DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 25, 2017

BIOMERIEUX, INC.
NATHAN HARDESTY
MANAGER, REGULATORY AFFAIRS MICROBIOLOGY
595 ANGLUM RD.
HAZELWOOD MO 63042

Re: K162950
Trade/Device Name: VITEK MS
Regulation Number: 21 CFR 866.3361
Regulation Name: Mass spectrometer system for clinical use for the identification of microorganisms
Regulatory Class: II
Product Code: PEX
Dated: June 16, 2017
Received: June 19, 2017

Dear Mr. Hardesty:

This letter corrects our substantially equivalent letter of July 22, 2017.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements

as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kristian M. Roth -S For:

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162950

Device Name
VITEK® MS

Indications for Use *(Describe)*
VITEK® MS is a mass spectrometry system using matrix-assisted laser desorption/ionization – time of flight mass spectrometry (MALDI-TOF MS) 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, yeast and mould infections.

(See Attached for 'List of Claimed Organisms')

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Indications for Use Attachment

Abiotrophia defectiva
Achromobacter denitrificans [1]
Achromobacter xylosoxidans [1]
Acinetobacter baumannii complex
Acinetobacter haemolyticus
Acinetobacter junii
Acinetobacter lwoffii
Actinomyces meyeri
Actinomyces neuii
Actinomyces odontolyticus
Aerococcus viridans
Aeromonas hydrophila/caviae [2]
Aeromonas sobria [2] [3]
Aggregatibacter actinomycetemcomitans
Aggregatibacter aphrophilus
Aggregatibacter segnis
Alcaligenes faecalis ssp faecalis
Bacteroides caccae
Bacteroides fragilis
Bacteroides ovatus [4]
Bacteroides thetaiotaomicron
Bacteroides uniformis
Bacteroides vulgatus
Bordetella parapertussis
Bordetella pertussis
Brevundimonas diminuta
Burkholderia multivorans
Campylobacter coli
Campylobacter jejuni
Candida albicans
Candida dubliniensis
Candida famata
Candida glabrata
Candida guilliermondii
Candida haemulonii
Candida inconspicua
Candida intermedia
Candida kefyr
Candida krusei
Candida lambica
Candida lipolytica
Candida lusitaniae
Candida norvegensis
Candida parapsilosis
Candida pelliculosa
Candida rugosa
Candida tropicalis
Candida utilis
Candida zeylanoides
Chryseobacterium indologenes
Citrobacter amalonaticus
Citrobacter braaki [5]
Citrobacter freundii [5]
Citrobacter koseri
Citrobacter youngae [5]
Clostridium clostridioforme
Clostridium difficile
Clostridium perfringens
Clostridium ramosum
Corynebacterium jeikeium
Cronobacter sakazakii
Cryptococcus neoformans
Edwardsiella hoshinae
Edwardsiella tarda
Eikenella corrodens
Elizabethkingia meningoseptica
Enterobacter aerogenes
Enterobacter asburiae [6]
Enterobacter cancerogenus
Enterobacter cloacae [6]
Enterococcus avium
Enterococcus casseliflavus
Enterococcus durans
Enterococcus faecalis
Enterococcus faecium
Enterococcus gallinarum
Escherichia coli [7]
Escherichia fergusonii
Escherichia hermannii
Ewingella americana
Finegoldia magna
Fusobacterium necrophorum
Fusobacterium nucleatum
Gardnerella vaginalis
Gemella haemolysans
Gemella morbillorum

Granulicatella adiacens
Haemophilus influenzae
Haemophilus parahaemolyticus
Haemophilus parainfluenzae
Hafnia alvei
Kingella denitrificans
Kingella kingae
Klebsiella oxytoca
Klebsiella pneumoniae
Kodamaea ohmeri
Lactococcus garvieae
Lactococcus lactis ssp lactis [8]
Leclercia adecarboxylata
Legionella pneumophila
Leuconostoc mesenteroides
Leuconostoc pseudomesenteroides
Listeria monocytogenes
Malassezia furfur
Malassezia pachydermatis
Micrococcus luteus
Mobiluncus curtisii
Moraxella (Branhamella) catarrhalis
Morganella morganii
Neisseria cinerea
Neisseria gonorrhoeae [9]
Neisseria meningitidis
Neisseria mucosa [10]
Ochrobactrum anthropi
Oligella ureolytica
Oligella urethralis
Pantoea agglomerans
Parvimonas micra
Pasteurella multocida
Pediococcus acidilactici
Peptoniphilus asaccharolyticus
Peptostreptococcus anaerobius
Pluralibacter gergoviae
Prevotella bivia
Prevotella buccae
Prevotella denticola
Prevotella intermedia
Prevotella melaninogenica
Propionibacterium acnes
Proteus mirabilis
Proteus penneri [11]
Proteus vulgaris [11]
Providencia rettgeri
Providencia stuartii
Pseudomonas aeruginosa
Pseudomonas fluorescens
Pseudomonas putida
Pseudomonas stutzeri
Ralstonia pickettii
Raoultella ornithinolytica
Raoultella planticola
Rhizobium radiobacter
Rhodotorula mucilaginosa
Rothia mucilaginosa
Saccharomyces cerevisiae
Salmonella group [9]
Saprochaete capitata
Serratia fonticola
Serratia liquefaciens
Serratia marcescens
Serratia odorifera
Sphingobacterium multivorum
Sphingobacterium spiritivorum
Sphingomonas paucimobilis
Staphylococcus aureus
Staphylococcus capitis
Staphylococcus cohnii ssp cohnii
Staphylococcus cohnii ssp urealyticus
Staphylococcus epidermidis
Staphylococcus haemolyticus
Staphylococcus hominis ssp hominis [12]
Staphylococcus lugdunensis
Staphylococcus saprophyticus
Staphylococcus schleiferi
Staphylococcus sciuri
Staphylococcus simulans
Staphylococcus warneri
Stenotrophomonas maltophilia
Streptococcus agalactiae
Streptococcus anginosus
Streptococcus constellatus
Streptococcus dysgalactiae
Streptococcus gallolyticus ssp gallolyticus

Streptococcus infantarius ssp coli
Streptococcus infantarius ssp infantarius
Streptococcus intermedius
Streptococcus mitis/Streptococcus oralis
Streptococcus mutans
Streptococcus pneumoniae
Streptococcus pyogenes
Streptococcus salivarius ssp salivarius [13]
Streptococcus sanguinis
Trichosporon asahii
Trichosporon inkin
Trichosporon mucoides
Vibrio cholerae
Vibrio parahaemolyticus
Vibrio vulnificus
Yersinia enterocolitica
Yersinia frederiksenii
Yersinia intermedia
Yersinia kristensenii
Yersinia pseudotuberculosis [14]

MYCOBACTERIUM

Mycobacterium abscessus
Mycobacterium avium
Mycobacterium chelonae
Mycobacterium fortuitum group: [15]
- *Mycobacterium alvei*
- *Mycobacterium farcinogenes*
- *Mycobacterium fortuitum*
- *Mycobacterium houstonense*
- *Mycobacterium peregrinum*
- *Mycobacterium porcinum*
- *Mycobacterium senegalense*

Mycobacterium gordonae
Mycobacterium haemophilum
Mycobacterium immunogenum
Mycobacterium intracellulare
Mycobacterium kansasii
Mycobacterium lentiflavum
Mycobacterium malmoense
Mycobacterium marinum
Mycobacterium mucogenicum
Mycobacterium scrofulaceum
Mycobacterium simiae
Mycobacterium smegmatis
Mycobacterium szulgai
Mycobacterium tuberculosis complex: [16]
- *Mycobacterium africanum*
- *Mycobacterium bovis*
- *Mycobacterium canettii*
- *Mycobacterium microti*
- *Mycobacterium pinnipedii*
- *Mycobacterium tuberculosis*

Mycobacterium xenopi

NOCARDIA

Nocardia abscessus
Nocardia asteroides
Nocardia brasiliensis
Nocardia cyriacigeorgica
Nocardia farcinica
Nocardia nova [17]
Nocardia otitidiscaviarum
Nocardia paucivorans
Nocardia pseudobrasiliensis
Nocardia transvalensis
Nocardia veterana
Nocardia wallacei

MOULDS

Acremonium sclerotigenum
Alternaria alternata
Aspergillus brasiliensis
Aspergillus flavus/oryzae
Aspergillus fumigatus
Aspergillus lentulus
Aspergillus nidulans
Aspergillus niger complex
Aspergillus sydowii
Aspergillus terreus complex [18]
Aspergillus calidoustus
Aspergillus versicolor
Blastomyces dermatitidis
Cladophialophora bantiana
Coccidioides immitis/posadasii
Curvularia hawaiiensis
Curvularia spicifera
Epidermophyton floccosum
Exophiala dermatitidis

Exophiala xenobiotica [19]
Exserohilum rostratum [19]
Fusarium oxysporum complex
Fusarium proliferatum
Fusarium solani complex
Histoplasma capsulatum
Lecythophora hoffmannii
Lichtheimia corymbifera
Microsporum audouinii
Microsporum canis
Microsporum gypseum
Mucor racemosus complex [20]
Paecilomyces variotii complex
Penicillium chrysogenum
Pseudallescheria boydii
Purpureocillium lilacinum
Rasamsonia argillacea complex [21]
Rhizopus arrhizus complex
Rhizopus microsporus complex
Sarocladium kiliense
Scedosporium apiospermum
Scedosporium prolificans
Sporothrix schenckii complex
Trichophyton interdigitale
Trichophyton rubrum
Trichophyton tonsurans
Trichophyton verrucosum
Trichophyton violaceum [22]

1. *Achromobacter denitrificans* and *Achromobacter xylosoxidans* identifications should be considered as a slashline result, *Achromobacter denitrificans/ Achromobacter xylosoxidans*. The final identification should be confirmed before sending the final selection to the LIS or to the VITEK® 2 for AST results

2. *Aeromonas hydrophila/caviae* and *Aeromonas sobria* should be considered as an *Aeromonas* species group identification.

3. In KB V3.0.0, *Aeromonas sobria* is displayed as a low discrimination result with *Aeromonas veronii* but only *Aeromonas sobria* has been clinically validated.

4. In KB V3.0.0, *Bacteroides ovatus* is grouped in a slashline with *Bacteroides xylanisolvens*. It is not possible to distinguish between the two species. *B. ovatus* is more commonly associated with human infection.

5. *Citrobacter freundii*, *Citrobacter braakii* and *Citrobacter youngae* should be considered as *Citrobacter freundii* complex.

6. *Enterobacter cloacae* and *Enterobacter asburiae* identifications should be considered as a slashline result, *Enterobacter cloacae/ Enterobacter asburiae*. The final identification should be confirmed before sending the final selection to the LIS or to the VITEK® 2 for AST results.

7. *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.

8. In KB V3.0.0 *Lactococcus lactis ssp lactis* is integrated in a new group *Lactococcus lactis* (with two other subspecies *Lactococcus lactis ssp cremoris* and *Lactococcus lactis ssp hordniae*). In the *Lactococcus lactis* group only subspecies *Lactococcus lactis ssp lactis* has been clinically validated.

9. Confirmatory tests recommended for *Neisseria gonorrhea* and *Salmonella* species.

10. In KB V3.0.0, *Neisseria mucosa* is grouped in a slashline with *Neisseria sicca*. It is not possible to distinguish between the two species. Both species have been associated with human infection.

11. *Proteus penneri* and *Proteus vulgaris* identifications should be considered as a slashline result, *Proteus penneri/ Proteus vulgaris*.

12. In KB V3.0.0 *Staphylococcus hominis ssp hominis* is integrated in a new group *Staphylococus.hominis* (with another subspecies *S. hominis ssp novobiosepticus*). In the *Staphylococus.hominis* group only subspecies *Staphylococcus hominis ssp hominis* has been clinically validated.

13. In KB V3.0.0, *Streptococcus salivarius* ssp *salivarius* is displayed as a low discrimination result with *Streptococcus salivarius* ssp *thermophilus* and *Streptococcus vestibularis* but only *Streptococcus salivarius* ssp *salivarius* has been clinically validated.

14. There is a possibility of cross-identification between *Yersinia similis* and *Yersinia pseudotuberculosis*

15. The *Mycobacterium fortuitum* complex or group displayed in VITEK® MS includes the seven most prominent and closely related species. The VITEK® MS group differs from the ones reported in the literature that may include up to 13 species.

16. The *Mycobacterium tuberculosis* complex displayed in VITEK® MS includes the four most prevalent species based on different worldwide geographic regions. It does not include two additional species *Mycobacterium microti* and *Mycobacterium pinnipedii* as reported in the literature.

17. In KB V3.0.0, *Nocardia nova* is displayed as a low discrimination result with *Nocardia africana* but only *Nocardia nova* has been clinically validated.

18. Both *Aspergillus alabamensis* and *Aspergillus niveus* are not identified as *Aspergillus terreus* complex. No identification is expected with either species.

19. All of the no identifications for this organism were from multiple replicates of the same isolate.

20. *Mucor racemosus f. sphaerosporus* is not identified as *Mucor racemosus* complex. No identification is expected. The *Mucor racemosus* complex is comprised of *M. racemosus* f. *brunneus*, *M. racemosus* f. *chibinensis*, *M. racemosus* f. *racemosus*, and *M. racemosus* f. *sphaerosporus*.

21. 3 out of the 5 no identifications for this organism were from multiple replicates of the same isolate.

22. All of the discordant identifications for this organism were from multiple replicates of the same isolate.

510(k) SUMMARY

VITEK® MS

510(k) Submission Information:

Submitter's Name:	bioMérieux, SA
Address:	3 Route de Port Michaud La Balme les Grottes, 38390 (France)
Contact Person:	Nathan Hardesty Manager, Regulatory Affairs Microbiology
Phone Number:	314 -731-8666
Fax Number:	314-731-8689
Date of Preparation:	October 14, 2016

B. Device Name:

Formal/Trade Name:	VITEK® MS
Classification Name:	21 CFR 866.3361, Mass spectrometer system for clinical use for the identification of microorganisms
Common Name:	VITEK® MS, VITEK MS

C. Predicate Device: VITEK® MS (DEN130013 / K124067)

D. 510(k) Summary:

VITEK® MS is mass spectrometry system using matrix-assisted laser desorption/ionization–time of flight mass spectrometry (MALDI-TOF MS) 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, yeast and mould infections.

The VITEK® MS is intended for laboratory use by professional users who are trained in microbiology and good laboratory practices.

This 510(k) is an update to the VITEK® MS (Mass Spectrometry) clinical knowledge base (KB v3.0.0) for the purposes of identifying *Mycobacterium*, *Nocardia*, and mould isolates. As the VITEK® MS KB v3.0.0 update includes new indications for use on the VITEK® MS system, new clinical data was required to establish safety and effectiveness. To account for the detection of higher mass peaks, relevant for some

moulds and *Mycobacterium*, the VITEK® MS acquisition station software was optimized (in v1.5.0) .

Microorganism identifications are made via matrix-assisted laser desorption/ionization – time of flight mass spectrometry (MALDI-TOF MS) technology, which includes the three basic principles of ionization, separation, and detection. Depending on the isolate culture, the analyte sample may be directly spotted to a target slide, or for Mycobacterium, Nocardia and mould it must be processed/inactivated before adding to the target slide. Once spotted to the target slide, a matrix is added for the purpose of easy sublimation and strong absorbance in the laser wavelength employed by the instrument.

The slide is then loaded onto the instrument, where a laser targets the sample spot and pulses the isolate spot, resulting in vibrational excitation of matrix and analyte molecules. The matrix transfer protons to the analyte resulting in a positive charge. The ionized molecules are then accelerated in an electromagnetic field and a grid electrode in the ionization chamber. The velocity of the molecules depends on the mass-to-charge (m/z) ratio of the analyte, with heavier molecules having a higher moment of inertia resulting in a lower velocity.

The time of flight is measured precisely by the ions arrival at a particle detector. Based on the time of flight, the *m/z* ratio of each particle can be determined, and a mass spectrum of the analyte sample mixture is generated. The mass spectrum displays results as a series of peaks (spectrum) which correspond to the ionized proteins derived from the analyte sample. The mass spectra are sufficiently distinctive to allow taxonomic characterization at the genus and species.

Clinical performance testing for he VITEK® MS v3 / KB v3.0.0 was conducted at five sites, for the purpose of an expanded intended use for Mycobacterium, Nocardia, and moulds. Performance testing included a total of 2,695 Mycobacteria, Nocardia and mould isolates, and evaluation of performance was a comparison of the VITEK MS identification results to molecular sequencing methods (i.e. the reference method). Testing Mycobacteria isolates included samples from both solid and liquid culture media.

Clinical strains for all isolates tested from solid and liquid media at all sites combined show an acceptable agreement rate of 94.6% (correct single choice identification plus a low discrimination correct genus result), as well as with each organism group [moulds (92.7%), mycobacteria (96.5%) and *Nocardia* (97.9%)]. A combined very low error rate of 0.7% (19/2695) was obtained with all isolates tested, and the combined no identification rate was acceptable at 4.7% (127/2695).

When excluding No ID results, clinical strains for all isolates tested from solid and liquid media at all sites combined show a high agreement rate of 99.3% (correct single choice identification plus a low discrimination correct genus result), as well as high agreement

with each organism group [moulds (99.1%), mycobacteria (99.6%) and *Nocardia* (99.2%)]. A very low error rate of 0.7% (19/2568) was obtained with all isolates combined.

One hundred well-characterized challenge strains included 50 moulds, 35 mycobacteria and 15 *Nocardia* strains. Three trial sites tested the mould challenge strains, and three trial sites tested the mycobacteria and *Nocardia* challenge strains. 95.7% (287/300) of Challenge results were correct one choice, and 1.0% (3/300) of results were low discrimination correct genus, for a combined agreement of 96.7% (290/300), for the mould, mycobacteria and *Nocardia* challenge isolates tested at all sites combined. No misidentifications were obtained, and no identification was obtained with 10 (3.3%) of all challenge isolates tested at all sites combined.

When excluding the No ID Challenge results, 99.0% (287/290) of results were correct one choice, and 1.0% (3/290) of results were low discrimination correct genus, for a combined agreement of 100% (290/290) for the mould, mycobacteria and *Nocardia* challenge isolates tested at all clinical trial sites combined.

Quality control strains *Mycobacterium smegmatis*, ATCC 19420, and *Nocardia farcinica*, ATCC 3308, showed 100% agreement, the quality control strain *Aspergillus brasiliensis*, ATCC 16404, showed 97.5% agreement, and the negative control showed 99.7% agreement.