510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K222563

B Applicant

Becton, Dickinson and Company

C Proprietary and Established Names

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 a substantial equivalence determination for the BD Kiestra IdentifA instrument with the addition of the BD Kiestra ReadA camera system (with 25-MP camera) as well as the Bruker MALDI Biotyper sirius CA and sirius one CA systems.

The BD Kiestra IdentifA was originally cleared in K191964 and intended for use with the upstream BD Kiestra ReadA Compact (with 5-MP camera) for image acquisition and

downstream Bruker MALDI Biotyper CA system for microorganism ID. In this submission, the intended use is expanded to include the upstream BD Kiestra ReadA system (with 25-MP camera) for image acquisition and downstream Bruker MALDI Biotyper sirius CA and sirius one CA systems for microorganism ID. Additional detail about the similarities and differences between the systems is included in the *Device Description* and *Comparison with Predicate* sections below.

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 Indications for Use below.

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

Special Instruments for Use:

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. The ReadA Compact catalog number is 447206 and the ReadA catalog number is 446948.

Bruker MALDI Biotyper for Clinical Applications (MBT-CA)

When using 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):
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 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 Compact or BD Kiestra ReadA module. The BD Kiestra IdentifA automatically suspends the designated colonies in deionized

water and uses an onboard nephelometer to determine the resulting turbidity. The BD Kiestra IdentifA also automatically adjusts the organism concentration is 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 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 CA 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 (CA, sirius CA, or sirius one CA) 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**).

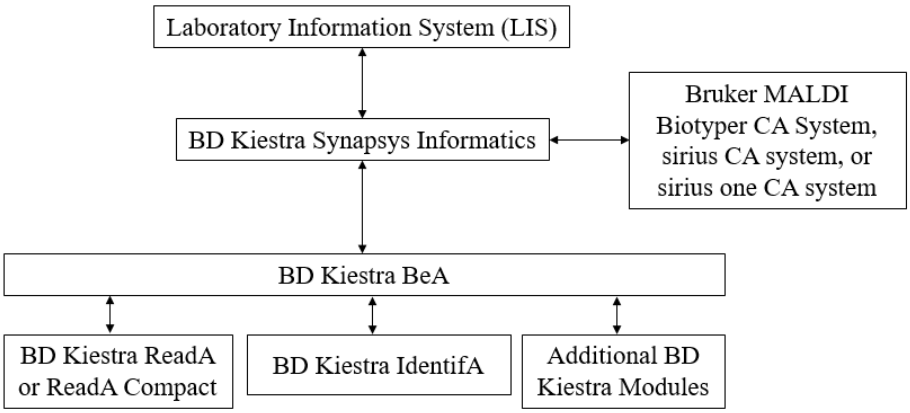

Figure 1. *Overview of software interactions for the BD Kiestra Laboratory Automation System.*

The BD Kiestra ReadA Compact or ReadA module is required for use in conjunction with the BD Kiestra IdentifA module for plate incubation and image capture. Additional software modules (the 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.

The BD Kiestra IdentifA with ReadA Compact (for image acquisition) and Bruker MALDI Biotyper CA (for microbial ID) was previously cleared in K191964. In this submission, the BD Kiestra IdentifA intended use is expanded to include the ReadA (for image acquisition) and Bruker MALDI Biotyper sirius CA and sirius one CA systems (for microbial ID). Briefly, the

upstream ReadA differs from the ReadA Compact in various camera and lens specifications. The downstream Bruker MALDI Biotyper sirius CA and sirius one CA systems differ from the Bruker MALDI Biotyper CA system in various electronics (including the laser), hardware upgrades, and improved vacuum function. The Bruker MALDI Biotyper sirius CA and sirius one CA systems both rely on the Bruker MALDI Biotyper CA Reference Library, as does the predicate Bruker MALDI Biotyper CA system. Additional details are provided in the *Comparison with Predicate* table in the *Substantial Equivalence Information* section below.

B Instrument Description Information:

1. Instrument Name:

   BD Kiestra IdentifA

2. Specimen Identification:

   The BD Kiestra ReadA or ReadA Compact have default parameters for image capture as well as user-defined settings. Images taken under the default parameters are always captured in addition to any 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 may either be 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 Compact or ReadA 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 homogenous 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 CA, sirius CA, or sirius one CA 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 Sampling and Handling:

   MALDI targets are manually transferred to the Bruker MALDI Biotyper CA, sirius CA, or sirius one CA system. These systems then perform 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 CA, sirius CA, or sirius one CA systems is

mediated by the Synapsys interface to enable transfer of the MALDI target map to the MALDI Biotyper instrument 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
Nephelometer calibration for the BD Kiestra IdentifA is performed as described in the K191964 Decision Summary. Briefly, calibration of the BD Kiestra IdentifA nephelometers is performed daily and monthly using calibrated McFarland standards.

5. Quality Control:

Quality control for the BD Kiestra IdentifA is performed as described in the K191964 Decision Summary. Briefly, the BD Kiestra IdentifA is used to spot the Bruker US IVD Bacterial Test Standard (BTS) during MALDI target plate preparation for quality control assessment of identification results from the Bruker MALDI Biotyper instruments. In summary, 100% of the target plates prepared for analysis in this submission passed QC.

V Substantial Equivalence Information:

A Predicate Device Name(s):
BD Kiestra IdentifA

B Predicate 510(k) Number(s):
K191964

C Comparison with Predicate(s):

Device & Predicate Device(s):	**Device:** **K222563**	**Predicate:** **K191964**
Device Trade Name	BD Kiestra IdentifA	Same
General Device Characteristic Similarities	**Device:** **K222563**	**Predicate:** **K191964**
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 BD Kiestra ReadA Compact and Bruker MALDI Biotyper CA System to aid in the diagnosis of bacterial and fungal infections.
Regulation	21 CFR § 866.3378	Same
Product Code	QQV, QBN	Same
Sample Type	Isolated colonies on plated culture media	Same
MALDI Target Preparation	Extended Direct Transfer (eDT) Sample Preparation Procedure	Same
Quality Controls	US IVD Bacterial Test Standard (BTS)	Same

Device & Predicate Device(s):	**Device:** **K222563**	**Predicate:** **K191964**
Targets and Target Loading on MALDI-TOF MS	MBT Biotarget 96 US IVD (96-spot disposable) target US IVD 48 Spot (48-spot reusable) target, manual loading	Same
Organism Preparation	Suspension of colonies prepared in deionized water by pipettor	Same
Number of Colonies Sampled	Up to 9 per microbial suspension or target spot	Same
Drying of Target Plate	35 ± 2°C	Same
Results Achieved	Prepared MALDI target	Same
Technology	Robotic x-y-z platform using pipetting system and onboard nephelometer	Same
BD Kiestra ReadA Module Camera Specifications	BD Kiestra Optis camera, LED strobe light, black or white background settings	Same
Bruker MALDI Biotyper System Reference Library	MALDI Biotyper CA (MBT-CA) Reference Library	Same
Bruker MALDI Biotyper System Reagents	US IVD BTS US IVD HCCA portioned matrix	Same
General Device Characteristic Differences	**Device:** **K222563**	**Predicate:** **K191964**
BD Kiestra ReadA Module	ReadA (with 25-MP camera) or ReadA Compact (with 5-MP camera)	ReadA Compact (with 5-MP camera)
BD Kiestra ReadA Module Camera Specifications	*ReadA Features:* 25-MP camera, F12 fixed aperture, image resolution of 5,120 x 5,120 pixels, Bi-telecentric lens, Python xK CMOS image sensor, 175 ± 8 mm working distance ReadA Compact also included in workflow	*ReadA Compact Features:* 5-MP camera, F2.8 fixed aperture, image resolution of 2,000 x 2,000 pixels, fixed focal length lens, progressive scan CCD monochrome and color image sensor, 224 mm working distance (adjusted as needed at set-up)
Colony Plate Visualization	Digital image from the BD ReadA or ReadA Compact module	Digital image from the BD ReadA Compact module
Bruker MALDI Biotyper System	Bruker MALDI Biotyper CA System, Bruker MALDI Biotyper sirius CA System,	Bruker MALDI Biotyper CA System

Device & Predicate Device(s):	Device: K222563	Predicate: K191964
	Bruker MALDI Biotyper sirius one CA System	
Bruker MALDI Biotyper System Specifications	*Biotyper sirius CA and sirius one CA Systems:* Smartbeam solid state laser (200 Hz repetition rate), new vacuum system Biotyper CA System also included in the workflow	*Biotyper CA System:* Nitrogen laser (60 Hz repetition rate), original vacuum system

VI Standards/Guidance Documents Referenced:

Deciding When to Submit a 510(k) for a Change to an Existing Device; Guidance for Industry and Food and Drug Administration Staff (issued October 25, 2017)

VII Performance Characteristics (if/when applicable):

The isolates used in the analytical studies were type strains as well as non-type strains (i.e., clinical isolates from multiple sources), which were archived and identified via MALDI-TOF MS identification with manual sample preparation. These previous identifications were designated as the expected identities of the isolates. The interpretive criteria for species identification was used, as described in the labeling for the Bruker MALDI Biotyper systems and summarized below in **Table 1**.

Table 1. Interpretive criteria for species identification using the Bruker MALDI Biotyper.

Confidence Level	Log(Score) Value
High	≥ 2.00
Low	1.70 - 1.99 [1]
No identification	< 1.70 [1]

[1] Additional testing required to determine or confirm organism identity

A Analytical Performance:

1. Precision/Reproducibility:

   The precision/reproducibility for microorganism identification as well as nephelometer accuracy and reproducibility was previously evaluated. Refer to the Decision Summary for K191964.

2. Linearity:

   Not applicable.

3. Analytical Specificity/Interference:

Not applicable.

4. Accuracy (Instrument):

Colony Picking Accuracy

The ability of the BD Kiestra IdentifA to pick colonies designated by the operator from a digital image obtained by the BD Kiestra ReadA (with 25-MP camera) was evaluated. Mixed cultures of *Escherichia coli* (ATCC 25922; representative of large bacterial colonies) and *Streptococcus pyogenes* (ATCC 19615; representative of small bacterial colonies) were plated on TSA with 5% sheep blood agar and incubated aerobically for 24 hours (100 plates) and 48 hours (105 plates) at 35°C in one BD Kiestra ReadA. Two colonies per plate were picked by one operator and used to prepare target plates for analysis with a single Bruker MALDI Biotyper CA System (the predicate MALDI-MS system). Two-hundred (200) isolates were processed on a 48-spot polished steel MALDI target plate, and 208 isolates were processed on a 96-spot disposable MALDI target plate. A total of 410 colonies (205 plates x 2 colonies picked per plate) were picked and tested for Bruker MALDI identification.

Picking of the correct colonies was confirmed by visual inspection of the plates and comparison to the original digital images. All (100%) of the 410 colonies were picked successfully. Colony picking accuracy was also assessed by MALDI identification accuracy. Two isolates from the 96-spot disposable MALDI target plate were aborted with no MALDI result, due to BD Kiestra IdentifA instrument errors after colony picking, yielding a total of 410 total MALDI target spots and 408 MALDI identification results. Of the 408 results, all (100%) provided the expected identification, with Log(score) values ≥ 2.00.

These results demonstrate the accuracy of colony picking using digital images acquired by the BD Kiestra ReadA and subsequent organism ID with the Bruker MALDI Biotyper CA System (the predicate system) and are acceptable.

Accuracy of Identification

Accuracy of MALDI-TOF MS organism identification with samples prepared by the BD Kiestra IdentifA was evaluated in an Identification Equivalency Study. One BD Kiestra IdentifA (with two upstream ReadA systems) was used to prepare target spots from 37 isolates of Gram-positive bacteria (n=18), Gram-negative bacteria (n=15), and yeasts (n=4) (**Table 2**). The selected isolates were chosen to represent a diverse range of species and colony morphologies that are encountered in clinical microbiology. Organisms were inoculated on TSA II + 5% Sheep's Blood media plates (for bacteria) or SAB Dextrose media plates (for yeast) and incubated at 35°C with O_2 or CO_2 (as needed) for 18-48 hours. User-selected colonies from each plate were used to create an isolate suspension using the BD Kiestra IdentifA. Isolate suspensions were spotted in duplicate on either the 48-spot reusable polished steel or 96-spot disposable target plates. After spotting, the target plates were transferred to the Bruker MALDI Biotyper CA system (predicate) to read the first spot. The same plate was then transferred to the Bruker MALDI Biotyper sirius CA system to read

the second spot. Target plates with each organism were prepared and read on both systems for three days to assess repeatability (one target plate/test/isolate/day). Two Bruker MALDI Biotyper CA systems (predicate), two Bruker MALDI Biotyper sirius CA systems, and one BD Kiestra IdentifA were used.

The Bruker MALDI Biotyper sirius one CA system was not used in this study because it is identical to the Bruker MALDI Biotyper sirius CA system, with the exception of negative ion detection mode available for Research Use Only. The BD Kiestra IdentifA utilizes the Biotyper systems in CA mode, and therefore the negative ion detection mode is not applicable. The two Bruker systems are functionally identical in CA mode and therefore the Bruker MALDI Biotyper sirius CA system results are used to support equivalence of the sirius one CA system as well.

Table 2. Organisms used in the identification equivalency study.

Organism	**# of strains included**
Enterococcus faecalis	2
Enterococcus faecium	2
Staphylococcus aureus	2
Staphylococcus epidermidis	2
Staphylococcus hominis	1
Staphylococcus lugdunensis	1
Staphylococcus saprophyticus	2
Staphylococcus simulans	1
Streptococcus pneumoniae	2
Streptococcus pyogenes	2
Streptococcus agalactiae	1
Gram-positive bacteria	**18**
Acinetobacter baumannii	2
Enterobacter cloacae	2
Escherichia coli	2
Klebsiella oxytoca	2
Klebsiella pneumoniae	2
Morganella morganii	1
Proteus mirabilis	2
Pseudomonas aeruginosa	2
Gram-negative bacteria	**15**
Candida albicans	1
Candida glabrata	1
Cryptococcus neoformans var. *grubii*	1
Saccharomyces cerevisiae	1
Yeast/fungi	**4**

A total of 111 isolates (37 organisms x 3 days of testing) were tested on each Bruker MALDI Biotyper system. Seventy-eight (78) samples/spots (70.3%) were processed with the 48-spot

polished steel plate and 33 samples/spots (29.7%) were processed with the 96-spot disposable plate on each Bruker MALDI Biotyper system. Results from both Bruker Biotyper systems were compared to the expected result for each isolate to determine agreement, and performance was compared between both methods. Analysis was based on designated results as Concordant, Discordant, or No identification based on the MALDI Log(score) as shown in the tables below.

For each isolate suspension, 100% of duplicate spots produced the same identification and these identifications were concordant with the expected MALDI ID. For each isolate suspension, the two spots' log(score) are in the same log(score) range for 108 of the 111 tested organisms (97.3%). No isolates had more than one log(score) range difference.

Tables 3-5 show percent agreement between results from target plates prepared with the BD Kiestra IdentifA (with ReadA) and analyzed on the Bruker Biotyper sirius CA system compared to the expected identity for previously-identified, known Gram-positive bacteria, Gram-negative bacteria, and yeast.

Table 3. Agreement for Gram-negative bacteria (Bruker MALDI Biotyper sirius CA system ID compared to expected organism ID)

Expected Identity	Number of Results	Log(score)					
		Concordant		Discordant		No Identification	
		≥ 2.00	1.70-1.99	≥ 2.00	1.70-1.99	< 1.70	No Peaks
Acinetobacter baumannii / nosocomialis group	6	6	0	0	0	0	0
Enterobacter cloacae complex	6	6	0	0	0	0	0
Escherichia coli	6	6	0	0	0	0	0
Klebsiella oxytoca / Raoultella ornithinolytica	6	6	0	0	0	0	0
Klebsiella pneumoniae	6	6	0	0	0	0	0
Morganella morganii	3	3	0	0	0	0	0
Proteus mirabilis	6	6	0	0	0	0	0
Pseudomonas aeruginosa	6	6	0	0	0	0	0
Total (%)	**45**	**45 (100%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**
		45 (100%)		**0 (0%)**		**0 (0%)**	

Table 4. Agreement for Gram-positive bacteria (Bruker MALDI Biotyper sirius CA system ID compared to expected organism ID)

Expected Identity	Number of Results	Log(score)					
		Concordant		Discordant		No Identification	
		≥ 2.00	1.70-1.99	≥ 2.00	1.70-1.99	< 1.70	No Peaks
Enterococcus faecalis	6	6	0	0	0	0	0
Enterococcus faecium	6	6	0	0	0	0	0
Staphylococcus aureus	6	6	0	0	0	0	0
Staphylococcus epidermidis	6	6	0	0	0	0	0
Staphylococcus hominis	3	3	0	0	0	0	0
Staphylococcus lugdunensis	3	3	0	0	0	0	0
Staphylococcus saprophyticus	6	6	0	0	0	0	0
Staphylococcus simulans	3	3	0	0	0	0	0

Expected Identity	Number of Results	Log(score)					
		Concordant		Discordant		No Identification	
		≥ 2.00	1.70-1.99	≥ 2.00	1.70-1.99	< 1.70	No Peaks
Streptococcus agalactiae	3	3	0	0	0	0	0
Streptococcus pneumoniae	6	6	0	0	0	0	0
Streptococcus pyogenes	6	6	0	0	0	0	0
Total (%)	**54**	**54 (100%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**
		54 (100%)		**0 (0%)**		**0 (0%)**	

Table 5. Agreement for yeast (Bruker MALDI Biotyper sirius CA system ID compared to expected organism ID)

Expected Identity	Number of Results	Log(score)					
		Concordant		Discordant		No Identification	
		≥ 2.00	1.70-1.99	≥ 2.00	1.70-1.99	< 1.70	No Peaks
Candida albicans	3	2	1	0	0	0	0
Candida glabrata	3	3	0	0	0	0	0
Cryptococcus neoformans var. *grubii*	3	1	2	0	0	0	0
Saccharomyces cerevisiae	3	2	1	0	0	0	0
Total (%)	**12**	**8 (66.7%)**	**4 (33.3%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**
		12 (100%)		**0(0%)**		**0 (0%)**	

Tables 6-8 show percent agreement between results from target plates prepared with the BD Kiestra IdentifA (with ReadA system) and analyzed on the Bruker Biotyper sirius CA system compared to results from target plates prepared with the BD Kiestra IdentifA (with ReadA system) and analyzed on the Bruker MALDI Biotyper CA system (predicate) for Gram-positive bacteria, Gram-negative bacteria, and yeast.

Table 6. Agreement for Gram-negative bacteria (Bruker MALDI Biotyper sirius CA system ID compared to predicate Bruker MALDI Biotyper CA system ID)

Bruker MALDI Biotyper CA ID	Number of Results	Log(score)					
		Concordant		Discordant		No Identification	
		≥ 2.00	1.70-1.99	≥ 2.00	1.70-1.99	< 1.70	No Peaks
Acinetobacter baumannii / nosocomialis group	6	6	0	0	0	0	0
Enterobacter cloacae complex	6	6	0	0	0	0	0
Escherichia coli	6	6	0	0	0	0	0
Klebsiella oxytoca / Raoultella ornithinolytica	6	6	0	0	0	0	0
Klebsiella pneumoniae	6	6	0	0	0	0	0
Morganella morganii	3	3	0	0	0	0	0
Proteus mirabilis	6	6	0	0	0	0	0
Pseudomonas aeruginosa	6	6	0	0	0	0	0
Total (%)	**45**	**45 (100%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**
		45 (100%)		**0 (0%)**		**0 (0%)**	

Table 7. Agreement for Gram-positive bacteria (Bruker MALDI Biotyper sirius CA system ID compared to predicate Bruker MALDI Biotyper CA system ID)

Bruker MALDI Biotyper CA ID	Number of Results	Log(score)					
		Concordant		Discordant		No Identification	
		≥ 2.00	1.70-1.99	≥ 2.00	1.70-1.99	< 1.70	No Peaks
Enterococcus faecalis	6	6	0	0	0	0	0
Enterococcus faecium	6	6	0	0	0	0	0
Staphylococcus aureus	6	6	0	0	0	0	0
Staphylococcus epidermidis	6	6	0	0	0	0	0
Staphylococcus hominis	3	3	0	0	0	0	0
Staphylococcus lugdunensis	3	3	0	0	0	0	0
Staphylococcus saprophyticus	6	6	0	0	0	0	0
Staphylococcus simulans	3	3	0	0	0	0	0
Streptococcus agalactiae	3	3	0	0	0	0	0
Streptococcus pneumoniae	6	6	0	0	0	0	0
Streptococcus pyogenes	6	6	0	0	0	0	0
Total (%)	**54**	**54 (100%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**	**0 (0%)**
		54 (100%)		**0 (0%)**		**0 (0%)**	

Table 8. Agreement for yeast (Bruker MALDI Biotyper sirius CA system ID compared to predicate Bruker MALDI Biotyper CA system ID)

Bruker MALDI Biotyper CA ID	Number of Results	Log(score)					
		Concordant		Discordant		No Identification	
		≥ 2.00	1.70-1.99	≥ 2.00	1.70-1.99	< 1.70	No Peaks
Candida albicans	3	2	0	0	1 [1]	0	0
Candida glabrata	3	3	0	0	0	0	0
Cryptococcus neoformans var. *grubii*	3	0	2	1 [2]	0	0	0
Saccharomyces cerevisiae	3	1	1	1 [3]	0	0	0
Total (%)	**12**	**5 (66.7%)**	**3 (33.3%)**	**2 (0%)**	**1 (0%)**	**0 (0%)**	**0 (0%)**
		8 (75%)		**3 (25%)**		**0 (0%)**	

[1] Biotyper sirius system identified *Candida glabrata* with a log(score) 1.70-1.99, compared to Biotyper CA system log(score) of ≥ 2.00

[2] Biotyper sirius system identified *Cryptococcus neoformans* var. *grubii* with a log(score) ≥ 2.00, compared to Biotyper CA system log(score) of 1.70-1.99

[3] Biotyper sirius system identified *Saccharomyces cerevisiae* with a log(score) ≥ 2.00, compared to Biotyper CA system log(score) of 1.70-1.99

Identification results from the Bruker MALDI Biotyper CA (predicate) and Bruker MALDI Biotyper sirius CA systems were compared to the expected result for each isolate to determine % agreement. Agreement for both methods was compared to demonstrate equivalent performance of the BD Kiestra IdentifA (with ReadA) to prepare targets for use with the Bruker MALDI Biotyper CA system and Bruker MALDI Biotyper sirius CA system (**Table 9**).

Table 9. Summary of Log(scores) observed with samples prepared using BD Kiestra IdentifA with Bruker MALDI Biotyper CA (predicate) vs. Bruker MALDI Biotyper sirius CA

Organism Group ***(n = results acquired per system)***	**Disposition vs. Expected**	**MALDI Log(score)**	**Number of Isolates (%)**	
			Bruker MALDI Biotyper CA	**Bruker MALDI Biotyper sirius CA**
Gram-negative bacteria *(n = 45)*	Concordant	≥ 2.00	45 (100%)	45 (100%)
		1.70-1.99	0 (0%)	0 (0%)
	Discordant	≥ 2.00	0 (0%)	0 (0%)
		1.70-1.99	0 (0%)	0 (0%)
	No Identification	< 1.70	0 (0%)	0 (0%)
		No Peaks	0 (0%)	0 (0%)
Gram-positive bacteria *(n = 54)*	Concordant	≥ 2.00	54 (100%)	54 (100%)
		1.70-1.99	0 (0%)	0 (0%)
	Discordant	≥ 2.00	0 (0%)	0 (0%)
		1.70-1.99	0 (0%)	0 (0%)
	No Identification	< 1.70	0 (0%)	0 (0%)
		No Peaks	0 (0%)	0 (0%)
Yeast *(n=12)*	Concordant	≥ 2.00	7 (58.3%)	8 (66.7%)
		1.70-1.99	5 (41.7%)	4 (33.3%)
	Discordant	≥ 2.00	0 (0%)	0 (0%)
		1.70-1.99	0 (0%)	0 (0%)
	No Identification	< 1.70	0 (0%)	0 (0%)
		No Peaks	0 (0%)	0 (0%)
All Isolates/Results Combined *(n=111)*	Concordant	≥ 2.00	106 (95.5%)	107 (96.4%)
		1.70-1.99	5 (4.5%)	4 (3.6%)
	Discordant	≥ 2.00	0 (0%)	0 (0%)
		1.70-1.99	0 (0%)	0 (0%)
	No Identification	< 1.70	0 (0%)	0 (0%)
		No Peaks	0 (0%)	0 (0%)

Overall, similar agreement with the expected results was observed with target plates prepared by the BD Kiestra IdentifA with upstream ReadA (with 25-MP camera) and analyzed with the Bruker MALDI Biotyper CA System and Bruker MALDI Biotyper sirius CA System. The results are acceptable.

5. Carry-Over:

Cross-contamination for the BD Kiestra IdentifA was previously evaluated in K191964. Refer to the Decision Summary for additional information.

B Other Supportive Instrument Performance Characteristics Data:

Image Quality Analysis Study

An image quality analysis study was performed to evaluate the equivalence of operator interpretation of specific colony characteristics from visualization of digital plate images

generated by the BD Kiestra ReadA Compact vs. ReadA. The ReadA Compact was cleared with the predicate system and has a 5-MP camera, whereas the ReadA has a 25-MP camera.

Fifteen microorganisms representing varying colony morphologies (**Table 10**) were plated in three dilutions (10^3, 10^4, 10^5 CFU/mL in saline) on two types of solid media whole plates: MacConkey agar and trypticase soy agar with 5% Sheep Blood. Each dilution was inoculated onto four plates per media. All suspensions were prepared and plated by one BD Kiestra InoqulA system. Inoculated plates were incubated at 35°C ± 2°C for 18 – 48 hours. One plate was incubated and imaged in the ReadA Compact, and the other three were incubated and imaged with three separate ReadA instruments. One ReadA system was a stand-alone device, and the other two were connected to BD Kiestra Total Lab Automation (TLA) systems. All systems used default image parameters and presented images from each system to the reader via the BD Synapsys Informatics Solution software for visualization and interpretation.

Three operators representative of the intended user interpreted the culture plate images and assigned a minimal morphological identifier (MMI) code based on colony morphology/hemolysis/size/color characteristics (**Table 11**). MMI results for each plate captured by the ReadA system were compared to those from the predicate ReadA Compact.

Table 10. Organisms evaluated in the Image Quality Analysis Study and expected MMI results.

Organism	*Expected MMI Code*	
	TSA + 5% Sheep Blood	*MacConkey*
Escherichia coli	GN	LF
Enterobacter cloacae	GN	LF
Providencia rettgeri	GN	NLF
Morganella morganii	GN	NLF
Klebsiella pneumoniae	GN	LF
Serratia marcescens	GN	LF
Pseudomonas aeruginosa	GN	NLF
Proteus mirabilis	SP	NLF
Staphylococcus saprophyticus	GP-CR/WH	NG
Streptococcus agalactiae (Group B *Streptococcus)*	β-HEM	NG
Streptococcus pneumoniae	α-HEM	NG
Staphylococcus epidermidis	GP-CR/WH	NG
Staphylococcus aureus	GP-CR/WH	NG
Enterococcus faecalis	No-HEM	NG
Candida albicans	YST-CR/WH	NG

Table 11. MMI codes and descriptions.

Media Type	*MMI Code*	*MMI Code Description*
TSA + 5% Sheep Blood	α-HEM	Small, alpha-hemolytic
	β-HEM	Small, beta-hemolytic
	No-HEM	Small, non-hemolytic
	SP	Possible *Proteus* species and related, high-mobility species
	GN	Gram negative or coliform-like colonies
	GP-CR/WH	Cream/White colonies, possible *Staphylococcus* species
	YST-CR/WH	Cream/White colonies, feet may be present, possible *Candida albicans*

Media Type	*MMI Code*	*MMI Code Description*
	OTHER	Growth does not fit defined MMI codes
	INV	Invalid
	NG	No growth
MacConkey	NLF	Non-lactose fermenter
	LF	Lactose fermenter
	OTHER	Growth does not fit defined MMI codes
	INV	Invalid
	NG	No growth

A total of 270 plate images were captured with the ReadA (15 microorganisms x 3 dilutions x 2 media types x 3 ReadA systems). A total of 90 plate images were captured with the ReadA Compact (15 microorganisms x 3 dilutions x 2 media types x 1 ReadA Compact system). There was a grand total of 360 MMI results. MMI agreements are summarized in **Table 12**. Results are also presented as comparison tables showing the number of matching MMI calls and percent agreement of ReadA vs. ReadA Compact reads stratified by media type. (**Tables 13-14**). Agreement ≥95% for MMI results was deemed acceptable.

Table 12. Summary of MMI agreement for images from ReadA vs. ReadA Compact

BD Kiestra ReadA System	**MMI Agreement (%)**	
	TSA II + 5% Sheep Blood	**MacConkey II Agar**
ReadA #1 (standalone)	45/45 (100%)	45/45 (100%)
ReadA #2 (TLA track)	44/44 (100%)	44/44 (100%)
ReadA #3 (TLA track)	45/46 (98%)	46/46 (100%)
Overall	*134/135 (99%)*	*135/135 (100%)*

Table 13. ReadA vs. ReadA Compact image read by MMIs for Trypticase Soy Agar + 5% Sheep Blood

TSA + 5% Sheep Blood (*n=135*)		**ReadA Compact (5-MP camera)**										
		α-HEM	**β-HEM**	**No-HEM**	**SP**	**GN**	**GP-CR/WH**	**YST-CR/WH**	**OTHER**	**INV**	**NG**	***TOT.***
ReadA (25-MP camera)	**α-HEM**	9	0	0	0	0	0	0	0	0	0	*9*
	β-HEM	0	9	0	0	0	0	0	0	0	0	*9*
	No-HEM	0	0	12	0	0	0	0	0	0	0	*12*
	SP	0	0	0	9	0	0	0	0	0	0	*9*
	GN	0	0	0	0	63	0	0	0	0	0	*63*
	GP-CR/WH	0	0	0	0	0	24	0	0	0	0	*24*
	YST-CR/WH	0	0	0	0	0	0	8	0	0	0	*8*
	OTHER	0	0	0	0	0	0	0	0	0	0	*0*
	INV	0	0	0	0	0	0	0	0	0	0	*0*
	NG	0	0	0	0	0	0	1	0	0	0	*1*
	TOTAL	*9*	*9*	*12*	*9*	*63*	*24*	*9*	*0*	*0*	*0*	*135*
Agreement (%)	***By MMI***	**100**	**100**	**100**	**100**	**100**	**100**	**89**	**N/A**	**N/A**	**N/A**	
	By MMI*	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**N/A**	**N/A**	**N/A**	
	TOTAL ǂ	**100%**										
	TOTAL †	**99%**										

***** Percent agreement excludes NG category

ǂ Total percent agreement *excludes* OTHER, INV, and NG categories

† Total percent agreement *includes* OTHER, INV, and NG categories

Table 14. ReadA vs. ReadA Compact image read by MMIs for MacConkey Agar

MacConkey Agar (*n=135*)		**ReadA Compact (5-MP Camera)**					
		NLF	**LF**	**OTHER**	**INV**	**NG**	***TOTAL***
ReadA (25-MP camera)	**NLF**	42	0	0	0	0	*42*
	LF	0	30	0	0	0	*30*
	OTHER	0	0	0	0	0	*0*
	INV	0	0	0	0	0	*0*
	NG	0	0	0	0	63	*63*
	TOTAL	*42*	*30*	*0*	*0*	*63*	*135*
Agreement (%)	***By MMI***	**100**	**100**	**N/A**	**N/A**	**100**	
	By MMI*	**100**	**100**	**N/A**	**N/A**	**N/A**	
	TOTAL ǂ	**100%**					
	TOTAL†	**100%**					

* Percent agreement excludes NG category
ǂ Total percent agreement *excludes* OTHER, INV, and NG categories
† Total percent agreement *includes* OTHER, INV, and NG categories

The overall MMI precent agreement between the BD Kiestra ReadA (25-MP camera) and BD Kiestra ReadA Compact (5-MP camera) was 99% for TSA + 5% Sheep Blood media and 100% for MacConkey media. There was one discrepant result in which an operator categorized a ReadA image as "no growth" and a ReadA Compact image as MMI code "YST-CR/WH". However, it was taken into consideration that image visualization and MMI categorization measures are not the intended use of the IdentifA; rather, these studies are used to demonstrate the equivalence of the quality of the digital image acquired with the ReadA to select colonies for picking by the IdentifA to images from the ReadA Compact. In addition, "Other" and "NG" categories were not considered. The overall percent agreement was above the acceptance criteria. The results are acceptable.

Additional other supportive information for the BD Kiestra IdentifA was previously evaluated in K191964. Refer to the Decision Summary for additional information.

VIII Proposed Labeling:

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

IX Conclusion:

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