardsiella hoshinae*
Bacteroides ovatus	*Edwardsiella tarda*
Bacteroides thetaiotaomicron	*Eikenella corrodens*
Bacteroides uniformis	*Elizabethkingia meningoseptica*
Bacteroides vulgatus	*Enterobacter aerogenes*
Bordetella parapertussis	*Enterobacter asburiae*[4]
Bordetella pertussis	*Enterobacter cancerogenus*
Brevundimonas diminuta	*Enterobacter cloacae*[4]
Burkholderia multivorans	*Enterobacter gergoviae*
Campylobacter coli	*Enterococcus avium*
Campylobacter jejuni	*Enterococcus casseliflavus*
Candida albicans	*Enterococcus durans*
Candida dubliniensis	*Enterococcus faecalis*
Candida famata	*Enterococcus faecium*
Candida glabrata	*Enterococcus gallinarum*
Candida guilliermondii	*Escherichia coli*[5]
Candida haemulonii	*Escherichia fergusonii*
Candida inconspicua	*Escherichia hermannii*
Candida intermedia	*Ewingella americana*
Candida kefyr	*Finegoldia magna*
Candida krusei	*Fusobacterium necrophorum*
Candida lambica	*Fusobacterium nucleatum*
Candida lipolytica	*Gardnerella vaginalis*
Candida lusitaniae	*Gemella haemolysans*
Candida norvegensis	*Gemella morbillorum*
Candida parapsilosis	*Geotrichum capitatum*

Granulicatella adiacens	*Proteus mirabilis*
Haemophilus influenzae	*Proteus penneri*[7]
Haemophilus parahaemolyticus	*Proteus vulgaris*[7]
Haemophilus parainfluenzae	*Providencia rettgeri*
Hafnia alvei	*Providencia stuartii*
Kingella denitrificans	*Pseudomonas aeruginosa*
Kingella kingae	*Pseudomonas fluorescens*
Klebsiella oxytoca	*Pseudomonas putida*
Klebsiella pneumoniae	*Pseudomonas stutzeri*
Kodamaea ohmeri	*Ralstonia pickettii*
Lactococcus garvieae	*Raoultella ornithinolytica*
Lactococcus lactis ssp lactis	*Raoultella planticola*
Leclercia adecarboxylata	*Rhizobium radiobacter*
Legionella pneumophila	*Rhodotorula mucilaginosa*
Leuconostoc mesenteroides	*Rothia mucilaginosa*
Leuconostoc pseudomesenteroides	*Saccharomyces cerevisiae*
Listeria monocytogenes	*Salmonella group*[6]
Malassezia furfur	*Serratia fonticola*
Malassezia pachydermatis	*Serratia liquefaciens*
Micrococcus luteus/lylae	*Serratia marcescens*
Mobiluncus curtisii	*Serratia odorifera*
Moraxella (Branhamella) catarrhalis	*Sphingobacterium multivorum*
Morganella morganii	*Sphingobacterium spiritivorum*
Neisseria cinerea	*Sphingomonas paucimobilis*
Neisseria gonorrhoeae[6]	*Staphylococcus aureus*
Neisseria meningitidis	*Staphylococcus capitis*
Neisseria mucosa	*Staphylococcus cohnii ssp cohnii*
Ochrobactrum anthropi	*Staphylococcus cohnii ssp urealyticus*
Oligella ureolytica	*Staphylococcus epidermidis*
Oligella urethralis	*Staphylococcus haemolyticus*
Pantoea agglomerans	*Staphylococcus hominis ssp hominis*
Parvimonas micra	*Staphylococcus lugdunensis*
Pasteurella multocida	*Staphylococcus saprophyticus*
Pediococcus acidilactici	*Staphylococcus schleiferi*
Peptoniphilus asaccharolyticus	*Staphylococcus sciuri*
Peptostreptococcus anaerobius	*Staphylococcus simulans*
Prevotella bivia	*Staphylococcus warneri*
Prevotella buccae	*Stenotrophomonas maltophilia*
Prevotella denticola	*Streptococcus agalactiae*
Prevotella intermedia	*Streptococcus anginosus*
Prevotella melaninogenica	*Streptococcus constellatus*
Propionibacterium acnes	*Streptococcus dysgalactiae*
	Streptococcus gallolyticus ssp gallolyticus

Streptococcus infantarius ssp coli	*Trichosporon inkin*
Streptococcus infantarius ssp infantarius	*Trichosporon mucoides*
Streptococcus intermedius	*Vibrio cholerae*
Streptococcus mitis/Streptococcus oralis	*Vibrio parahaemolyticus*
Streptococcus mutans	*Vibrio vulnificus*
Streptococcus pneumoniae	*Yersinia enterocolitica*
Streptococcus pyogenes	*Yersinia frederiksenii*
Streptococcus salivarius ssp salivarius	*Yersinia intermedia*
Streptococcus sanguinis	*Yersinia kristensenii*
Trichosporon asahii	*Yersinia pseudotuberculosis*

1. *Achromobacter denitrificans* and *Achromobacter xylosoxidans* identifications should be considered as a slashline result, *Achromobacter denitrificans/ Achromobacter xylosoxidans*.
2. *Aeromonas hydrophila/caviae* and *Aeromonas sobria* should be considered as an *Aeromonas* species group identification.
3. *Citrobacter freundii*, *Citrobacter braakii* and *Citrobacter youngae* should be considered as *Citrobacter freundii* complex.
4. *Enterobacter cloacae* and *Enterobacter asburiae* identifications should be considered as a slashline result, *Enterobacter cloacae/ Enterobacter asburiae*.
5. *Shigella* species and *E. coli* O157 are identified as *Escherichia coli*. Confirmatory tests are required to differentiate *Escherichia coli* from *Shigella* species or *E. coli* O157.
6. Confirmatory tests recommended for *Neisseria gonorrhea* and *Salmonella* species.
7. *Proteus penneri* and *Proteus vulgaris* identifications should be considered as a slashline result, *Proteus penneri/ Proteus vulgaris*.

The Vitek®MS is a prescription device under 21 CFR Part 801.109. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Vitek®MS into class II under the generic name, "mass spectrometer system for clinical use for the identification of microorganisms."

FDA identifies this generic type of device as follows: Mass spectrometer system for clinical use for the identification of microorganisms

A mass spectrometer system for clinical use for the identification of microorganisms is a qualitative *in vitro* diagnostic device intended for the identification of microorganisms cultured from human specimens. The device is comprised of an ionization source, a mass analyzer and a spectral database. The device is indicated for use in conjunction with other clinical and laboratory findings to aid in the diagnosis of bacterial and fungal infections.

Section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on

July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On January 3, 2013, FDA filed your de novo request for classification of the Vitek®MS into class II. The petition was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Vitek®MS into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the de novo request, FDA has determined that the Vitek®MS intended for use as follows:

> VITEK®MS is a mass spectrometer system using matrix-assisted laser desorption/ ionization - time of flight (MALDI-TOF) for the identification of microorganisms cultured from human specimens.
>
> The VITEK®MS is a qualitative *in vitro* diagnostic device indicated for use in conjunction with other clinical and laboratory findings to aid in the diagnosis of bacterial and yeast infections.
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> <u>List of claimed organisms</u>

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Aerococcus viridans	*Bordetella parapertussis*
Aeromonas hydrophila/caviae[2]	*Bordetella pertussis*
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Burkholderia multivorans	*Campylobacter coli*
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Candida tropicalis	*Hafnia alvei*
Candida utilis	*Kingella denitrificans*
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Citrobacter braaki [3]	*Kodamaea ohmeri*
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can be classified in class II with the establishment of special controls for this type of device. FDA believes that the class II special controls identified later in this order, along with the applicable general controls, provide reasonable assurance of the safety and effectiveness of the device type.

Table- Potentia1 Risks and Required Mitigations

Identified Potential Risk	**Required Mitigation Measures**
Incorrect identification of a pathogenic microorganism can lead to improper patient management.	1) Premarket notification submissions must include detailed documentation for device software, including, but not limited to, standalone software applications and hardware-based devices that incorporate software. 2) Premarket notification submissions must include database implementation methodology, construction parameters and quality assurance protocols.
Failure to correctly interpret test results	1) A detailed explanation of the interpretation of results and acceptance criteria must be included in the device's 21 CFR 809.10(b)(9) compliant labeling.

Failure to correctly operate the instrument	1) As part of the risk management activities performed as part of your 21 CFR 820.30 design controls, you must document an appropriate end user device training program that will be offered as part of your efforts to mitigate the risk of failure to correctly operate the instrument. 2) Premarket notification submissions must include details on the appropriate end user device training program that will be offered while marketing the device.

In addition to the general controls of the FD&C Act, a mass spectrometer system for clinical use for the identification of microorganisms is subject to the following special controls:

1) Premarket notification submissions must include detailed documentation for device software, including, but not limited to, standalone software applications and hardware-based devices that incorporate software.

2) Premarket notification submissions must include database implementation methodology, construction parameters and quality assurance protocols.

3) A detailed explanation of the interpretation of results and acceptance criteria must be included in the device's 21 CFR 809.10(b)(9) compliant labeling.

4) As part of the risk management activities performed as part of your 21 CFR 820.30 design controls, you must document an appropriate end user device training program that will be offered as part of your efforts to mitigate the risk of failure to correctly operate the instrument.

5) Premarket notification submissions must include details on the appropriate end user device training program that will be offered while marketing the device.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the mass spectrometer system for clinical use for the identification of microorganisms they intend to market and receive clearance to market from FDA prior to marketing the device.

A notice announcing this classification 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, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may market your device subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Yvonne Shea at 301-796-0576.

Sincerely yours,

Uwe Scherf -S for

Sally Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostics and
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Center for Devices and
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