August 31, 2023

Becton, Dickinson and Company
Laura Stewart
Senior Manager, Regulatory Affairs
7 Loveton Circle
Mail Code 694
Sparks, Maryland 21152

Re: K222563
Trade/Device Name: BD Kiestra IdentifA
Regulation Number: 21 CFR 866.3378
Regulation Name: Clinical Mass Spectrometry Microorganism Identification And Differentiation System
Regulatory Class: Class II
Product Code: QQV, QBN
Dated: June 2, 2023
Received: June 5, 2023

Dear Laura Stewart:

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,

Ribhi Shawar -S

Ribhi Shawar, Ph.D. (ABMM)
Branch Chief,
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222563

Device Name
BD Kiestra IdentifA

Indications for Use *(Describe)*
The BD Kiestra IdentifA module is an automated in vitro diagnostic specimen preparation system for use with the BD Kiestra Laboratory Automation Solution to prepare MALDI targets for the Bruker MALDI Biotyper System (CA, sirius CA, or sirius one CA) for the qualitative identification and differentiation of microorganisms using matrix-assisted laser desorption/ionization-time of flight mass spectrometry (MALDI-TOF MS) analysis of colonies grown on plated culture media from human specimens.

The BD Kiestra IdentifA is indicated for use in the clinical laboratory with the BD Kiestra ReadA or ReadA Compact and Bruker MALDI Biotyper System (CA, sirius CA, or sirius one CA) to aid in the diagnosis of bacterial and fungal infections.

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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510(k) Summary

BD Kiestra™ IdentifA

Summary Preparation Date:
8/24/2023

I Background Information

A 510(k) Number

K222563

B Applicant

BD Integrated Diagnostic Solutions
Becton, Dickinson and Company
7 Loveton Circle
Sparks, Maryland 21152
Establishment Registration Number: 1119779
Contact: Laura Stewart
Telephone: 410-316-4000

C Proprietary and Established Name

BD Kiestra™ IdentifA

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QQV	Class II	21 CFR 866.3378 – Clinical Mass Spectrometry Microorganism Identification And Differentiation System	MI – Microbiology
QBN	Class II	21 CFR 866.3378 – Clinical Mass Spectrometry Microorganism Identification And Differentiation System	MI – Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain substantial equivalence determination for the BD Kiestra™ IdentifA instrument with the addition of the BD Kiestra ReadA camera system as well as the Bruker MALDI Biotyper sirius CA and sirius one CA systems.

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B Type of Test:

Qualitative *in vitro* diagnostic device for identification and differentiation of microorganisms cultured from human specimens by automation of target preparation for mass spectrometry analysis.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indication(s) for Use

B Indication(s) for Use:

The BD Kiestra™ IdentifA module is an automated in vitro diagnostic specimen preparation system for use with the BD Kiestra™ Laboratory Automation Solution to prepare MALDI targets for the Bruker MALDI Biotyper® System (CA, sirius CA, or sirius one CA) for the qualitative identification and differentiation of microorganisms using matrix-assisted laser desorption/ionization-time of flight mass spectrometry (MALDI-TOF MS) analysis of colonies grown on plated culture media from human specimens.

The BD Kiestra™ IdentifA is indicated for use in the clinical laboratory with the BD Kiestra ReadA or ReadA Compact and Bruker MALDI Biotyper® System (CA, sirius CA, or sirius one CA) to aid in the diagnosis of bacterial and fungal infections.

C Special Conditions for Use Statement(s):

- Rx – For Prescription Use Only
- IVD – For In Vitro Diagnostic Use Only

D Special Instrument Requirements:

1. BD Kiestra™ ReadA and ReadA Compact

The BD Kiestra™ ReadA or ReadA Compact module is required for use in conjunction with the BD Kiestra™ IdentifA to obtain the digital image the IdentifA uses for colony selection and target preparation. The ReadA or ReadA Compact is an essential component to the performance of the IdentifA and, together with the IdentifA and the Bruker MALDI Biotyper® System (CA, sirius CA, or sirius one CA), comprises a test system for the qualitative identification and differentiation of microorganisms. Any change to the ReadA or ReadA Compact will be assessed and appropriate verification and validation will be performed as applicable to assure proper function of the BD Kiestra™ IdentifA.

2. Bruker MALDI Biotyper® for Clinical Applications (MBT-CA)

When using the BD Kiestra™ IdentifA, refer to the most recent version of the Bruker MALDI Biotyper® System labeling (CA, sirius CA, or sirius one CA).

Performance of the BD Kiestra IdentifA was evaluated with the following culture media that are validated as compatible with the Bruker MALDI Biotyper® System (CA, sirius CA, or sirius one CA):

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Trypticase Soy Agar with 5% Sheep Blood
MacConkey Agar
Columbia CNA Agar with 5% Sheep Blood
Chocolate Agar
Sabouraud-Dextrose Agar
CDC Anaerobe Agar 5% Sheep Blood
Campylobacter Agar with 5 Antimicrobics and 10% Sheep Blood

Performance of the BD Kiestra IdentifA has not been established with the following culture media that are validated as compatible on the Bruker MALDI Biotyper® System (CA, sirius CA, or sirius one CA):

Bacteroides Bile Esculin Agar with Amikacin
Bordet Gengou Agar with 15% Sheep Blood
Clostridium Difficile Agar with 7% Sheep Blood
Buffered Charcoal Yeast Extract Agar
Buffered Charcoal Yeast Extract Agar with Polymixin, Anisomycin and Vancomycin
Brucella Agar with 5% Horse Blood
CDC Anaerobe 5% Sheep Blood Agar with Phenylethyl Alcohol
CDC Anaerobe Laked Sheep Blood Agar with Kanamycin and Vancomycin
Modified Thayer-Martin Agar

IV Device/System Characteristics:

A Device Description:

The BD Kiestra™ IdentifA automates preparation of MALDI targets for the Bruker MALDI Biotyper® CA System, sirius CA system, and/or sirius one CA System that are used in clinical laboratories for identification and differentiation of organisms grown on plated media by Matrix-Assisted Laser Desorption/Ionization Time-of-Flight Mass Spectrometry (MALDI-TOF MS). The system comprises of the BD Kiestra™ IdentifA module (including the associated software and onboard nephelometers and pipetting system), formic acid and automation-compatible transfer vials (for HCCA matrix and Bacterial Test Standard (BTS), which are obtained directly from Bruker and manually transferred to the vials for use on the instrument), consumables (pipette tips and cuvette arrays for preparation of organism suspensions and fluid movement), and nephelometer calibration standards (McFarland standard vials for measuring turbidity of microbial suspensions).

When identification of an organism growing on a culture medium plate is required, a technologist designates specific colonies for picking by the BD Kiestra™ IdentifA module using a digital image of the plate obtained using the BD Kiestra™ ReadA or ReadA Compact module. The BD Kiestra™ IdentifA automatically suspends the designated colonies in deionized water and uses an onboard nephelometer to determine the resulting turbidity. The organism concentration is adjusted automatically by picking additional designated colonies or by appropriate dilution of the suspension to achieve a turbidity within a targeted range of McFarland values. Based on the final organism concentration, the BD Kiestra™ IdentifA pipets one or more aliquots of the microbial suspension onto a MALDI target (either reusable 48-spot or disposable 96-spot targets) and dries the spots at elevated temperature.

The BD Kiestra™ IdentifA performs the extended Direct Transfer (eDT) Sample Preparation Procedure from Bruker whereby the instrument overlays the dried sample spot on the MALDI

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target with formic acid and matrix. The BD Kiestra™ IdentifA also spots the BTS used for quality control of MALDI-TOF MS organism identification. Once spots are dry, the technologist manually removes the target from the BD Kiestra™ IdentifA and loads it into the Bruker MALDI Biotyper® System for analysis. Information regarding the location of each sample and BTS on the targets and the associated MALDI-TOF MS results are transmitted between the BD Kiestra™ IdentifA and Bruker MALDI Biotyper® System via the Synapsys Informatics, the main software interface, and the BD Kiestra™ BeA, the data interface hub module that communicates with all the other modules including the BD Kiestra™ IdentifA. In addition to preparing the MALDI target, if requested, the BD Kiestra™ IdentifA will also dilute the organism suspension to a standardized turbidity of 0.5 McFarland.

Modules of the BD Kiestra™ System each have their own operating software that communicates via the central BeA data interface hub module with the Synapsys user interface which in turn sends and receives information to/from the Laboratory Information System (LIS) (**Figure 1**).

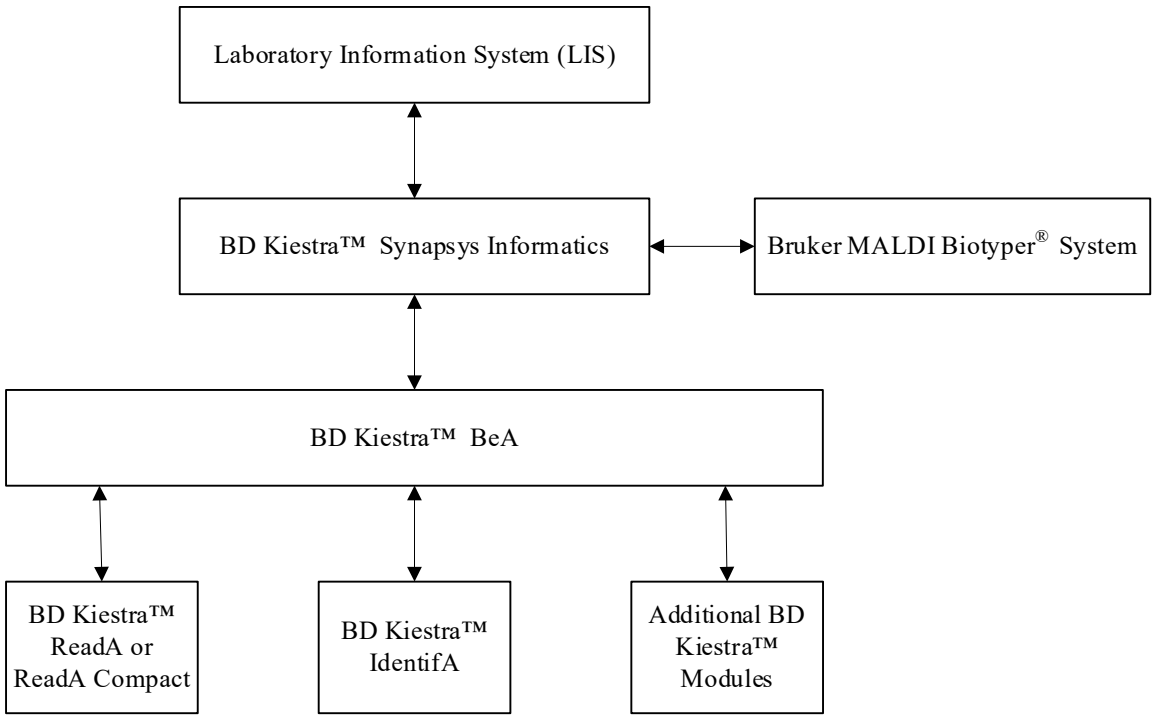

Figure 1: Overview of software interfaces for the BD Kiestra™ Laboratory Automation System

The BD Kiestra™ ReadA or ReadA Compact module is required for use in conjunction with the BD Kiestra™ IdentifA module for image capture. Culture plate incubation may be done offline and then moved to the BD Kiestra™ ReadA or ReadA Compact module for imaging, or incubation can be done in the ReadA and then remain in the ReadA for imaging. Additional software modules (BD Synapsys Informatics and BD Kiestra™ BeA) are also required for the function of the BD Kiestra™ IdentifA, and these modules reside on the BD Kiestra™ Laboratory Automation Solution. The digital image is used by the BD Kiestra™ IdentifA for image analysis and colony designation by the operator.

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B Instrument Description Information:

1. Instrument Name:

   BD Kiestra™ IdentifA

2. Specimen Sampling and Handling:

   The BD Kiestra™ ReadA or ReadA Compact has default parameters for image capture as well as user-defined settings. Images taken under the default parameters are always captured in addition to any further images taken under conditions of illumination and background that are specified by the user. Each of the images is presented to the user via the Synapsis interface.

   Culture plates for processing by the BD Kiestra™ IdentifA are loaded manually or via an automated conveyor, depending on the instrument configuration. Plates are identified by the BD Kiestra™ IdentifA by scanning a linear barcode on the side of the bottom half of each plate. The BD Kiestra™ IdentifA then queries the Synapsys software via the BeA data interface to obtain patient information and details of the testing to be performed. Colonies are identified by a technologist from a digital image of each culture plate obtained from the ReadA or ReadA Compact and designated for picking via the BD Kiestra™ IdentifA. Specific colonies' locations are identified by polar coordinates that are calculated relative to the position of the barcode label. The BD Kiestra™ IdentifA automatically orientates each plate based on the location of the barcode, picks the designated colonies and prepares a suspension in deionized water. Mucoid colonies are detected automatically and processed using a modified procedure to reduce the potential for contamination and ensure homogeneity of the suspension. The turbidity of the final suspension is measured and adjusted as necessary to within a target range of McFarland values. One or more aliquots of the suspension is used to prepare a MALDI target, which is dried at elevated temperature and manually transferred to the Bruker MALDI Biotyper® System for analysis. The location into which each microbial suspension is spotted on the MALDI target together with other relevant tracking parameters for the microbial suspension prepared by the BD Kiestra™ IdentifA are posted to the Synapsis interface via the BeA module.

3. Specimen Identification:

   MALDI targets are manually transferred to the Bruker MALDI Biotyper® System, which performs microbial differentiation and species identification of microorganisms via matrix-assisted laser desorption/ionization-time of flight mass spectrometry (MALDI-TOF MS) analysis. Two-way communication between the BD Kiestra™ IdentifA and Bruker MALDI Biotyper® System is mediated by the Synapsys interface to enable transfer of the MALDI target map to the MALDI Biotyper® System and subsequent receipt of microbial identification results that are displayed to the user.

4. Calibration:

   Camera Calibration

   Calibration of the BD Kiestra™ ReadA or ReadA Compact camera must be performed each time the camera is cleaned or when the position of the camera is changed. Calibration and reference plates containing a plastic disk with red/green/blue print and a barcode label are provided with the system for use with the built-in software calibration wizard, OPTIS, to verify the accuracy of barcode reading, image dimensions and quality. Imaging area detection first selects the appropriate area of the image that contains the plate. Black calibration determines the average grey value and signal-to-noise ratio (SNR) in black images (all lights off). Plate

holder detection uses various inputs to determine the position of the plate holder. Lights calibration adjusts lighting power to ensure homogenous illumination. Linearity calibration ensures that increased exposure of an object results increased signal intensity in each channel of the Bayer filter. SNR calibration determines the SNR as a function of input grey value. White balance and light references calibration normalize RGB channel intensities so that a white object appears white when imaged by the camera system. Pixel calibration accounts for chromatic aberrations and geometrical distortions. When acquiring an image, multiple images of the same scene are evaluated to reduce potential noise and runtime checks are performed to ensure consistency with calibration. Additionally, Petri dishes are imaged with top, side, and bottom illumination utilizing black or white contrasting backgrounds to maximize information and allow reading of plates by microbiologists. After successful image capture, images are normalized and adjusted according to calibrated metrics to improve image quality and reduce variability across each instrument.

Nephelometer Calibration

Calibration of the BD Kiestra™ IdentifA nephelometers must be performed once a month using the provided calibration cuvette array standards (0.2, 0.5, 1.0 and 3.0 McFarland). Additional verification of the nephelometers must be performed daily using the 0.5 McFarland cuvette array. MALDI target preparation will not resume until daily verification passes.

5. Quality Control:

Use of the Bruker US IVD Bacterial Test Standard (BTS) is required to obtain valid identification results with the Bruker MALDI Biotyper® System. The BD Kiestra™ IdentifA uses a modified workflow for preparation and spotting of the BTS solution whereby the volume of solvent is increased to improve the precision of automated pipetting. The modified BTS workflow was verified by conducting a study to validate equivalency of using a double volume of BTS solution (2 µL) compared to the standard volume (1 µL). BTS was prepared per the manufacturer's instructions for use (diluted in 50 µL solvent), and 1 µL was dispensed onto 48- and 96-spot MALDI targets for 102 spots. BTS was then prepared using twice the amount (100 µL) of solvent, and 2 µL was dispensed onto MALDI targets for a total of 430 spots. The modified BTS workflow for BTS spots prepared using the BD Kiestra™ IdentifA performs equivalently to the standard workflow with 423 (98.4%) spots yielding Log(score) values ≥ 2.00 (high-confidence identification) and no statistical difference in performance (paired chi square P value = 0.368) compared to the standard workflow. The results from K191964 are acceptable. No changes were made to Quality Control for this submission.

V Substantial Equivalence Information:

A Predicate Device Name(s):

BD Kiestra™ IdentifA

B Predicate 510(k) Number(s):

K191964

C Comparison with Predicate(s):

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Table 1: Comparison to the Predicate Device

Device & Predicate Device:	**Device:** K222563	**Predicate:** K191964
Device Trade Name	Same	BD Kiestra™ IdentifA
General Device Characteristic Differences		
Intended Use/Indications For Use	The BD Kiestra™ IdentifA module is an automated in vitro diagnostic specimen preparation system for use with the BD Kiestra™ Laboratory Automation Solution to prepare MALDI targets for the Bruker MALDI Biotyper® System (CA, sirius CA, or sirius one CA) for the qualitative identification and differentiation of microorganisms using matrix-assisted laser desorption/ionization-time of flight mass spectrometry (MALDI-TOF MS) analysis of colonies grown on plated culture media from human specimens. The BD Kiestra™ IdentifA is indicated for use in the clinical laboratory with the BD Kiestra™ ReadA or ReadA Compact and Bruker MALDI Biotyper® System (CA, sirius CA, or sirius one CA) to aid in the diagnosis of bacterial and fungal infections.	The BD Kiestra™ IdentifA module is an automated in vitro diagnostic specimen preparation system for use with the BD Kiestra™ Laboratory Automation Solution to prepare MALDI targets for the Bruker MALDI Biotyper® CA System for the qualitative identification and differentiation of microorganisms using matrix-assisted laser desorption/ionization-time of flight mass spectrometry (MALDI-TOF MS) analysis of colonies grown on plated culture media from human specimens. The BD Kiestra™ IdentifA is indicated for use in the clinical laboratory with the ReadA Compact and Bruker MALDI Biotyper® CA System to aid in the diagnosis of bacterial and fungal infections.
BD Kiestra™ ReadA module	ReadA or ReadA Compact	ReadA Compact
Bruker MALDI Biotyper® System	Bruker MALDI Biotyper® CA System, Bruker MALDI Biotyper® sirius CA System, or Bruker MALDI Biotyper® sirius one CA System	Bruker MALDI Biotyper® CA System
General Device Characteristic Similarities		
Regulation	Same	21 CFR § 866.3378
Product Code	Same	QQV, QBN
Sample Type	Same	Isolated colonies on plated culture media
MALDI Target Preparation	Same	Extended Direct Transfer (eDT) Sample Preparation Procedure

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Device & Predicate Device:	Device: K222563	Predicate: K191964
Amount of Organism on Target	Same	Meets Bruker's Limit of Detection
Quality Controls	Same	US IVD Bacterial Test Standard (BTS)
Matrix	Same	US IVD HCCA Matrix
Targets	Same	MBT Biotarget 96 US IVD (96-spot disposable) target US IVD 48 Spot (48-spot reusable) target
Target Loading on MALDI-TOF MS	Same	Manual
Colony Plate Visualization	Digital image from the BD ReadA or ReadA Compact module	Digital image from the BD ReadA Compact module
Organism Preparation	Same	Suspension of colonies prepared in deionized water by pipettor
Number of Colonies Sampled	Same	Up to 9 per microbial suspension or target spot
Alternative Methods of MALDI Target Preparation	Same	None
Sample and Reagent Application	Same	Automated
Drying of Target Plate	Same	35 ± 2°C
Results Achieved	Same	Prepared MALDI target
Results Reported	Same	None
Technology	Same	Robotic x-y-z platform using pipetting system and onboard nephelometry

D Substantial Equivalence:

Table 1 provides the similarities and differences between the BD Kiestra™ IdentifA and the predicate device. In addition to the items identified, there is no difference between the BD Kiestra™ IdentifA and the predicate device in terms of human factors, design, analytical performance, carryover, limit of detection, reagent deck stability, and electrical, chemical, thermal, and mechanical safety.

The studies conducted support that the modified device, BD Kiestra™ IdentifA is substantially equivalent to the predicate device. The differences are not critical to the intended use of the device and do not affect safety and efficacy.

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VI Standards/Guidance Documents Referenced:

- *Deciding When to Submit a 510(k) for a Change to an Existing Device* (issued October 25, 2017).

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Accuracy (Instrument):

Colony Picking Accuracy, Camera Equivalency, and Identification Accuracy
The ability of the BD Kiestra IdentifA to pick the colonies designated by the operator from the digital image obtained by the BD Kiestra™ ReadA, visual interpretation of images generated by the BD Kiestra ReadA with a 25MP camera versus BD Kiestra ReadA Compact with a 5MP camera, and evaluation of IVD Bruker MALDI Biotyper® sirius CA System analysis was assessed in three separate studies described below.

Study 1:
In the first study, one BD Kiestra IdentifA instrument was used to pick designated colonies from 205 mixed cultures of *Escherichia coli* (ATCC 25922; as representative of large bacterial colonies) and *Streptococcus pyogenes* (ATCC 19615; as representative of small bacterial colonies) plated on TSA with 5% sheep blood agar and incubated aerobically for 24 and 48 hours at 35°C. Picking of the correct colonies was confirmed by visual inspection of the plates and comparison to the original digital images. All (100%) 1230 colonies were picked successfully.

Picking of colonies was confirmed by Bruker MALDI identification using the interpretive criteria for species identification described in Bruker MALDI labeling for High Confidence (log score ≥ 2.00), Low Confidence (log score 1.70-1.99), and No Identification (log score < 1.70) levels. Confirmation of colony picking accuracy was conducted with a IVD Bruker MALDI Biotyper® sirius CA System for analysis. Two (2) isolates were aborted with no MALDI result, leaving a total of 408 isolate MALDI ID results. All (100%) of 408 MALDI target spots provided the expected identification, with High Confidence Log(score) values ≥ 2.00. These results demonstrate the accuracy of colony picking and are acceptable.

The results of the study showed the BD Kiestra™ ReadA met the same acceptance criteria as previously shown for the BD Kiestra™ ReadA Compact (see K191964). Therefore, the BD Kiestra™ IdentifA pick accuracy performance utilizing the BD Kiestra™ ReadA is equivalent to BD Kiestra™ IdentifA pick accuracy performance utilizing the BD Kiestra™ ReadA Compact.

Study 2:
In the second study, 15 microorganisms representing varying colony morphologies were plated in three dilutions (10^3, 10^4, 10^5 CFU/mL) on two types of solid media: 1) BD BBL™ MacConkey II Agar (MAC), and 2) BD BBL™ Trypticase Soy Agar™ with 5% Sheep Blood (TSA II). Culture plate images were captured by one BD Kiestra ReadA™ Compact system with a 5MP camera and three BD Kiestra ReadA™ systems with 25MP cameras. Three operators representative of the intended user interpreted the culture plate images and assigned a minimal morphological identification (MMI) code based on colony

morphology/hemolysis/size/color characteristics. MMI results for each plate image captured by the BD Kiestra™ ReadA was compared to those from the BD Kiestra™ ReadA Compact. A total of 270 plate images were captured with the BD Kiestra™ ReadA system with a 25MP camera (15 microorganisms x 3 dilutions x 2 media types x 3 systems) and a total of 90 plate images were captured with the BD Kiestra™ ReadA Compact with a 5MP camera (15 microorganisms x 3 dilutions x 2 media types x 1 system).

The overall MMI percent agreement between BD Kiestra™ ReadA (25MP) and the BD Kiestra™ ReadA Compact (5MP) plate images was 99% for TSA II media and 100% for MAC media. Two of the three BD Kiestra™ ReadA (25MP) systems had 100% agreement with the BD Kiestra™ ReadA Compact (5MP) system. On the third BD Kiestra™ ReadA (25MP) system, one reader had one organism result, *Candida albicans* on TSA II media, that resulted in a "no growth" (NG) MMI result versus the expected "cream/white colonies, feet may be present, possible *Candida albicans*" (YST-CR/WH) result. That reader's BD Kiestra™ ReadA Compact (5MP) system result for the same organism yielded the expected MMI code. This discrepancy occurred for the lowest dilution (10^3 CFU/mL), which was anticipated to result in some NG outcomes. Due to the challenging inoculum concentration and that this discrepancy was observed for a singular result, it was determined that there are no significant discrepancies or trending observed for any specific colony types that would necessitate any limitations in device labeling.

The results of the study demonstrated that the 5MP camera on the BD Kiestra™ ReadA Compact system generates equivalent images to the 25MP camera on the BD Kiestra™ ReadA system. The camera utilized had no impact on the user's interpretation of the culture plate image. Therefore, the BD Kiestra™ ReadA and BD Kiestra™ ReadA Compact systems are equivalent and both are acceptable for use with the BD Kiestra™ IdentifA system.

Study 3:
In the third study, a total of 37 Gram-positive bacteria, Gram-negative bacteria, and yeast organisms were cultured from stock isolates onto TSA II with 5% SB media plates for bacteria, and onto SAB Dextrose media plates for yeast. The plates were incubated in O_2 or CO_2, as appropriate, at 35 °C ± 2 °C for 18-24 hours.

Using the BD Synapsys™ informatics system, isolated colonies were selected and a MALDI test was ordered for each selected isolate on each plate. An isolate suspension was created for each organism on a BD Kiestra™ IdentifA and Bruker MALDI target plates were spotted using either 48-spot reusable polished steel or 96-spot disposable target plates. Two (2) spots were utilized per suspension on the target plates. For each organism (utilizing a single suspension source), the target plates were transferred to a Bruker MALDI Biotyper® CA System to read the first spot, and the same target plate was then transferred to a Bruker MALDI Biotyper® sirius CA System to read the second spot. Each organism was read on both Bruker MALDI Biotyper® Systems for three (3) days to verify repeatability. Isolate results from the Bruker MALDI Biotyper® CA System and the Bruker MALDI Biotyper® sirius CA System were compared for MALDI ID differences using the Bruker interpretive criteria for species identification described in Study 1. The two spots' log(score) values were in the same log(score) value range for 100% (111/111) of the tested organisms. No isolates had more than one log(score) value range difference.

The results of the study showed the BD Kiestra™ IdentifA can be used to prepare Bruker MALDI target plates that can be analyzed on either the Bruker MALDI Biotyper® CA

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System, or Bruker MALDI Biotyper® sirius CA System, meeting the same acceptance criteria as previously shown in K191964 and producing equivalent identification results on either MALDI system. This study utilized the Bruker MALDI Biotyper® sirius CA System, but the results are applicable to both the sirius CA system and the Bruker MALDI Biotyper® sirius one CA System, as there is no difference between the two systems in CA mode.

2. Linearity:

   Not applicable.

3. Analytical Specificity/Interference:

   Not applicable.

4. Assay Reportable Range:

   Not applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Not applicable.

6. Detection Limit:

   Not applicable.

7. Assay Cut-Off:

   Not applicable.

B Clinical Studies:

1. Clinical Sensitivity:

   Not applicable

2. Clinical Specificity:

   Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable

C Clinical Cut-Off:

Not applicable

D Expected Values/Reference Range:

Not applicable

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

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IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.