November 3, 2021

Becton, Dickinson and Company
Laura Stewart
Senior Manager Regulatory Affairs
7 Loveton Circle, MC 964
Sparks, Maryland 21152

Re: K191964
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: March 13, 2020
Received: March 16, 2020

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, Ph.D. (ABMM)
Chief
General Bacteriology and Antimicrobial Susceptibility Branch
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

Indications for Use

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

510(k) Number *(if known)*
K191964

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 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.

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:

10/21/2021

Submitted by:

BD Diagnostic Systems
Becton, Dickinson and Company
7 Loveton Circle
Sparks, Maryland 21152

Contact:
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Email: laura.stewart@bd.com

Proprietary Names:
BD Kiestra™ IdentifA

Common Names:
BD Kiestra IdentifA

Regulatory Information

Regulation section:
21 CFR 866.3378 - Clinical mass spectrometry microorganism identification and differentiation device

Classification:
Class II

Review Panel:
Microbiology

Product Code:
QQV, QBN

Predicate Device

Bruker MALDI Biotyper CA

Similarities and Differences of BD Kiestra™ IdentifA to Predicate

Similarities		
Item	***Device:*** ***BD Kiestra™ IdentifA***	***Predicate:*** ***Bruker MALDI Biotyper CA System***
Sample Type	Bacterial colonies isolated from culture on plated media.	Same
Method of MALDI target preparation	Extended Direct Transfer Sample Preparation Procedure	Same
Amount of organism on target	Meets Bruker Limit of Detection	Same
Quality Controls	US IVD Bacterial Test Standard (BTS)	Same
Matrix	US IVD HCCA matrix	Same
Targets	MBT Biotarget 96 US IVD (96-spot disposable) and US IVD 48 Spot (48-spot reusable) targets	Same
Loading of target on Bruker instrument	Manual	Same
Differences		
Item	***Device:*** ***BD Kiestra™ IdentifA***	***Predicate:*** ***Bruker MALDI Biotyper CA System***
Intended 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 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 in the diagnosis of bacterial and fungal infections.	The MALDI Biotyper CA System is a mass spectrometer system using matrix-assisted laser desorption/ionization - time of flight (MALDI-TOF) for the identification and differentiation of microorganisms cultured from human specimens. The MALDI Biotyper CA 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.
Colony Visualization	Digital image from the BD ReadA Compact	Direct
Organism preparation	Suspension in deionized water from organism picked by way of a pipettor	Organism placed directly to target by way of stick.
Number of Colonies	Up to 9 per suspension or per spot	One per target spot
Alternative methods of MALDI target preparation	None	Direct Transfer (DT) and Extraction (Ext) Sample Preparation Procedure
Sample and reagent application	Automated	Manual
Drying of targets	35ºC ± 2ºC	Ambient temperature
Results Achieved	Prepared MALDI target	Identification of the organism
Result Reported	None	Identification of the organism
Technology	Robotic x-y-z platform using pipettors and onboard nephelometry	Mass spectrometer using matrix-assisted laser desorption/ionization – time of flight (MALDI-TOF)

Device Establishment

Becton, Dickinson and Company
7 Loveton Circle
Sparks, Maryland 21152
Registration Number: 1119779

Performance Standards
N/A

Intended 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 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.

Special Conditions for Use Statement: For *in vitro* diagnostic use. For prescription use.

Special Instrument Requirements:
Standalone or integrated into the BD Kiestra™ Laboratory Automation System

BD Kiestra™ ReadA Compact, v 1.1

MALDI Biotyper CA (Bruker)

Device Description

The BD Kiestra™ IdentifA is an instrument which automates picking of technologist-selected colonies from plated media and prepares a Bruker MALDI target for identification and differentiation of organisms. The BD Kiestra IdentifA includes the following components (Note: Bruker MALDI targets, Matrix and Bacterial Test Standard (BTS) are required, however, they are obtained directly from Bruker Daltonik GmbH):

- BD Kiestra IdentifA instrument and software with onboard pipetting and nephelometry.
- BD formic acid, deionized water, pipet tips, Matrix and BTS transfer vials.
- BD Kiestra IdentifA nephelometer calibration standards (0.2, 0.5, 1.0 and 3.0 McFarland).
- BD Kiestra IdentifA cuvette array.

When a MALDI identification is ordered by a technologist, the technologist selects the colonies from an image of a plated medium obtained using the BD Kiestra™ ReadA Compact. The coordinates of the colonies and the plated medium are transferred to BD Kiestra IdentifA where the colonies are picked. The colonies are suspended in deionized water and the onboard nephelometer determines the McFarland turbidity. Based on the McFarland, BD Kiestra IdentifA pipets the organism suspension onto a Bruker MALDI target. The BD Kiestra IdentifA uses the Bruker extended Direct Transfer method for preparation

of the MALDI target by overlaying formic acid and Bruker Matrix onto the target spot. In addition, BTS spots are prepared on the target slide for quality control. Once dried, the technologist manually removes the target and loads onto the Bruker MALDI Biotyper CA System. The BD Kiestra IdentifA transfers the location of sample and BTS spots to the MALDI Biotyper CA. If requested by the technologist, BD Kiestra IdentifA will also dilute the organism suspension to a target of 0.5 McFarland.

The BD Kiestra IdentifA can be used as a standalone instrument or integrated into the BD Kiestra Laboratory Automation System. The standalone instrument utilizes an input/output module for manual plate loading, which handles de-stacking and stacking of plates. When physically integrated into the BD Kiestra Laboratory Automation System, BD Kiestra IdentifA is connected to a track by way of a connection module for automatic plate transfer. BD Kiestra IdentifA software is responsible for the instrument functionality and a touchscreen is mounted on the frame of the instrument for user interface.

Device Comparison

The BD Kiestra™ IdentifA demonstrated substantially equivalent performance when compared with the FDA cleared Bruker MALDI Biotyper CA with manual extended Direct Transfer method. This premarket notification provides data supporting the use of the BD Kiestra™ IdentifA for automated preparation of a MALDI target.

Summary of Substantial Equivalence[1] Testing

The BD Kiestra™ IdentifA has demonstrated substantially equivalent performance when compared to the Bruker MALDI Biotyper CA.

Analytical Performance

Internal analytical testing confirmed the performance of BD Kiestra IdentifA automated sample processing compared to the FDA cleared Bruker MALDI manual sample processing using the extended Direct Transfer (eDT) method.

Accuracy of the BD Kiestra IdentifA:

Colony Picking

The ability of the BD Kiestra IdentifA to pick colonies designated by the operator in the digital image obtained by the BD Kiestra ReadA Compact was evaluated. Two organisms, *Escherichia coli* and *Streptococcus pyogenes*, were inoculated on 200 mixed culture plates. Colonies from both isolates on each plate were selected by a technologist and picked by BD Kiestra IdentifA. Picking of each colony was confirmed visually, and prepared target spots were identified on Bruker MALDI Biotyper CA. One thousand two hundred (1,200) colonies (100%) were successfully selected and picked by the BD Kiestra IdentifA, and 400 target spots (100%) provided the expected identification, with Log(score) values ≥ 2.00.

Organism Identification

Accuracy of organism identification with samples prepared by the BD Kiestra IdentifA was evaluated in the Identification Equivalency Study. A total of 464 isolates of Gram-positive bacteria, Gram-negative bacteria and yeasts were tested using 3 BD Kiestra IdentifA instruments and compared to results by manual sample preparation, i.e. performing the extended Direct Transfer (eDT) Procedure and spotting on

[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

a MALDI target according to the previously FDA-cleared Bruker MALDI Biotyper CA user manual. Results from both methods of preparation were compared in the table below.

BD Kiestra IdentifA performance compared to the expected result compared to manual sample preparation:

Method	Log(score)					
	Concordant		Discordant		No Identification	
	≥2.00	1.70-1.99	≥2.00	1.70-1.99	<1.70	No Peaks
BD Kiestra IdentifA	388 (83.6)	25 (5.4)	9 (1.9)	2 (0.4)	22 (4.7)	18 (3.9)
Manual	387 (83.4)	28 (6.0)	10 (2.2)	0 (0.0)	21 (4.5)	18 (3.9)

Of the 397 samples with positive organism identification (Log(score) ≥ 2.00), BD Kiestra IdentifA processing yielded 388 (97.7%) of the isolates matching the expected identification. Sample processing with the Bruker manual eDT method yielded 387 (97.5%) of the isolates matching the expected identification. This demonstrates that the BD Kiestra IdentifA performs equivalently to manually prepared samples to provide accurate results on the Bruker MALDI Biotyper CA.

Results from the BD Kiestra IdentifA were compared to the expected result for each isolate to determine agreement in the tables below.

BD Kiestra IdentifA performance compared to the expected result, by species:

BD Kiestra IdentifA agreement in comparison to expected identity for Gram-negative bacteria

Expected Identity	*N*	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	10	10	0	0	0	0	0
Bacteroides fragilis	2	2	0	0	0	0	0
Campylobacter coli	3	3	0	0	0	0	0
Campylobacter jejuni	3	3	0	0	0	0	0
Campylobacter lari	1	0	0	0	0	1	0
Citrobacter amalonaticus complex	1	1	0	0	0	0	0
Citrobacter freundii complex	4	4	0	0	0	0	0
Citrobacter koseri	9	9	0	0	0	0	0
Eikenella corrodens	2	2	0	0	0	0	0
Enterobacter aerogenes	9	9	0	0	0	0	0
Enterobacter cloacae complex	7	7	0	0	0	0	0
Escherichia coli	37	37	0	0	0	0	0
Gardnerella vaginalis	2	0	1	1 [2]	0	0	0
Haemophilus influenzae	4	4	0	0	0	0	0
Haemophilus parainfluenzae	2	2	0	0	0	0	0
Hafnia alvei	1	1	0	0	0	0	0
Klebsiella oxytoca/Raoultella ornithinolytica	13	12	0	0	0	0	1
Klebsiella pneumoniae	20	19	0	0	0	0	1
Moraxella sg *Branhamella catarrhalis*	2	2	0	0	0	0	0
Morganella morganii	12	12	0	0	0	0	0
Neisseria gonorrhoeae	1	1	0	0	0	0	0
Pantoea agglomerans	1	0	0	0	1 [6]	0	0
Porphyromonas gingivalis	1	0	0	1 [3]	0	0	0
Prevotella oralis	1	0	0	0	1 [7]	0	0
Proteus mirabilis	9	9	0	0	0	0	0
Proteus vulgaris group	14	11	0	0	0	0	3
Providencia stuartii	10	8	0	1 [4]	0	0	1
Pseudomonas aeruginosa	15	15	0	0	0	0	0
Salmonella sp.	4	4	0	0	0	0	0
Serratia liquefaciens	2	2	0	0	0	0	0
Serratia marcescens	14	13	0	1 [5]	0	0	0
Shigella sonnei	3	3 [1]	0	0	0	0	0
Stenotrophomonas maltophilia	5	5	0	0	0	0	0
Total (%)	**224**	**210 (93.8)**	**1 (0.4)**	**4 (1.8)**	**2 (0.9)**	**1 (0.4)**	**6 (2.7)**
		211 (94.2)		**6 (2.7)**		**7 (3.1)**	

[1] Identified as *Escherichia coli* in accordance with a known Limitation of the Bruker MALDI Biotyper CA
[2] Identified as *Lactobacillus rhamnosus*; concordant with the result obtained with manual sample preparation
[3] Identified as *Veillonella parvula*; concordant with the result obtained with manual sample preparation
[4] Identified as *Citrobacter freundii* complex; concordant with the result obtained with manual sample preparation
[5] Identified as *Enterobacter cloacae* complex; concordant with the result obtained with manual sample preparation
[6] Identified as *Escherichia* species; manual result provided *Escherichia vulneris* (log score of 2.03)
[7] Identified as *Bacteroides* species; manual result provided unspecified (log score of 1.6)

BD Kiestra IdentifA agreement in comparison to expected identity for Gram-positive bacteria

Expected Identity	*N*	Log(Score)					
		Concordant		Discordant		No Identification	
		≥2.00	1.70-1.99	≥2.00	1.70-1.99	<1.70	No Peaks
Corynebacterium jeikeium	3	3	0	0	0	0	0
Corynebacterium urealyticum	1	0	0	0	0	1	0
Enterococcus avium	2	2	0	0	0	0	0
Enterococcus casseliflavus	3	3	0	0	0	0	0
Enterococcus faecalis	12	11	0	0	0	0	1
Enterococcus faecium	19	17	1	1 [2]	0	0	0
Enterococcus gallinarum	5	5	0	0	0	0	0
Propionibacterium acnes	2	0	1	0	0	1	0
Rothia dentocariosa	3	1	0	0	0	0	2
Staphylococcus aureus	21	20	0	0	0	0	1
Staphylococcus cohnii	1	0	1	0	0	0	0
Staphylococcus epidermidis	16	15	0	0	0	1	0
Staphylococcus haemolyticus	6	1	4	0	0	1	0
Staphylococcus hominis	3	3	0	0	0	0	0
Staphylococcus lugdunensis	1	1	0	0	0	0	0
Staphylococcus saprophyticus	3	3	0	0	0	0	0
Staphylococcus sciuri	1	0	0	0	0	1	0
Staphylococcus simulans	2	2	0	0	0	0	0
Staphylococcus warneri	1	1	0	0	0	0	0
Staphylococcus xylosus	1	1	0	0	0	0	0
Streptococcus agalactiae	25	24	0	1 [3]	0	0	0
Streptococcus anginosus	1	1	0	0	0	0	0
Streptococcus dysgalactiae	8	8	0	0	0	0	0
Streptococcus gordonii	1	0	1	0	0	0	0
Streptococcus infantarius	1	1 [1]	0	0	0	0	0
Streptococcus mitis/oralis group	4	2	1	0	0	1	0
Streptococcus parasanguinis	1	1	0	0	0	0	0
Streptococcus pneumoniae	32	19	6	1 [4]	0	3	3
Streptococcus pyogenes	10	9	0	1 [5]	0	0	0
Total (%)	**189**	**154 (81.5)**	**15 (7.9)**	**4 (2.1)**	**0 (0.0)**	**9 (4.8)**	**7 (3.7)**
		169 (89.4)		**4 (2.1)**		**16 (8.5)**	

[1] Identified as *Streptococcus lutetiensis* in accordance with a known Limitation of the Bruker MALDI Biotyper CA
[2] Identified as *Enterococcus faecalis*; concordant with the result obtained with manual sample preparation
[3] Identified as *Streptococcus pyogenes*; concordant with the result obtained with manual sample preparation
[4] Identified as *Streptococcus mitis/oralis* group; concordant with the result obtained with manual sample preparation
[5] Identified as *Streptococcus agalactiae*; concordant with the result obtained with manual sample preparation

BD Kiestra IdentifA agreement in comparison to expected identity for yeast

Expected Identity	*N*	Log(Score)					
		Concordant		Discordant		No Identification	
		≥2.00	1.70-1.99	≥2.00	1.70-1.99	<1.70	No Peaks
Candida albicans	8	6	2	0	0	0	0
Candida dubliniensis	2	2	0	0	0	0	0
Candida glabrata	5	3	0	0	0	2	0
Candida guilliermondii	1	1	0	0	0	0	0
Candida kefyr	2	0	2	0	0	0	0
Candida parapsilosis	3	1	2	0	0	0	0
Candida pelliculosa	1	0	1	0	0	0	0
Candida sphaerica	1	0	0	0	0	1	0
Cryptococcus gattii	3	3	0	0	0	0	0
Cryptococcus neoformans var. *grubii*	2	1	0	0	0	0	1
Cryptococcus neoformans var. *neoformans*	3	0	0	1 [2]	0	1	1
Cryptococcus neoformans var. Not Known	1	1 [1]	0	0	0	0	0
Geotrichum candidum	3	0	1	0	0	2	0
Magnusiomyces capitatus	1	0	0	0	0	1	0
Pichia angusta	2	0	0	0	0	1	1
Saccharomyces cerevisiae	2	1	1	0	0	0	0
Trichosporon aquatile	1	0	0	0	0	1	0
Trichosporon asahii	4	3	0	0	0	1	0
Trichosporon inkin	2	2	0	0	0	0	0
Trichosporon mucoides group	2	0	0	0	0	1	1
Ttrichosporon ovoides	1	0	0	0	0	0	1
Trichosporon pullulans	1	0	0	0	0	1	0
Total (%)	**51**	**24 (47.1)**	**9 (17.6)**	**1 (2.0)**	**0 (0)**	**12 (23.5)**	**5 (9.8)**
		33 (64.7)		**1 (2.0)**		**17 (33.3)**	

[1] Identified as *Cryptococcus neoformans* var. *grubii*
[2] Identified as *Candida lusitaniae*; concordant with the result obtained with manual sample preparation

A substantially lower proportion of concordant results for yeast species than for either Gram-positive or Gram-negative bacteria was noted. Consistent with the original Bruker's system, the BD Kiestra IdentifA User's Manual will recommend that yeast species or any samples that produce a Low Confidence Identification or No Identification Result should be manually prepared using the Bruker's Extraction (Ext) Test Procedure and/or an alternative method of organism identification.

Twenty-five (25) isolates included in the study represented species that were not listed in the Bruker MALDI Biotyper CA Reference Library. Both the BD Kiestra IdentifA and Bruker manual eDT method processing accurately yielded no peaks/no identification for these strains not in the Bruker US IVD database on the Bruker MALDI Biotyper CA.

The results of the accuracy study demonstrate that the BD Kiestra IdentifA performs acceptably compared to manually prepared samples to provide accurate results on the Bruker MALDI Biotyper CA.

Reproducibility of the BD Kiestra IdentifA

Reproducibility of organism identification when performed using the BD Kiestra IdentifA for preparation of samples was evaluated. Strains with known identifications were processed on three BD Kiestra IdentifA modules by three groups of technologists using three lots of reagents in triplicate for three days (3 days × 3 replicates × 3 instruments = 27 data points per strain). The inoculated MALDI targets were loaded onto the Bruker MALDI Biotyper CA System for identification. The table below provides the reproducibility data by organism.

BD Kiestra IdentifA Reproducibility by Organism

Organism Name	Strain#	No. Tests Performed	No. Log Score ≥2.00	% Agreement
Escherichia coli	25922	27	27	100%
Escherichia coli	35218	27	27	100%
Enterobacter (Klebsiella) aerogenes	13048	27	27	100%
Pseudomonas aeruginosa	27853	27	27	100%
Proteus mirabilis	10070	27	27	100%
Alcaligenes faecalis	9139	27	26	96%
Staphylococcus aureus	29213	27	27	100%
Staphylococcus aureus (MRSA)	43300	27	27	100%
Staphylococcus epidermidis	274	27	27	100%
Enterococcus faecalis	29212	27	27	100%
Streptococcus agalactiae	9812	27	27	100%
Streptococcus pyogenes	2979	27	26	96%
Bacillus cereus	1059	27	27	100%
Corynebacterium jeikeium	11246	27	10	37%
Candida albicans	18804	27	20	74%

All except two strains had a Log(score) ≥ 2.00 > 95% of the time between BD Kiestra IdentifA modules, replicates, groups, and lots. *Corynebacterium jeikeium* and *Candida albicans* reproducibility were evaluated by manual preparation using the eDT method and also did not meet the acceptance criteria of ≥ 95%. Due to the results of the Bruker manual eDT method, the failure to meet acceptance criteria was not attributed to performance of the BD Kiestra IdentifA because this low confidence identification is a property of the original Bruker's system and not the BD Kiestra IdentifA.

The results of the reproducibility study demonstrate that the BD Kiestra IdentifA performs equivalently to manually prepared samples to provide reproducible results on the Bruker MALDI Biotyper CA. The results of the Reproducibility Study were determined to be acceptable.

Limit of Detection of the BD Kiestra IdentifA

The ability of the BD Kiestra IdentifA to obtain the expected organism identification with microbial suspensions at or above the limit of detection as defined for the BD Kiestra IdentifA (0.2 McFarland) was evaluated. Organism suspensions of at least 0.2 McFarland (0.2 – 0.3 McFarland) were inoculated onto eight MALDI target spots and processed on BD Kiestra IdentifA. The MALDI targets were analyzed by the Bruker MALDI Biotyper CA to obtain a log(score).

BD Kiestra IdentifA Limit of Detection

MALDI Identification Performance		
		Result
Gram positive	*Staphylococcus aureus* 25923	8/8
	Enterococcus faecium 19434	8/8
	Enterococcus faecalis 29212	8/8
Gram negative	*Enterobacter cloacae* 13047	8/8
	Klebsiella pneumoniae 13883	8/8
	Proteus vulgaris 13315	8/8
	Pseudomonas aeruginosa 27853	8/8
	Escherichia coli 25922	8/8
	Acinetobacter baumannii 19606	8/8
Yeast	*Saccharomyces cerevisiae* 1125A	3/8

For each organism, 6/8 replicates should result in a correct identification. All of the organisms obtained 8/8 acceptable MALDI identifications except *Saccharomyces cerevisiae*. For *S. cerevisiae*, 3/8 replicates produced the expected result and 5/8 were reported as "No Peaks." There were no incorrect identifications for any organism. The inability to obtain a High Confidence Identification when the concentration of yeast in a sample is at the low end of the specified range for turbidity is noted. Consistent with the original Bruker's system, the BD Kiestra IdentifA User's Manual recommends that yeast species or any samples that produce a Low Confidence Identification or No Identification Result should be manually prepared using the Bruker's Extraction (Ext) Test Procedure and/or use an alternative method of organism identification. The concentration of organisms present near the LoD for the BD Kiestra IdentifA (0.2 to 0.3 McFarland) was shown to be equivalent to the claimed LoD for the manual extended Direct Transfer (eDT) method of sample preparation for the Bruker MALDI Biotyper CA (CFU/target spot).

Cross-contamination of BD Kiestra IdentifA

A cross-contamination study was performed in support of the original 510(k) submission. Since the original submission, multiple software updates were made including a modification to remove a delay in pipette tip retraction during target spotting, and further validations were performed. A final cross-contamination study was performed on the most updated software version for the candidate device and is described below.

A cross-contamination study was conducted to evaluate the potential for cross-contamination using the BD Kiestra IdentifA within and between culture plates and between spots on the MALDI target. One hundred plated media were inoculated with a strain of *Staphylococcus aureus* and one hundred plated media were inoculated with a strain of *Klebsiella pneumoniae.* The inoculated media were processed on

BD Kiestra IdentifA, alternating the two hundred inoculated media with two hundred uninoculated media. The inoculated and uninoculated samples yielded the correct results 100% of the time; "No peaks" or "No identification" on Bruker MALDI from all uninoculated samples and the correct identification on Bruker MALDI with a log score ≥2.00 from all inoculated samples.

An examination of instruments in the field was also conducted. Over 58,000 samples have been processed across the 3 BD Kiestra IdentifA instruments running in Europe since January 2020, without any cross-contamination events reported.

Conclusions Drawn from Substantial Equivalence Studies

The data collected from the substantial equivalence studies demonstrate that specimen and MALDI target preparation on the BD Kiestra™ IdentifA is substantially equivalent to the predicate, Bruker MALDI Biotyper CA, DEN 170081 April 20, 2018.