



bioMerieux, Inc.
Nathan Hardesty
Sr. Manager, Regulatory Affairs Microbiology
595 Anglum Rd.
Hazelwood, Missouri 63042

March 15, 2022

Re: K212461
Trade/Device Name: Vitek MS Prime
Regulation Number: 21 CFR 866.3378
Regulation Name: Clinical Mass Spectrometry Microorganism Identification And Differentiation System
Regulatory Class: Class II
Product Code: QBN
Dated: August 3, 2021
Received: August 6, 2021

Dear Nathan Hardesty:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2023

See PRA Statement below.

Indications for Use

510(k) Number (if known)

To be assigned

Device Name

VITEK® MS PRIME

Indications for Use (Describe)

VITEK® MS PRIME 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 PRIME system 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 fungal 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**List of Claimed Organisms****Gram Negative / Positive
Bacteria & Yeast**

Abiotrophia defectiva
Achromobacter denitrificans
Achromobacter xylosoxidans
Acinetobacter baumannii
Acinetobacter calcoaceticus
Acinetobacter haemolyticus
Acinetobacter johnsonii
Acinetobacter junii
Acinetobacter lwoffii
Acinetobacter nosocomialis
Acinetobacter pittii
Actinomyces bovis
Actinomyces israelii
Actinomyces meyeri
Actinomyces naeslundii
Actinomyces neuii
Actinomyces odontolyticus
Actinotignum schaalii
Aerococcus viridans
Aeromonas hydrophila
Aeromonas jandaei
Aeromonas punctata (caviae)
Aeromonas sobria
Aggregatibacter
 actinomycetemcomitans
Aggregatibacter aphrophilus
Aggregatibacter segnis
Alcaligenes faecalis ssp faecalis
Bacteroides caccae
Bacteroides eggerthii
Bacteroides fragilis
Bacteroides ovatus / xylanisolvens
Bacteroides pyogenes
Bacteroides stercoris
Bacteroides thetaiotaomicron
Bacteroides uniformis
Bacteroides vulgatus
Bifidobacterium spp
Bilophila wadsworthia
Bordetella avium
Bordetella bronchiseptica
Bordetella parapertussis
Bordetella pertussis
Brevundimonas diminuta
Brevundimonas vesicularis
Brucella spp

Burkholderia cenocepacia
Burkholderia cepacia
Burkholderia contaminans
Burkholderia gladioli
Burkholderia multivorans
Burkholderia vietnamiensis
Campylobacter coli
Campylobacter jejuni
Campylobacter rectus
Candida albicans
Candida auris
Candida dubliniensis
Candida duobushaemulonii
Candida famata
Candida glabrata
Candida guilliermondii
Candida haemulonii
Candida inconspicua
Candida intermedia
Candida kefyr
Candida krusei
Candida lambica
Candida lipolytica
Candida lusitaniae
Candida metapsilosis
Candida norvegensis
Candida orthopsilosis
Candida parapsilosis
Candida pelliculosa
Candida rugosa
Candida tropicalis
Candida utilis
Candida zeylanoides
Cedecea davisae
Cedecea lapagei
Cedecea neteri
Chryseobacterium gleum
Chryseobacterium indologenes
Citrobacter amalonaticus
Citrobacter braakii
Citrobacter farmeri
Citrobacter freundii
Citrobacter koseri
Citrobacter youngae
Clostridium baratii
Clostridium beijerinckii
Clostridium butyricum
Clostridium cadaveris

Clostridium clostridioforme
Clostridium difficile
Clostridium innocuum
Clostridium novyi
Clostridium perfringens
Clostridium ramosum
Clostridium septicum
Clostridium sporogenes
Clostridium tertium
Clostridium tetani
Comamonas testosteroni
Corynebacterium jeikeium
Cronobacter muytjensii
Cronobacter sakazakii
Cronobacter turicensis
Cryptococcus gattii
Cryptococcus neoformans
Curtobacterium flaccumfaciens
Delftia acidovorans
Edwardsiella hoshinae
Edwardsiella tarda
Eikenella corrodens
Elizabethkingia anophelis
Elizabethkingia meningoseptica
Elizabethkingia miricola
Enterobacter aerogenes
Enterobacter cloacae
Enterobacter asburiae
Enterobacter cancerogenus
Enterobacter hormaechei
Enterobacter kobei
Enterobacter ludwigii
Enterococcus avium
Enterococcus casseliflavus
Enterococcus durans
Enterococcus faecalis
Enterococcus faecium
Enterococcus gallinarum
Enterococcus hirae
Escherichia coli
Escherichia fergusonii
Escherichia hermannii
Escherichia vulneris
Ewingella americana
Finegoldia magna
Fusobacterium mortiferum
Fusobacterium necrophorum
Fusobacterium nucleatum
Fusobacterium periodonticum
Gardnerella vaginalis
Gemella haemolysans
Gemella morbillorum
Granulicatella adiacens
Haemophilus influenzae
Haemophilus parahaemolyticus
Haemophilus parainfluenzae
Hafnia alvei
Hathewayia histolytica
Kingella denitrificans
Kingella kingae
Klebsiella oxytoca
Klebsiella pneumoniae
Kluyvera ascorbata
Kluyvera cryocrescens
Kluyvera intermedia
Kocuria rhizophila
Kodamaea ohmeri
Lactococcus garvieae
Lactococcus lactis
Leclercia adecarboxylata
Legionella pneumophila
Lelliottia amnigena
Leuconostoc mesenteroides
Leuconostoc
 pseudomesenteroides
Listeria monocytogenes
Malassezia furfur
Malassezia pachydermatis
Mannheimia haemolytica
Micrococcus luteus
Mobiluncus curtisii
Moraxella catarrhalis
Moraxella lacunata
Moraxella nonliquefaciens
Moraxella osloensis
Morganella morganii
Myroides spp
Neisseria cinerea
Neisseria gonorrhoeae
Neisseria meningitidis
Neisseria mucosa / sicca
Ochrobactrum anthropi
Oligella ureolytica
Oligella urethralis
Paeniclostridium sordellii
Pantoea agglomerans
Pantoea dispersa

Paraclostridium bifermentans
Parvimonas micra
Pasteurella aerogenes
Pasteurella multocida
Pediococcus acidilactici
Peptoniphilus asaccharolyticus
Peptostreptococcus anaerobius
Plesiomonas shigelloides
Pluralibacter gergoviae
Porphyromonas asaccharolytica / uenonis
Porphyromonas gingivalis
Prevotella bivia
Prevotella buccae
Prevotella denticola
Prevotella intermedia
Prevotella loescheii
Prevotella melaninogenica
Prevotella oralis
Prevotella oris
Propionibacterium acidipropionici
Propionibacterium acnes
Propionibacterium avidum
Propionibacterium granulosum
Propionibacterium propionicum
Proteus mirabilis
Proteus penneri
Proteus vulgaris
Providencia alcalifaciens
Providencia rettgeri
Providencia rustigianii
Providencia stuartii
Pseudomonas aeruginosa
Pseudomonas alcaligenes
Pseudomonas fluorescens
Pseudomonas luteola
Pseudomonas mendocina
Pseudomonas oryzihabitans
Pseudomonas putida
Pseudomonas stutzeri
Ralstonia pickettii
Raoultella ornithinolytica
Raoultella planticola
Raoultella terrigena
Rhizobium radiobacter
Rhodotorula mucilaginosa
Rothia mucilaginosa
Saccharomyces cerevisiae
Salmonella enterica ssp enterica
Saprochaete capitata
Serratia ficaria
Serratia fonticola
Serratia grimesii
Serratia liquefaciens
Serratia marcescens
Serratia odorifera
Serratia plymuthica
Serratia proteamaculans
Serratia quinivorans
Serratia rubidaea
Shewanella putrefaciens
Sphingobacterium multivorum
Sphingobacterium spiritivorum
Sphingomonas paucimobilis
Staphylococcus aureus
Staphylococcus auricularis
Staphylococcus capitis
Staphylococcus chromogenes
Staphylococcus cohnii ssp cohnii
Staphylococcus cohnii ssp urealyticus
Staphylococcus epidermidis
Staphylococcus haemolyticus
Staphylococcus hominis
Staphylococcus hyicus
Staphylococcus intermedius
Staphylococcus kloosii
Staphylococcus lentus
Staphylococcus lugdunensis
Staphylococcus pseudintermedius
Staphylococcus saprophyticus
Staphylococcus schleiferi
Staphylococcus sciuri
Staphylococcus simulans
Staphylococcus warneri
Staphylococcus xylosus
Stenotrophomonas maltophilia
Streptococcus agalactiae
Streptococcus alactolyticus
Streptococcus anginosus
Streptococcus canis
Streptococcus constellatus
Streptococcus cristatus
Streptococcus dysgalactiae ssp dysgalactiae
Streptococcus dysgalactiae ssp equisimilis
Streptococcus equi ssp equi
Streptococcus equi ssp zooepidemicus
Streptococcus equinus
Streptococcus gallolyticus ssp gallolyticus
Streptococcus gallolyticus ssp pasteurianus
Streptococcus gordonii

Streptococcus infantarius ssp *coli* (*Str.lutetiensis*)
Streptococcus infantarius ssp *infantarius*
Streptococcus intermedius
Streptococcus mitis / *Streptococcus oralis*
Streptococcus mutans
Streptococcus parasanguinis
Streptococcus pneumoniae
Streptococcus pseudoporcinus
Streptococcus pyogenes
Streptococcus salivarius ssp *salivarius*
Streptococcus sanguinis
Streptococcus sobrinus
Streptococcus suis
Streptococcus uberis
Streptococcus vestibularis
Tannerella forsythia
Veillonella dispar
Vibrio alginolyticus
Vibrio cholerae
Vibrio fluvialis
Vibrio metschnikovii
Vibrio mimicus
Vibrio parahaemolyticus
Vibrio vulnificus
Yersinia aldovae
Yersinia enterocolitica
Yersinia frederiksenii
Yersinia intermedia
Yersinia kristensenii
Yersinia pseudotuberculosis
Yersinia ruckeri

Mycobacterium

Mycobacterium abscessus
Mycobacterium avium
Mycobacterium chelonae
Mycobacterium fortuitum group
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
Mycobacterium xenopi

Nocardia

Nocardia abscessus
Nocardia africana / *nova*
Nocardia asteroides
Nocardia brasiliensis
Nocardia cyriacigeorgica
Nocardia farcinica
Nocardia otitidiscaviarum
Nocardia paucivorans
Nocardia pseudobrasiliensis
Nocardia transvalensis
Nocardia veterana
Nocardia wallacei

Mould

Acremonium sclerotigenum
Alternaria alternata
Aspergillus brasiliensis
Aspergillus calidoustus / *ustus*
Aspergillus flavus / *oryzae*
Aspergillus fumigatus
Aspergillus lentulus
Aspergillus nidulans
Aspergillus niger complex
Aspergillus sydowii
Aspergillus terreus complex
Aspergillus versicolor
Blastomyces dermatitidis
Cladophialophora bantiana
Coccidioides immitis / *posadasii*
Curvularia hawaiiensis
Curvularia spicifera
Epidermophyton floccosum
Exophiala dermatitidis
Exophiala xenobiotica
Exserohilum rostratum
Fusarium oxysporum complex
Fusarium proliferatum
Fusarium solani complex
Histoplasma capsulatum
Lecythophora hoffmannii
Lichtheimia corymbifera
Microsporum audouinii

Microsporium canis
Microsporium gypseum
Mucor racemosus complex
Paecilomyces variotii complex
Penicillium chrysogenum
Pseudallescheria boydii
Purpureocillium lilacinum
Rasamsonia argillacea complex
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
Trichosporon asahii
Trichosporon dermatis / mucoides
Trichosporon inkin



510(k) SUMMARY

VITEK® MS PRIME

A. 510(k) Submission Information:

Submitter's Name: bioMérieux, Inc. on behalf of bioMérieux SA
Manufacturer: 3 Route de Port Michaud
Address: La Balme les Grottes, 38390 (France)
Contact Person: Nathan Hardesty
Associate Director, Regulatory Affairs Microbiology
Phone Number: 314 -731-8666
Fax Number: 314-731-8689
Date of Preparation: March 2, 2022

B. Device Name and Classification:

Formal/Trade Name: VITEK® MS PRIME
Regulation: 21 CFR 866.3378
Classification Name: Clinical Mass Spectrometry Microorganism Identification and Differentiation System
Common Name: VITEK MS PRIME

C. Predicate Device: VITEK® MS (K181412)

Item	Device: VITEK® MS PRIME	Predicate: VITEK® MS (K181412)
Similarities		
Intended Use Same – the only difference is that for the VITEK® MS PRIME the reference to yeast and mould was simplified (i.e. combined to indicate “fungal.”)	VITEK® MS PRIME 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 PRIME system is a qualitative <i>in vitro</i> diagnostic device indicated for use in	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 PRIME system is a qualitative <i>in vitro</i> diagnostic device indicated for use in

595 Anglum Rd., Hazelwood, MO 63042 United States

Phone : 314-731-8500 - Fax : 314-731-8700 www.biomerieux.com

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Item	Device: VITEK® MS PRIME	Predicate: VITEK® MS (K181412)
Similarities		
	conjunction with other clinical and laboratory findings to aid in the diagnosis of bacterial and fungal infections.	conjunction with other clinical and laboratory findings to aid in the diagnosis of bacterial, yeast and mould infections.
Where Used	Clinical laboratories (used by trained clinicians)	Same
Test Methodology	Use of MALDI-TOF MS technology for microorganism identification, as a qualitative <i>in vitro</i> diagnostic device to be used in conjunction with other clinical and laboratory findings to aid in the diagnosis of bacterial and fungal infections	Same
Analyte Tested	Microorganisms cultured from human specimens. The bacterial and fungal cultures are from solid media, or in the case of Mycobacteria may be isolated from either solid or liquid media.	Same
Preparation Reagents / Components / Set Up Methods	<ul style="list-style-type: none"> • CHCA Matrix • FA Reagent • VITEK® MS DS Target Slides • Myco. / Nocardia Preparation Kit (and liquid media components for Mycobacteria) • Mould Preparation Kit 	Same
Knowledge Base	KB v3.2	Same

Item	Device: VITEK® MS PRIME	Predicate: VITEK® MS (K181412)
Differences		
Instrument	<ol style="list-style-type: none"> 1. Benchtop model – with shorter flight tube 2. Laser - neodymium-doped yttrium fluoride lasing (YFL) laser 3. Multichannel plate detector in a photomultiplier tube 4. Optics are on access for irradiation 5. Load and go approach for loading slides onto the system – system can load up to 16 slides with the option for slide prioritization. 	<ol style="list-style-type: none"> 1. Floor standing model – with longer flight tube 2. Nitrogen based 3. Multiple dynode detector 4. Optics used for irradiation are asymmetrical of deflectors 5. Maximum of four slides can be loaded onto the instrument (slides must be read in the order that they were loaded).
Accelerated ions	Cations	Cations and anions
Rastering Pattern	Continuous raster path across the	Rastering is accomplished by firing

Item	Device: VITEK® MS PRIME	Predicate: VITEK® MS (K181412)
Differences		
	slide spot. The “profile” for the sample is defined as an average of 50 spectra obtained by as many consecutive laser shots.	the laser at the first raster point (five shots are made to obtain one profile). If the profile is good, then the laser will re-shoot the same spot to acquire a new profile. If there are two consecutive failed profiles then the laser moves to the next raster point. The acquisition process stops when the target of 100 good profiles is achieved, or when all raster points have been visited.

D. 510(k) Summary:

Intended Use:

VITEK® MS PRIME 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 PRIME system 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 fungal infections.

List of Claimed Organisms

Gram Negative / Positive Bacteria & Yeast

Abiotrophia defectiva
Achromobacter denitrificans
Achromobacter xylosoxidans
Acinetobacter baumannii
Acinetobacter calcoaceticus
Acinetobacter haemolyticus
Acinetobacter johnsonii
Acinetobacter junii
Acinetobacter lwoffii
Acinetobacter nosocomialis
Acinetobacter pittii
Actinomyces bovis
Actinomyces israelii
Actinomyces meyeri
Actinomyces naeslundii
Actinomyces neuii
Actinomyces odontolyticus
Actinotignum schaalii
Aerococcus viridans
Aeromonas hydrophila
Aeromonas jandaei

Aeromonas punctata (caviae)
Aeromonas sobria
Aggregatibacter
actinomycetemcomitans
Aggregatibacter aphrophilus
Aggregatibacter segnis
Alcaligenes faecalis ssp faecalis
Bacteroides caccae
Bacteroides eggerthii
Bacteroides fragilis
Bacteroides ovatus / xylanisolvens
Bacteroides pyogenes
Bacteroides stercoris
Bacteroides thetaiotaomicron
Bacteroides uniformis
Bacteroides vulgatus
Bifidobacterium spp
Bilophila wadsworthia
Bordetella avium
Bordetella bronchiseptica
Bordetella parapertussis
Bordetella pertussis
Brevundimonas diminuta
Brevundimonas vesicularis
Brucella spp

Burkholderia cenocepacia
Burkholderia cepacia
Burkholderia contaminans
Burkholderia gladioli
Burkholderia multivorans
Burkholderia vietnamiensis
Campylobacter coli
Campylobacter jejuni
Campylobacter rectus
Candida albicans
Candida auris
Candida dubliniensis
Candida duobushaemulonii
Candida famata
Candida glabrata
Candida guilliermondii
Candida haemulonii
Candida inconspicua
Candida intermedia
Candida kefyr
Candida krusei
Candida lambica
Candida lipolytica
Candida lusitanae
Candida metapsilosis
Candida norvegensis
Candida orthopsilosis
Candida parapsilosis
Candida pelliculosa
Candida rugosa
Candida tropicalis
Candida utilis
Candida zeylanoides
Cedecea davisae
Cedecea lapagei
Cedecea neteri
Chryseobacterium gleum
Chryseobacterium indologenes
Citrobacter amalonaticus
Citrobacter braakii
Citrobacter farmeri
Citrobacter freundii
Citrobacter koseri
Citrobacter youngae
Clostridium baratii
Clostridium beijerinckii
Clostridium butyricum
Clostridium cadaveris
Clostridium clostridioforme
Clostridium difficile
Clostridium innocuum
Clostridium novyi
Clostridium perfringens
Clostridium ramosum
Clostridium septicum
Clostridium sporogenes
Clostridium tertium
Clostridium tetani
Comamonas testosteroni
Corynebacterium jeikeium
Cronobacter muytjensii
Cronobacter sakazakii
Cronobacter turicensis
Cryptococcus gattii
Cryptococcus neoformans
Curtobacterium flaccumfaciens
Delftia acidovorans
Edwardsiella hoshinae
Edwardsiella tarda
Eikenella corrodens
Elizabethkingia anophelis
Elizabethkingia meningoseptica
Elizabethkingia miricola
Enterobacter aerogenes
Enterobacter cloacae
Enterobacter asburiae
Enterobacter cancerogenus
Enterobacter hormaechei
Enterobacter kobei
Enterobacter ludwigii
Enterococcus avium
Enterococcus casseliflavus
Enterococcus durans
Enterococcus faecalis
Enterococcus faecium
Enterococcus gallinarum
Enterococcus hirae
Escherichia coli
Escherichia fergusonii
Escherichia hermannii
Escherichia vulneris
Ewingella americana
Fingoldia magna
Fusobacterium mortiferum
Fusobacterium necrophorum
Fusobacterium nucleatum
Fusobacterium periodonticum
Gardnerella vaginalis
Gemella haemolysans
Gemella morbillorum
Granulicatella adiacens
Haemophilus influenzae
Haemophilus parahaemolyticus
Haemophilus parainfluenzae
Hafnia alvei
Hathewayia histolytica
Kingella denitrificans
Kingella kingae
Klebsiella oxytoca
Klebsiella pneumoniae
Kluyvera ascorbata
Kluyvera cryocrescens

Kluyvera intermedia
Kocuria rhizophila
Kodamaea ohmeri
Lactococcus garvieae
Lactococcus lactis
Leclercia adecarboxylata
Legionella pneumophila
Lelliottia amnigena
Leuconostoc mesenteroides
Leuconostoc pseudomesenteroides
Listeria monocytogenes
Malassezia furfur
Malassezia pachydermatis
Mannheimia haemolytica
Micrococcus luteus
Mobiluncus curtisii
Moraxella catarrhalis
Moraxella lacunata
Moraxella nonliquefaciens
Moraxella osloensis
Morganella morganii
Myroides spp
Neisseria cinerea
Neisseria gonorrhoeae
Neisseria meningitidis
Neisseria mucosa / sicca
Ochrobactrum anthropi
Oligella ureolytica
Oligella urethralis
Paeniclostridium sordellii
Pantoea agglomerans
Pantoea dispersa
Paraclostridium bifermentans
Parvimonas micra
Pasteurella aerogenes
Pasteurella multocida
Pediococcus acidilactici
Peptoniphilus asaccharolyticus
Peptostreptococcus anaerobius
Plesiomonas shigelloides
Pluralibacter gergoviae
Porphyromonas asaccharolytica / uenonis
Porphyromonas gingivalis
Prevotella bivia
Prevotella buccae
Prevotella denticola
Prevotella intermedia
Prevotella loescheii
Prevotella melaninogenica
Prevotella oralis
Prevotella oris
Propionibacterium acidipropionici
Propionibacterium acnes
Propionibacterium avidum
Propionibacterium granulosum
Propionibacterium propionicum
Proteus mirabilis
Proteus penneri
Proteus vulgaris
Providencia alcalifaciens
Providencia rettgeri
Providencia rustigianii
Providencia stuartii
Pseudomonas aeruginosa
Pseudomonas alcaligenes
Pseudomonas fluorescens
Pseudomonas luteola
Pseudomonas mendocina
Pseudomonas oryzihabitans
Pseudomonas putida
Pseudomonas stutzeri
Ralstonia pickettii
Raoultella ornithinolytica
Raoultella planticola
Raoultella terrigena
Rhizobium radiobacter
Rhodotorula mucilaginosa
Rothia mucilaginosa
Saccharomyces cerevisiae
Salmonella enterica ssp enterica
Saprochaete capitata
Serratia ficaria
Serratia fonticola
Serratia grimesii
Serratia liquefaciens
Serratia marcescens
Serratia odorifera
Serratia plymuthica
Serratia proteamaculans
Serratia quinivorans
Serratia rubidaea
Shewanella putrefaciens
Sphingobacterium multivorum
Sphingobacterium spiritivorum
Sphingomonas paucimobilis
Staphylococcus aureus
Staphylococcus auricularis
Staphylococcus capitis
Staphylococcus chromogenes
Staphylococcus cohnii ssp cohnii
Staphylococcus cohnii ssp urealyticus
Staphylococcus epidermidis
Staphylococcus haemolyticus
Staphylococcus hominis
Staphylococcus hyicus
Staphylococcus intermedius
Staphylococcus kloosii
Staphylococcus lentus
Staphylococcus lugdunensis
Staphylococcus pseudintermedius
Staphylococcus saprophyticus

Staphylococcus schleiferi
Staphylococcus sciuri
Staphylococcus simulans
Staphylococcus warneri
Staphylococcus xylosus
Stenotrophomonas maltophilia
Streptococcus agalactiae
Streptococcus alactolyticus
Streptococcus anginosus
Streptococcus canis
Streptococcus constellatus
Streptococcus cristatus
Streptococcus dysgalactiae ssp
dysgalactiae
Streptococcus dysgalactiae ssp
equisimilis
Streptococcus equi ssp *equi*
Streptococcus equi ssp *zooepidemicus*
Streptococcus equinus
Streptococcus gallolyticus ssp *gallolyticus*
Streptococcus gallolyticus ssp
pasteurianus
Streptococcus gordonii
Streptococcus infantarius ssp *coli*
(*Str.lutetiensis*)
Streptococcus infantarius ssp *infantarius*
Streptococcus intermedius
Streptococcus mitis / *Streptococcus oralis*
Streptococcus mutans
Streptococcus parasanguinis
Streptococcus pneumoniae
Streptococcus pseudoporcinus
Streptococcus pyogenes
Streptococcus salivarius ssp *salivarius*
Streptococcus sanguinis
Streptococcus sobrinus
Streptococcus suis
Streptococcus uberis
Streptococcus vestibularis
Tannerella forsythia
Veillonella dispar
Vibrio alginolyticus
Vibrio cholerae
Vibrio fluvialis
Vibrio metschnikovii
Vibrio mimicus
Vibrio parahaemolyticus
Vibrio vulnificus
Yersinia aldovae
Yersinia enterocolitica
Yersinia frederiksenii
Yersinia intermedia
Yersinia kristensenii
Yersinia pseudotuberculosis
Yersinia ruckeri

Mycobacterium

Mycobacterium abscessus
Mycobacterium avium
Mycobacterium chelonae
Mycobacterium fortuitum group
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
Mycobacterium xenopi

Nocardia

Nocardia abscessus
Nocardia africana / *nova*
Nocardia asteroides
Nocardia brasiliensis
Nocardia cyriacigeorgica
Nocardia farcinica
Nocardia otitidiscaviarum
Nocardia paucivorans
Nocardia pseudobrasiliensis
Nocardia transvalensis
Nocardia veterana
Nocardia wallacei

Mould

Acremonium sclerotigenum
Alternaria alternata
Aspergillus brasiliensis
Aspergillus calidoustus / *ustus*
Aspergillus flavus / *oryzae*
Aspergillus fumigatus
Aspergillus lentulus
Aspergillus nidulans
Aspergillus niger complex
Aspergillus sydowii
Aspergillus terreus complex
Aspergillus versicolor
Blastomyces dermatitidis
Cladophialophora bantiana
Coccidioides immitis / *posadasii*
Curvularia hawaiiensis
Curvularia spicifera

Epidermophyton floccosum
Exophiala dermatitidis
Exophiala xenobiotica
Exserohilum rostratum
Fusarium oxysporum complex
Fusarium proliferatum
Fusarium solani complex
Histoplasma capsulatum
Lecythophora hoffmannii
Lichtheimia corymbifera
Microsporium audouinii
Microsporium canis
Microsporium gypseum
Mucor racemosus complex
Paecilomyces variotii complex
Penicillium chrysogenum
Pseudallescheria boydii

Purpureocillium lilacinum
Rasamsonia argillacea complex
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
Trichosporon asahii
Trichosporon dermatis / mucoides
Trichosporon inkin

Device Description:

This 510(k) submission introduces the VITEK® MS PRIME System. The VITEK® MS PRIME is intended for laboratory use by professional users who are trained in microbiology and good laboratory practices.

The VITEK® MS PRIME makes microorganism identifications 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.

As a first step, a VITEK® MS-DS Target Slide is prepared in accordance with the instructions for use.

NOTE: Depending on the culture, the analyte sample (i.e. microorganism from cultured media) 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 the specimen (cultured from the appropriate media) is 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.

NOTE: The VITEK® MS PRIME is a Class 1 laser product, containing a Class 4 Neodymium-doped yttrium lithium fluoride (Nd:YLF) laser – the laser operates at a wavelength of 349 nm.

The prepared slide is then loaded onto the VITEK® MS PRIME 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. So as part of the first basic principle, the ionized molecules are then accelerated in an electromagnetic field and a grid electrode in the ionization chamber.

The acceleration in the electromagnetic field is the beginning of the second basic principle (i.e. the separation process that is based of the time-of-flight principle). 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.

As a final step in the basic principle of MALDI-ToF technology (i.e. detection) the time of flight is

measured precisely by the ions arrival at a particle detector. This speed of the ions in flight depends on their mass - with heavier molecules having a higher moment of inertia resulting in a lower velocity. The time of transit 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 recorded signal is processed and presented as a spectrum of intensity versus mass in Daltons (Da). The mass spectrum displays results as a series of peaks (spectrum) which correspond to the ionized proteins derived from the analyte sample. And for identification of an unknown organism, the resulting mass spectra are sufficiently distinctive to allow taxonomic characterization at the genus and species when compared against the VITEK® MS Knowledge Base.

VITEK® MS PRIME Performance Summary:

Biological equivalency:

As part of the VITEK® MS PRIME verification activities, a biological equivalency study was performed to test the clinically validated species as included in the current VITEK® MS Knowledge Base. The biological equivalency study corresponds to the 479 claimed species, and the strains tested during the study included critical pathogens, from all microorganism groups combined: i.e. Gram-positive aerobic and anaerobic bacteria, Gram negative aerobic and anaerobic bacteria (including *Brucella*), yeasts, moulds, *Mycobacterium* (from both solid and liquid culture media), and *Nocardia*.

The biological equivalency performance is calculated from 1461 samples (487 unique tests in triplicate) and is presented below.

NOTE: Two species from the 479 claimed species (*Coccidioides immitis* and *C. posadasii*) were not tested due to lack of available strains

Biological equivalency performance of each organism group tested on the VITEK® MS PRIME is highlighted below,

- Gram positive organisms (99.0% for correct single choice ID or low discrimination to the correct genus)
- Gram negative organisms (97.2% for correct single choice ID or low discrimination to the correct genus)
- Yeast (100% for correct single choice ID or low discrimination to the correct genus)
- *Mycobacteria* from solid culture media (100% for correct single choice ID or low discrimination to the correct genus)
- *Mycobacteria* from liquid culture media (97.62% for correct single choice ID or low discrimination to the correct genus)
- Moulds (97.4% for correct single choice ID or low discrimination to the correct genus)
- *Nocardia* (100% for correct single choice ID or low discrimination to the correct genus).

The VITEK® MS PRIME biological equivalency performance demonstrated an error (i.e. a Discordant Identification) rate of 0.3% (5/1461) with the clinically validated isolates tested. In addition, the combined no identification rate for the VITEK® MS PRIME was 1.6% (23/1461).

In summary a minimum 95% agreement (in comparison with the reference method) was met during the biological equivalency study.

Clinical Performance Evaluation:

The clinical performance evaluation for the VITEK® MS PRIME used an equivalency approach

with the VITEK® MS – 100 species (with five strains each) from the list of FDA Indications for use for Knowledge Base (KB) v3.2. Performance was determined by comparing the VITEK® MS PRIME identification to a one choice or multiple choice (more than one species) reference identification obtained during previous clinical studies.

When tested on the VITEK® MS PRIME, clinical isolates tested from all sites combined (for correct single choice identification, or a low discrimination correct genus result) showed an agreement rate of 98.4% (492/500). Clinical Performance of each organism group tested on the VITEK® MS PRIME is highlighted below,

- Gram positive organisms (99.3% for correct single choice ID or low discrimination to the correct genus)
- Gram negative organisms (98.8% for correct single choice ID or low discrimination to the correct genus)
- Yeast (95.3% for correct single choice ID or low discrimination to the correct genus)
- *Mycobacteria* (100% for correct single choice ID or low discrimination to the correct genus)
- Moulds (98.0% for correct single choice ID or low discrimination to the correct genus)
- *Nocardia* (100% for correct single choice ID or low discrimination to the correct genus).

The VITEK® MS PRIME clinical performance evaluation demonstrated an error (Discordant Identification) rate of 0.4% (2/500) with the clinical isolates tested that were tested. In addition, the combined no identification rate for the VITEK® MS PRIME was 1.2% (6/500).

In summary a minimum 95% agreement (in comparison with the reference method) was met for the following:

- Overall performance for all species combined from all sites, including and excluding No ID results
- Overall performance for the following organism groups: Gram positive, Gram negative, *Mycobacteria*, *Nocardia*, moulds, and yeasts from all sites combined, including and excluding No ID results
- Overall performance for each organism classification (aerobic Gram positive, anaerobic Gram positive, aerobic Gram negative and anaerobic Gram negative) from all sites combined, including and excluding No ID results.

Challenge Isolate Results:

100.0% (100/100) agreement was obtained for the 100 challenge strains tested – identification results were received for all isolates (i.e. there were no No ID results), and there were no discrepant results (i.e. misidentifications).

Quality Control Results:

98.3% agreement was obtained with all quality control strains tested at all sites.

Reproducibility Results:

For Reproducibility testing a 99.5% agreement was achieved for Reproducibility strains tested on the VITEK® MS PRIME.

Conclusion:

The clinical performance data as presented in this submission supports a substantial equivalence decision for the VITEK® MS PRIME. The VITEK® MS PRIME shows 98.4% (492/500) agreement for clinical isolates tested, with two discordant results (0.4%) and six no identification (1.2%) results. When excluding No ID results, performance is 99.6% (492/494) agreement with the same discordant rate of 0.4%.