December 27, 2021

COPAN WASP S.r.l.
% Enrico Bisson
Consultant
Studio D'ingegneria Enrico Bisson
Via Marzia 9
Abano Terme, 35031 Italy

Re: K193138
Trade/Device Name: Colibri System
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 16, 2020
Received: June 19, 2020

Dear Enrico Bisson:

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)*
K193138

Device Name
Colibrí System

Indications for Use *(Describe)*
The Colibrí System is an in vitro diagnostic device comprised of the Colibrí Vision System and Colibrí Preparation Station for use with the bioMérieux VITEK MS or Bruker MALDI Biotyper CA mass spectrometry systems for qualitative identification of isolated colonies of Gram-negative and Gram-positive bacterial species grown on solid culture media. The Colibrí System is a semi-automated pre-analytical processor that picks isolated colonies designated by the operator and uses a pipetting system to prepare MALDI-TOF MS (Matrix-Assisted Laser Desorption/Ionization-Time Of Flight Mass Spectrometry) target slides. The Colibrí software records the identity of each sample and its position on the target slide and communicates this information electronically to the MALDI-TOF MS analyzer.

The Colibrí System is intended for use by trained healthcare professionals in clinical laboratories in conjunction with other clinical and laboratory findings, including Gram staining, to aid in the diagnosis of bacterial infections.

The Colibrí System has not been validated for use in identification of yeast species.

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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Traditional 510(k) Premarket Notification for Copan WASP Colibrí
510(K) SUMMARY

I. SUBMITTER

Applicant Name:	Copan WASP Srl Via A. Grandi 32 25125 Brescia, Italy +39 030 2687211 copan.regulatory@copangroup.com
Contact Person	Enrico Bisson ISOPLAN CONSULTING Studio di Ingegneria Enrico Bisson Via Marzia, 9 35031 Abano Terme (PD), Italy +39 030 2687211_+39 3286439091 copan.regulatory@copangroup.com
Establishment Registration Number:	3009288740
Date Prepared:	December 23, 2021

II. DEVICE NAME

Proprietary Name	Colibrí System
Common/Usual Name	Colibrí System
Classification Name	Clinical mass spectrometry microorganism identification and differentiation system (21 CFR 866.3378)
Device Class	II
Product Code	QQV, QBN
Panel	Microbiology

Traditional 510(k) Premarket Notification for Copan WASP Colibrí
510(K) SUMMARY

III. LEGALLY MARKETED PREDICATE DEVICE

Device Name	VITEK MS
510(K) Number	K181412

No reference Devices were used in this submission.

IV. DEVICE DESCRIPTION

The Copan Colibrí System is designed to be used as an accessory of the downstream MALDI-TOF analyzers automating various manual steps in the workflow for the preparation of samples for the identification of isolated colonies of microorganisms cultured from the human body.

The Colibrí System automates the preparation of MALDI target slides for the bioMérieux VITEK MS or the Bruker MALDI Biotyper 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 Colibrí Vision System and Colibrí Preparation Station and pipette tips as consumables. After appropriate plate incubation, the operator using the graphical User Interface (Image Reading Interface) chooses the plates exhibiting adequate growth and selects the isolated colonies to be processed assigning the automatic ID tasks. By using the Colibrí Vision System, specific colonies to be picked are designated by the operator on a digital plate. The Operator manually loads the plates in the Colibrí Preparation Station where colonies are automatically picked, spotted on the target slide and overlayed with the matrix.

When used in conjunction with the bioMérieux VITEK MS, the Colibrí System can prepare the 48-spot target slides by performing the direct spotting of colonies. The calibrator used for quality control is manually applied by the operator at the end of the automated colony spotting. When used in conjunction with the Bruker MALDI Biotyper CA System, the Colibrí System can prepare either reusable 48-spot or disposable 96-spot targets by performing the Direct Transfer Sample Procedure. The BTS used for quality control is manually applied by the operator at the end of the automated colony spotting.

The Colibrí software records the identity of each sample and its position on the target slide and communicates this information electronically to the MALDI-TOF MS analyzers.

Colibrí System requires three different calibrations. None of these calibration activities require user intervention if not in terms of periodical cleaning of the mechanical component as described in the dedicated section of the User Manual. Set-up calibration is performed during the device initial setup for the camera units positioned on the Colibrí Vision System and on the Colibrí Preparation Station. Auto-calibration is performed at the end of the initial set-up and periodically during the preventive maintenance to check that, in the Colibrí Preparation Station, all the mechanical references can be found inside the positioning tolerances, that the I/Os are responsive. Run-time calibration is

performed during the normal usage to automatically check the proper functioning of the Colibrí Vision System and the Colibrí Preparation Station.

V. INTENDED USE/INDICATIONS FOR USE

The Colibrí System is an in vitro diagnostic device comprised of the Colibrí Vision System and Colibrí Preparation Station for use with the bioMérieux VITEK MS or Bruker MALDI Biotyper CA mass spectrometry systems for qualitative identification of isolated colonies of Gram-negative and Gram-positive bacterial species grown on solid culture media. The Colibrí System is a semi-automated pre-analytical processor that picks isolated colonies designated by the operator and uses a pipetting system to prepare MALDI-TOF MS (Matrix-Assisted Laser Desorption/Ionization-Time Of Flight Mass Spectrometry) target slides. The Colibrí software records the identity of each sample and its position on the target slide and communicates this information electronically to the MALDI-TOF MS analyzer.

The Colibrí System is intended for use by trained healthcare professionals in clinical laboratories in conjunction with other clinical and laboratory findings, including Gram staining, to aid in the diagnosis of bacterial infections.

The Colibrí System has not been validated for use in identification of yeast species.

VI. COMPARISON TO PREDICATE DEVICE

The Colibrí System is designed to automatize the standard manual workflow for the preparation of targets for MALDI-TOF MS identification via Direct Colony Transfer decreasing the risk of cross-contamination among colonies grown on the culture plate and scratching from the media plate surface. Specifically, the Vision System aids the operator in selecting a single, well-isolated colony. The Preparation Station allows the automatic picking of the preselected colony, its spotting in the available position and the addition of the manufacturer recommended matrix.

With reference to the sample preparation flow, comparison with the predicate is provided in the following tables:

Similarities			
Item	**New Device**	**Primary Predicate Device**	**Other**
Device Name (K number)	**Colibrí System (K193138)**	**VITEK MS (K181412)**	**MALDI Biotyper CA System (DEN170081)**
Device Classification	Class II (special controls)	Class II (special controls)	Class II (special controls)
Regulation Number	21 CFR 866.3378 Clinical Mass Spectrometry Microorganism Identification and Differentiation System	21 CFR 866.3378 Clinical Mass Spectrometry Microorganism Identification and Differentiation System	21 CFR 866.3378 Clinical Mass Spectrometry Microorganism Identification and Differentiation System
Product Code	QQV: Automated System for Sample Preparation And	QBN: Mass Spectrometry, Maldi Tof, Microorganism Identification,	QBN: Mass Spectrometry, Maldi Tof, Microorganism Identification,

	Identification Of Microorganisms From Cultured Isolates By Mass Spectrometry	Cultured Isolates	Cultured Isolates
Indications for Use	The Colibrí System is an in vitro diagnostic device comprised of the Colibrí Vision System and Colibrí Preparation Station for use with the bioMérieux VITEK MS or Bruker MALDI Biotyper CA mass spectrometry systems for qualitative identification of isolated colonies of Gram-negative and Gram-positive bacterial species grown on solid culture media. The Colibrí System is a semi-automated pre-analytical processor that picks isolated colonies designated by the operator and uses a pipetting system to prepare MALDI-TOF MS (Matrix-Assisted Laser Desorption/Ionization-Time Of Flight Mass Spectrometry) target slides. The Colibrí software records the identity of each sample and its position on the target slide and communicates this information electronically to the MALDI-TOF MS analyzer. The Colibrí System is intended for use by trained healthcare professionals in clinical laboratories in conjunction with other clinical and laboratory findings, including Gram staining, to aid in the diagnosis of bacterial infections. The Colibrí System has not been validated for use in identification of yeast species.	VITEK MS is a mass spectrometry system using matrix-assisted laser desorption/ionization time of flight mass spectrometry (MALDI-TOF MS) for the identification of microorganisms cultured from human specimens. The VITEK MS 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, yeast and mould infections. (list of claimed organisms omitted for brevity; refer to K181412)	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. (list of validated organisms omitted for brevity; refer to DEN170081)
Sample/Media Type	Isolated bacterial colonies from any patient source on plated culture media. Acceptable media when Colibrí System is used in connection with VITEK MS: • Columbia blood agar with 5% sheep blood • Trypticase soy agar with 5% sheep blood • Chocolate agar • MacConkey Agar Acceptable media when Colibrí System is used in connection with MALDI Biotyper CA: • Columbia blood agar with 5%	Isolated bacterial colonies from any patient source on plated culture media. Acceptable media: • Columbia blood agar with 5% sheep blood • Trypticase soy agar with 5% sheep blood • Chocolate polyvitex agar • MacConkey agar	Isolated bacterial colonies from any patient source on plated culture media. Acceptable media: • Columbia blood agar with 5% sheep blood (Gram-negative bacteria) • Trypticase soy agar with 5% sheep blood (Gram-negative bacteria) • Chocolate agar (Gram-negative bacteria, Gram-positive bacteria) • MacConkey Agar (Gram-negative bacteria) • Columbia CNA agar with 5% sheep blood (Gram-positive bacteria)

	sheep blood • Trypticase soy agar with 5% sheep Blood • Chocolate agar • MacConkey Agar • Columbia CNA agar with 5% sheep blood • Bordet Gengou Agar with 15% sheep blood Note: media are selected among those recommended for the Legally marketed Predicate Devices and suitable for Gram-negative and Gram-positive bacteria. Strains used to evaluate Colibrí System performance characteristics have been selected among those claimed from the Legally marketed Predicate devices.		• Bordet Gengou Agar with 15% sheep blood (*Bordetella* species)
Method of Sample Preparation	Direct spotting to target/slide of Gram-negative and Gram-positive bacteria. A portion of microbial colony from an agar plate is automatically spotted on a VITEK MS-DS target slide or MALDI Biotyper target by using the pipetting system.	Direct spotting to slide of Gram-negative and Gram-positive bacteria. A portion of microbial colony from an agar plate is manually applied to a spot of VITEK MS-DS target slide using a 1uL loop.	Bacteria: Direct spotting to target of Gram-negative and Gram-positive bacteria. An isolated colony of bacteria is smeared as a thin film using a sterile colony transfer device, directly onto a sample position on a cleaned US IVD 48 Spot Target or an unused sample position of a MBT Biotarget 96 US IVD plate.
Target Slide	When connected with VITEK MS, following target may be processed: VITEK MS-DS Target Slides, 48 positions disposable plastic targets When connected with Bruker MALDI Biotyper CA, following targets may be processed: Bruker US IVD 48 Spot target Bruker MBT Biotarget 96 US IVD plate.	VITEK MS-DS Target Slides, 48 positions disposable plastic targets	IVD 48 Spot Target MBT Biotarget 96 US IVD plate.
Matrix	1 µL VITEK MS-CHCA matrix is automatically applied to the spot using the pipetting system. The dried target slide is then manually loaded into the VITEK MS instrument. 1 µL US IVD HCCA portioned is automatically applied to the spot using the pipetting system. The dried target slide is then manually loaded into the MALDI Biotyper CA instrument.	1 µL VITEK MS-CHCA is applied to the spot using a pipette. The dried target slide is then manually loaded into the VITEK MS instrument.	1 µL US IVD HCCA portioned is applied to the spot using a pipette. The dried target slide is then manually loaded into the MALDI Biotyper CA instrument
Calibration/	For VITEK MS: *Escherichia coli*	*Escherichia coli* ATCC 8739	US IVD Bacterial Test Standard

Quality Controls	ATCC 8739 (calibrator strain) and *Klebsiella aerogenes* ATCC 13048 (positive control strain) are manually spotted in predetermined positions. For MALDI Biotyper CA: US IVD Bacterial Test Standard (BTS) is manually spotted before loading in the instrument.	(calibrator strain) and *Klebsiella aerogenes* ATCC 13048 (positive control strain) are manually spotted in predetermined positions	(BTS) is manually spotted before loading in the instrument.
Culture Stability	For Bacteria: When connected with VITEK MS, incubation of culture should be 18 – 72hrs (18 – 48hrs for Chocolate Agar). When connected with MALDI Biotyper CA, incubation of culture should be 18 – 48hrs (+12hrs storage at RT).	For Bacteria: Incubation of culture should be 18 – 72hrs	For Bacteria: Incubation of culture should be between 18 – 48hrs (+12hrs storage at RT).
Spot Stability	When connected with VITEK MS, after matrix addition targets are stable for 48h at room temperature when held on the Colibrí deck and for 72h when held in the original box. When connected with MALDI Biotyper CA, after matrix addition targets are stable for 24h at room temperature.	After matrix addition, targets are stable for 72h when held in the original box.	After matrix addition, targets are stable for 24h at room temperature.
MALDI-TOF MS Analyzer	bioMérieux VITEK MS Bruker MALDI Biotyper CA	bioMérieux VITEK MS	Bruker MALDI Biotyper CA
Method of Testing	When connected with VITEK MS, direct testing from isolated colonies. When connected with Bruker MALDI Biotyper CA, direct testing from isolated colonies. If after initial analysis the log(score) is reported at <2.00, organisms may be processed by manual preparation using the Extraction (Ext) procedure or extended Direct Transfer.	For bacteria: Direct testing from isolated colonies	For bacteria: Direct testing from isolated colonies; If after initial analysis the log(score) is reported at <2.00, organisms may be processed using the Extraction (Ext) procedure or extended Direct Transfer (eDT, 70% aqueous formic acid) procedure. If eDT procedure still yields log (score) <2.00, organisms may be processed via Ext procedure.

Differences			
Item	**New Device**	**Primary Predicate Device**	**Other**
Device Name (K number)	**Colibrí System (K193138)**	**VITEK MS (K181412)**	**MALDI Biotyper CA System (DEN170081)**
Target Organism	Colibrí System has been validated for direct spotting to target/slide of Gram-negative and Gram-positive bacteria only.	VITEK MS also includes mycobacteria, nocardia, yeast and mould indications for use, an inactivation and extraction process is required for sample prep, prior to spotting the sample to the slide.	MALDI Biotyper CA also includes yeast indications for use. If after initial analysis the log(score) is reported at <2.00, organisms may be processed using the Extraction (Ext) procedure or extended Direct Transfer (eDT, 70% aqueous

Differences			
Item	**New Device**	**Primary Predicate Device**	**Other**
Device Name (K number)	**Colibrí System (K193138)**	**VITEK MS (K181412)**	**MALDI Biotyper CA System (DEN170081)**
			formic acid) procedure. If eDT procedure still yields log(score) <2.00, organisms may be processed via Ext procedure.
Colony Selection	The colony to be picked is selected by an operator on a digital plate using the Graphical User Interface of a Colibrí Vision System.	The colony to be picked is selected by an operator on a real plate through the visual inspection.	The colony to be picked is selected by an operator on a real plate through the visual inspection
Sample Traceability	A unique identifier (Sample ID) is automatically linked to each spot position and transferred to the MALDI-TOF MS analyzers through ethernet protocol communication.	Sample ID is manually entered by using the VITEK MS Prep Station.	Sample ID is manually entered by using the User Graphical Interface.
Method of Sample Preparation	The colony is picked and spotted on the target by automated preparation using the Colibrí Preparation Station	The colony is picked and spotted on the target by manual preparation by the operator.	The colony is picked and spotted on the target by manual preparation by the operator.
Culture Media	Colibrí System includes indications for use for bacterial isolates only (no yeast) from validated solid culture media either in whole or bi-plate format. Acceptable media: When connected with VITEK MS: • Trypticase Soy Agar + 5% sheep blood/ MacConkey When connected with MALDI Biotyper CA: • Trypticase Soy Agar + 5% sheep blood/ MacConkey • Columbia CNA Agar / MacConkey	Other acceptable media for bacteria and yeast: • BacT/ALERT MP • Brucella agar base • Buffered charcoal yeast extract • Campylosel agar • chromID CPS • Coletsos • Lowenstein-Jensen* • MGIT • Middlebrook 7H10 agar • Middlebrook 7H11 agar • Modified Sabouraud dextrose agar (glucose: 20 g/l - pH: 6.1) • Potato dextrose agar • Sabouraud dextrose agar (glucose: 40 g/l pH: 5.6) • Sabouraud dextrose agar with Gentamicin & Chloramphenicol • Trypticase soy agar • Trypticase soy agar with neutralizers VITEK MS includes mycobacteria indications for use from both solid & liquid culture media, and nocardia and mould indications for use from solid culture media only.	Other acceptable media for bacteria and yeast: • Brucella Agar with 5% horse blood (Gram-negative anaerobic bacteria, Gram-positive anaerobic bacteria) • CDC anaerobe Agar with 5% sheep blood (Gram-negative anaerobic bacteria, Gram-positive anaerobic bacteria) • CDC anaerobe 5% sheep blood Agar with phenylethyl alcohol (Gram-negative anaerobic bacteria, Gram- positive anaerobic bacteria) • CDC anaerobe laked sheep blood Agar with kanamycin and vancomycin (Gram-negative anaerobic bacilli) • Bacteroides bile esculin Agar with amikacin (Bacteroides species) • Clostridium difficile Agar with 7% sheep blood (*Clostridium difficile*) • Sabouraud-Dextrose Agar (yeasts) • Brain Heart Infusion Agar (yeasts) • Campylobacter Agar with 5 Antimicrobics and 10% Sheep Blood (*Campylobacter* species) • Buffered Charcoal Yeast Extract Agar • Buffered Charcoal Yeast

Differences			
Item	**New Device**	**Primary Predicate Device**	**Other**
Device Name (K number)	**Colibrí System (K193138)**	**VITEK MS (K181412)**	**MALDI Biotyper CA System (DEN170081)**
			Extract Selective Agar with polymyxin, anisomycin and vancomycin • Modified Thayer-Martin Agar MALDI Biotyper CA System includes indications for use for bacteria and yeast isolates from solid culture media.
Age of Culture	Bordet Gengou Agar with 15% sheep blood: incubation should be prolonged to 5 (+12hrs storage at RT) – 7 days.	For yeast: Incubation of culture should be 18 – 72hrs Incubation of *Brucella* spp should be 48 – 96 hrs (2 – 4 days)	For yeast: Incubation of culture should be between 18 – 36hrs
Method of Testing	Colibrí System has been validated for direct spotting to target/slide of Gram-negative and Gram-positive bacteria only.	(For yeast) Direct testing from isolated colonies (For mycobacteria, *Nocardia*, moulds) Inactivation and extraction prior to sample spotting on the target slide (For *Brucella* spp) Inactivation required prior to sample spotting on the target slide	(For yeast) Direct testing from isolated colonies; If after initial analysis the log(score) is reported at <2.00, organisms may be processed using the Extraction (Ext) procedure or extended Direct Transfer (eDT, 70% aqueous formic acid) procedure. If eDT procedure still yields log (score) <2.00, organisms may be processed via Ext procedure.

These differences do not affect substantial equivalence of Colibrí System and the Predicate Devices. Both Systems are intended for the identification of microorganisms cultured from human specimens

VII PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Analytical Studies

The performed analytical studies verified and validated the use of the Colibrí System in conjunction with the bioMérieux VITEK MS or Bruker MALDI Biotyper CA mass spectrometry systems. The analytical studies carried out to evaluate the performance of the Colibrí System demonstrated that the device can automatically prepare the proprietary branded target slide for both MALDI-TOF MS analyzers by spotting colonies and the necessary matrix, starting from Gram-negative and Gram-positive bacterial colonies grown on solid culture media. The used methodology (direct colony spotting) and claimed prerequisites for sample preparation are in line with the IVD analyzer

manufacturer IFU and with the relevant guidance.

Colony Picking for Microbial Identification Study

To assess the accuracy of Colibrí System in picking designated colonies of various microbial species from different culture media (whole and bi-plates), isolated colonies from mixed cultures prepared with "on-panel" Gram-positive and Gram-negative strains have been used to prepare the bioMérieux VITEK MS-DS and Bruker MALDI Biotyper CA System target slides. The preparation has been repeated on 3 different Colibrí Systems and compared to the manual preparation.
Colonies designated by the operator were picked correctly at 100% without any event in which a wrong colony was picked and no wrong identifications were obtained. For the VITEK MS, a total of 1390 spots were prepared: as overall, 98.4% of designated colonies has been identified correctly with high confidence in comparison to the expected strain identity.

Colony Picking Study identification results of the Colibrí System obtained with the bioMérieux VITEK MS stratified per species.

Test strain	Total no. of picked colonies	Correct Single Choice (≥60% Confidence value)	Low discrimination (<60% Confidence value)	No ID	Wrong ID	% agreement* between Colibrí and expected ID
Gram-positive						
Enterococcus faecalis	168	152	1	15	0	90.5%
Streptococcus agalactiae	162	156	0	6	0	96.3%
Staphylococcus aureus	292	292	0	0	0	100.0%
Total Gram-positive	622	600	1	21	0	96.5%
Gram-negative						
Klebsiella pneumoniae	310	310	0	0	0	100.0%
Proteus mirabilis	158	158	0	0	0	100.0%
Escherichia coli	300	300	0	0	0	100.0%
Total Gram-negative	768	768	0	0	0	100.0%
Total	1390	1368	1	21	0	98.4%

*Calculated as $Agreement(\%) = \frac{No.\ of\ correct\ results\ with\ Good\ Confidence\ value\ (\geq 60\%)}{Total\ number\ of\ picked\ colonies} x100$

For the Bruker MALDI Biotyper CA System, a total of 1690 spots were prepared: the identification performance varied among the species with a lower proportion of concordant results for Gram-positive species: nevertheless, the overall performance (calculated only on results providing High Confidence Log (Score)) is considered acceptable because no incorrect identification occurred. Colonies designated by the operator were picked correctly at 100% without any event in which a wrong colony was picked and no wrong identifications were obtained. In addition, consistent with the Instructions for Use of the Bruker MALDI Biotyper CA System, if a low-confidence identification or a no identification result is obtained, the Copan Colibrí System Package Insert will recommend repeat testing of the isolate manually using the extended Direct Transfer (eDT) or Extraction (Ext) Sample Preparation Procedure.

Colony Picking Study identification results of the Colibrí System obtained with the Bruker MALDI Biotyper CA System stratified per species.

Test strain	Total no. of picked colonies	High confidence ID Log (Score) ≥ 2	Low confidence ID 1.7≤ Log (Score) < 2	Combined performance	No ID	Wrong ID	% agreement* between Colibrí and expected ID
Gram-positive							
Enterococcus faecalis	150	122	22	144	6	0	81.3%
Streptococcus agalactiae	150	105	26	131	19	0	70.0%
Staphylococcus aureus	364	316	48	364	0	0	86.8%
Staphylococcus epidermidis	148	118	30	148	0	0	79.7%
Total Gram-positive	812	661	126	787	25	0	81.4%
Gram-negative							
Proteus mirabilis	168	168	0	168	0	0	100.0%
Klebsiella pneumoniae	330	330	0	330	0	0	100.0%
Escherichia coli	380	375	5	380	0	0	98.7%
Total Gram-negative	878	873	5	878	0	0	99.4%
Total	1690	1534	131	1665	25	0	90.8%

*Calculated as $\frac{No.\ of\ correct\ results\ with\ High\ Confidence\ Log\ (Score) \geq 2}{Total\ number\ of\ picked\ colonies} x100$

Positional Effect Study

The Positional Effect Study was performed to demonstrate that the Copan Colibrí System can prepare target spots for MALDI-TOF MS analysis at each location on the target slide. For this test, media plates showing growth of bacteria included in the knowledge databases of the bioMérieux VITEK MS and Bruker MALDI Biotyper CA System ("on-panel" strains) were used to challenge the accuracy of the Copan Colibrí System in spotting the picked colonies in all the target slide positions. The study conducted in conjunction with Bruker MALDI Biotyper CA System was performed using both the US IVD 48 Spot target (48-position reusable target) and the MBT Biotarget 96 US IVD (96-position disposable target) that have different geometry and spot diameters. No positional effect was detected, and no wrong identification results were obtained with either mass spectrometry analyzer.

Positional Effect Study identification results of the Colibrí System obtained with the bioMérieux VITEK MS

Test Strain	No. of spots	Correct Single Choice Confidence value ≥ 60%	Low Discrimination Confidence value < 60%	No ID	Wrong ID	% agreement* between Colibrí and expected ID *
Escherichia coli	432	432	0	0	0	100%
Staphylococcus aureus	432	431	0	1	0	99.8%

*Calculated as $\frac{No.\ of\ correct\ results\ with\ Good\ Confidence\ value\ (\geq 60\%)}{Total\ number\ of\ picked\ colonies} x100$

Positional Effect Study identification results of the Colibrí System obtained with the Bruker MALDI Biotyper CA System with US IVD 48 Spot target

Test Strain	No. of spots	Correct Identification with high confidence (Log score value 2.00-3.00)	Low Confidence Identification (Log score value 1.70-1.99)	Combined performance	No ID	Wrong ID	% agreement between Colibrí and expected ID *
Escherichia coli	432	431	1	432	0	0	99.8%
Staphylococcus aureus	432	418	14	432	0	0	96.8%

*Calculated as $\frac{No.\ of\ correct\ results\ with\ High\ Confidence\ Log\ (Score)\geq 2}{Total\ number\ of\ picked\ colonies} x100$

Positional Effect Study identification results of the Colibrí System obtained with MALDI Biotyper CA System with MBT Biotarget 96 US IVD

Test Strain	No. of spots	Correct Identification with high confidence (Log score value 2.00-3.00)	Low Confidence Identification (Log score value 1.70-1.99)	Combined performance	No ID	Wrong ID	% agreement between Colibrí and expected ID *
Escherichia coli	846	845	1	846	0	0	99.9%
Staphylococcus aureus	846	810	34	844	2	0	95.7%

*Calculated as $\frac{No.\ of\ correct\ results\ with\ High\ Confidence\ Log\ (Score)\geq 2}{Total\ number\ of\ picked\ colonies} x100$

Inclusivity Study

The Inclusivity Study was performed to demonstrate that Colibrí System is able to prepare targets with "on-panel" species that provide the same microbial identification as the manual preparation when analyzed with the bioMérieux VITEK MS and Bruker MALDI Biotyper CA Systems without false identifications. A variety of bacteria included in the knowledge databases of the bioMérieux VITEK MS or Bruker MALDI Biotyper CA System ("on-panel" strains) were included in this study. Strain selection criteria included representative isolates of different genera and organisms exhibiting a broad range of colony characteristics (size, morphology and viscoelastic proprieties). The study was designed as to include multiple strains of the most commonly isolated Gram-positive and Gram-negative species in the US, as well as examples of less common/rare pathogens. The identification results obtained by bioMérieux VITEK MS and Bruker MALDI Biotyper CA System

using the Copan Colibrí System as sample preparator were compared to the expected strain identity and to those obtained by manual preparation.

For the bioMérieux VITEK MS, the study was conducted by one operator on one Colibrí System and a total of 123 bacterial strains belonging to 29 different species were analyzed. An overall agreement of 97.2% in the identification results between organisms spotted automatically and the expected strain identity was found, and no wrong identification results were obtained with the automatic preparation. More specifically, 85.2% of picked colonies (334/392) provided an identification corresponding to the expected strain identity with a Confidence Value ≥ 60%. In addition, the calculation of agreement includes 47/48 colonies of *Enterobacter cloacae* and *Proteus vulgaris* reported with Low Discrimination as *Enterobacter cloacae/Enterobacter asburiae* and *Proteus penneri/Proteus vulgaris*, in accordance with the labeling for the VITEK MS analyzer.

For the Bruker MALDI Biotyper CA System, the study was conducted by one operator on two Colibrí Systems, one configured for the processing of the US IVD 48 Spot target (48-position reusable steel target) and the other for the MBT Biotarget 96 US IVD (96-position disposable target). A total of 124 bacterial strains belonging to 30 different species were analyzed: when Copan Colibrí System was used in conjunction with Bruker MALDI Biotyper CA System on the US IVD 48 Spot Target, 93.2% of picked colonies (436/468) provided an identification corresponding to the expected strain identity with a High confidence ID Log (Score) ≥ 2.
When Copan Colibrí System was used in conjunction with Bruker MALDI Biotyper CA System with the MBT Biotarget 96 US IVD, 85.7% of picked colonies provided an identification corresponding to the expected strain identity with a High confidence ID Log (Score) ≥ 2.
Performance of the Copan Colibrí System for preparation of Gram-positive target organisms for the Bruker MALDI Biotyper CA is lower when compared to manual preparation; however, none of the colonies in the study provided a wrong identification. Instructions will be included in the Colibrí System Package Insert for the operator to repeat testing of the isolate manually using the extended Direct Transfer (eDT) or Extraction (Ext) Sample Preparation Procedure if a low-confidence identification or no identification result is obtained. This is consistent with the Instructions for Use of the Bruker MALDI Biotyper CA System.

Traditional 510(k) Premarket Notification for
Copan WASP Colibrí
510(K) SUMMARY

Inclusivity Study identification results of the Colibrí System obtained with the bioMérieux VITEK MS and stratified per species

Test strain	Total no. of picked colonies	Correct Single Choice (≥60% Confidence value)		Low discrimination (<60% Confidence value)		No ID		Wrong ID		% agreement* between Colibrí and expected ID	% agreement** between manual and expected ID
		Colibrí	Manual	Colibrí	Manual	Colibrí	Manual	Colibrí	Manual		
Gram Positive											
Enterococcus faecalis	12	11	12	0	0	1	0	0	0	91.7%	100.0%
Enterococcus faecium	12	11	11	0	0	1	1	0	0	91.7%	91.7%
Listeria monocytogenes	4	4	3	0	0	0	1	0	0	100.0%	75.0%
Staphylococcus aureus	12	12	12	0	0	0	0	0	0	100.0%	100.0%
Staphylococcus epidermidis	12	12	12	0	0	0	0	0	0	100.0%	100.0%
Staphylococcus saprophyticus	8	6	6	0	0	2	2	0	0	75.0%	75.0%
Streptococcus agalactiae	16	13	15	0	0	3	1	0	0	81.3%	93.8%
Streptococcus pyogenes	8	7	7	0	0	1	1	0	0	87.5%	87.5%
Total Gram-positive	**84**	**76**	**78**	**0**	**0**	**8**	**6**	**0**	**0**	**90.5%**	**92.9%**
Gram Negative											
Acinobacter baumannii	24	24	20	0	0	0	4	0	0	100.0%	83.3%
Bacteroides fragilis	2	2	2	0	0	0	0	0	0	100.0%	100.0%
Citrobacter koseri	24	24	21	0	0	0	3	0	0	100.0%	87.5%
Eikenella corrodens	2	2	2	0	0	0	0	0	0	100.0%	100.0%
Enterobacter aerogenes/Klebsiella aerogenes	24	23	22	0	0	1	2	0	0	95.8%	91.7%
Enterobacter cloacae	24	0	0	23[a]	20[a]	1	4	0	0	95.8%[a]	83.3%[a]
Escherichia coli	24	24	23	0	0	0	1	0	0	100.0%	95.8%
Haemophilus influenzae	4	4	3	0	0	0	1	0	0	100.0%	75.0%
Klebsiella oxytoca	24	24	20	0	0	0	4	0	0	100.0%	83.3%
Klebsiella pneumoniae	24	23	21	0	0	1	3	0	0	95.8%	87.5%
Moraxella catarrhalis	4	4	4	0	0	0	0	0	0	100.0%	100.0%
Morganella morganii	16	16	15	0	0	0	1	0	0	100.0%	93.8%
Neisseria gonorrhoeae	4	4	4	0	0	0	0	0	0	100.0%	100.0%
Neisseria meningitidis	2	2	1	0	0	0	1	0	0	100.0%	50.0%

Traditional 510(k) Premarket Notification for Copan WASP Colibrí
510(K) SUMMARY

Test strain	Total no. of picked colonies	Correct Single Choice (≥60% Confidence value)		Low discrimination (<60% Confidence value)		No ID		Wrong ID		% agreement* between Colibrí and expected ID	% agreement** between manual and expected ID
		Colibrí	Manual	Colibrí	Manual	Colibrí	Manual	Colibrí	Manual		
Proteus mirabilis	24	24	23	0	0	0	1	0	0	100.0%	95.8%
Proteus vulgaris	24	0	0	24[b]	23[b]	0	1	0	0	100.0%[b]	95.8%[b]
Pseudomonas aeruginosa	24	24	24	0	0	0	0	0	0	100.0%	100.0%
Salmonella typhimurium	8	8	8	0	0	0	0	0	0	100.0%	100.0%
Serratia marcescens	16	16	16	0	0	0	0	0	0	100.0%	100.0%
Stenotrophomonas maltophilia	8	8	7	0	0	0	1	0	0	100.0%	87.5%
Vibrio parahaemolyticus	2	2	2	0	0	0	0	0	0	100.0%	100.0%
Total Gram-negative	**308**	**258**	**238**	**47**	**43**	**3**	**27**	**0**	**0**	**99.0%** [a, b]	**91.2%** [a, b]
Total	**392**	**334**	**316**	**47** [a, b]	**43** [a, b]	**11**	**33**	**0**	**0**	**97.2%** [a, b]	**91.6%** [a, b]

[a]According to VITEK MS instrument, *Enterobacter cloacae* identifications are considered as a slashline result, *Enterobacter cloacae/ Enterobacter asburiae* (50%/50%). Therefore, the Low discrimination results for this strain are included in the Agreement calculation

b According to VITEK MS instrument, *Proteus vulgaris* identifications are considered as a slashline result, *Proteus penneri/ Proteus vulgaris* (50%/50%). Therefore, the Low discrimination results for this strain are included in the Agreement calculation.

*Calculated as: $\text{Colibrí performance identification}(\%) = \frac{No.\ of correct\ results\ with\ Good\ Confidence\ value\ (\geq 60\%)}{Total\ number\ of\ picked\ colonies} x100$

**Calculated as: $\text{Manual performance identification}(\%) = \frac{No.\ of correct\ results\ with\ Good\ Confidence\ value\ (\geq 60\%)}{Total\ number\ of\ picked\ colonies} x100$

Traditional 510(k) Premarket Notification for
Copan WASP Colibrí
510(K) SUMMARY

Inclusivity Study identification results of the Colibrí System obtained with the Bruker MALDI Biotyper CA System on US IVD 48 Spot target and stratified per species

Test strain	Total no. of picked colonies	High confidence ID Log (Score) ≥2		Low confidence ID 1.7≤ Log (Score)<2		Combined performance		No ID		Wrong ID		% agreement* between Colibrí and expected ID	% agreement** between manual and expected ID
		Colibrí	Manual	Colibrí	Manual	Colibrí	Manual	Colibrí	Manual	Colibrí	Manual		
Gram Positive													
Enterococcus faecalis	24	19	24	4	0	23	24	1	0	0	0	79.2%	100.0%
Enterococcus faecium	24	21	24	3	0	24	24	0	0	0	0	87.5%	100.0%
Listeria monocytogenes	4	4	4	0	0	4	4	0	0	0	0	100.0%	100.0%
Staphylococcus aureus	24	21	24	3	0	24	24	0	0	0	0	87.5%	100.0%
Staphylococcus epidermidis	24	18	20	6	4	24	24	0	0	0	0	75.0%	83.3%
Staphylococcus saprophyticus	16	12	15	2	1	14	16	2	0	0	0	75.0%	93.8%
Streptococcus agalactiae	24	19	21	2	3	21	24	3	0	0	0	79.2%	87.5%
Streptococcus pyogenes	16	14	16	2	0	16	16	0	0	0	0	87.5%	100.0%
Total Gram-positive	**156**	**128**	**148**	**22**	**8**	**150**	**156**	**6**	**0**	**0**	**0**	**82.1%**	**94.9%**
Gram Negative													
Acinobacter baumannii	24	23	22	1	2	24	24	0	0	0	0	95.8%	91.7%
Bacteroides fragilis	2	2	2	0	0	2	2	0	0	0	0	100.0%	100.0%
Bordetella pertussis	2	2	2	0	0	2	2	0	0	0	0	100.0%	100.0%
Citrobacter koseri	24	24	24	0	0	24	24	0	0	0	0	100.0%	100.0%
Eikenella corrodens	4	4	4	0	0	4	4	0	0	0	0	100.0%	100.0%
Enterobacter aerogenes	24	24	24	0	0	24	24	0	0	0	0	100.0%	100.0%
Enterobacter cloacae	24	24	24	0	0	24	24	0	0	0	0	100.0%	100.0%

Traditional 510(k) Premarket Notification for Copan WASP Colibrí
510(K) SUMMARY

Test strain	Total no. of picked colonies	High confidence ID Log (Score) ≥2		Low confidence ID 1.7≤ Log (Score)<2		Combined performance		No ID		Wrong ID		% agreement* between Colibrí and expected ID	% agreement** between manual and expected ID
		Colibrí	Manual	Colibrí	Manual	Colibrí	Manual	Colibrí	Manual	Colibrí	Manual		
Escherichia coli	24	22	23	2	1	24	24	0	0	0	0	91.7%	95.8%
Haemophilus influenzae	4	4	4	0	0	4	4	0	0	0	0	100.0%	100.0%
Klebsiella oxytoca	24	24	24	0	0	24	24	0	0	0	0	100.0%	100.0%
Klebsiella pneumoniae	24	24	24	0	0	24	24	0	0	0	0	100.0%	100.0%
Moraxella catarrhalis	4	4	4	0	0	4	4	0	0	0	0	100.0%	100.0%
Morganella morganii	16	16	15	0	0	16	15	0	1	0	0	100.0%	93.8%
Neisseria gonorrhoeae	4	4	4	0	0	4	4	0	0	0	0	100.0%	100.0%
Neisseria meningitidis	2	2	2	0	0	2	2	0	0	0	0	100.0%	100.0%
Proteus mirabilis	24	24	24	0	0	24	24	0	0	0	0	100.0%	100.0%
Proteus vulgaris	24	23	23	1	1	24	24	0	0	0	0	95.8%	95.8%
Pseudomonas aeruginosa	24	24	24	0	0	24	24	0	0	0	0	100.0%	100.0%
Salmonella typhimurium and spp	8	8	8	0	0	8	8	0	0	0	0	100.0%	100.0%
Serratia marcescens	16	16	16	0	0	16	16	0	0	0	0	100.0%	100.0%
Stenotrophomonas maltophilia	8	8	8	0	0	8	8	0	0	0	0	100.0%	100.0%
Vibrio parahaemolyticus	2	2	2	0	0	2	2	0	0	0	0	100.0%	100.0%
Total Gram-negative	**312**	**308**	**307**	**4**	**4**	**312**	**311**	**0**	**1**	**0**	**0**	**98.7%**	**98.4%**
Total	**468**	**436**	**455**	**26**	**12**	**462**	**467**	**6**	**1**	**0**	**0**	**93.2%**	**97.2%**

*Calculated as: Colibrí performance identification (%) $= \frac{No.\ of\ correct\ results\ with\ Good\ Confidence\ value\ (\geq 60\%)}{Total\ number\ of\ picked\ colonies} x100$

**Calculated as: Manual performance identification (%) $= \frac{No.\ of correct\ results\ with\ Good\ Confidence\ value\ (\geq 60\%)}{Total\ number\ of\ picked\ colonies} x100$

Traditional 510(k) Premarket Notification for
Copan WASP Colibrí
510(K) SUMMARY

Inclusivity Study identification results of the Colibrí System obtained with the Bruker MALDI Biotyper CA System on MBT Biotarget 96 US IVD and stratified per species

Test strain	Total no. of picked colonies	High confidence ID Log(Score)≥2		Low confidence ID 1.7≤Log(Score)<2		Combined performance		No ID		Wrong ID		% agreement* between Colibrí and expected ID	% agreement** between manual and expected ID
		Colibrí	Manual	Colibrí	Manual	Colibrí	Manual	Colibrí	Manual	Colibrí	Manual		
Gram-positive													
Enterococcus faecalis	24	21	24	0	0	21	24	3	0	0	0	87.5%	100.0%
Enterococcus faecium	24	20	24	2	0	22	24	2	0	0	0	83.3%	100.0%
Listeria monocytogenes	4	4	4	0	0	4	4	0	0	0	0	100.0%	100.0%
Staphylococcus aureus	24	22	23	1	1	23	24	1	0	0	0	91.7%	95.8%
Staphylococcus epidermidis	24	9	10	11	11	20	21	4	3	0	0	37.5%	41.7%
Staphylococcus saprophyticus	16	9	13	2	2	11	15	5	1	0	0	56.3%	81.3%
Streptococcus agalactiae	24	7	9	10	9	17	18	7	6	0	0	29.2%	37.5%
Streptococcus pyogenes	16	13	16	3	0	16	16	0	0	0	0	81.3%	100.0%
Total Gram-positive	**156**	**105**	**123**	**29**	**23**	**134**	**146**	**22**	**10**	**0**	**0**	**67.3%**	**78.8%**
Gram-negative													
Acinobacter baumannii	24	24	20	0	3	24	23	0	1	0	0	100.0%	83.3%
Bacteroides fragilis	2	2	2	0	0	2	2	0	0	0	0	100.0%	100.0%
Bordetella pertussis	2	2	2	0	0	2	2	0	0	0	0	100.0%	100.0%
Citrobacter koseri	24	23	24	1	0	24	24	0	0	0	0	95.8%	100.0%
Eikenella corrodens	4	4	4	0	0	4	4	0	0	0	0	100.0%	100.0%
Enterobacter aerogenes/Klebsiella aerogenes	24	24	24	0	0	24	24	0	0	0	0	100.0%	100.0%
Enterobacter	24	21	22	2	2	23	24	1	0	0	0	87.5%	91.7%

Traditional 510(k) Premarket Notification for Copan WASP Colibrí
510(K) SUMMARY

Test strain	Total no. of picked colonies	High confidence ID Log(Score)≥2		Low confidence ID 1.7≤Log(Score)<2		Combined performance		No ID		Wrong ID		% agreement* between Colibrí and expected ID	% agreement** between manual and expected ID
		Colibrí	Manual	Colibrí	Manual	Colibrí	Manual	Colibrí	Manual	Colibrí	Manual		
cloacae													
Escherichia coli	24	20	18	4	5	24	23	0	1	0	0	83.3%	75.0%
Haemophilus influenzae	4	4	4	0	0	4	4	0	0	0	0	100.0%	100.0%
Klebsiella oxytoca	24	19	21	2	0	21	21	3	3	0	0	79.2%	87.5%
Klebsiella pneumoniae	24	22	20	1	1	23	21	1	3	0	0	91.7%	83.3%
Moraxella catarrhalis	4	4	4	0	0	4	4	0	0	0	0	100.0%	100.0%
Morganella morganii	16	16	16	0	0	16	16	0	0	0	0	100.0%	100.0%
Neisseria gonorrhoeae	4	4	4	0	0	4	4	0	0	0	0	100.0%	100.0%
Neisseria meningitidis	2	2	2	0	0	2	2	0	0	0	0	100.0%	100.0%
Proteus mirabilis	24	23	24	0	0	23	24	1	0	0	0	95.8%	100.0%
Proteus vulgaris	24	24	24	0	0	24	24	0	0	0	0	100.0%	100.0%
Pseudomonas aeruginosa	24	24	22	0	0	24	22	0	2	0	0	100.0%	91.7%
Salmonella typhimurium and spp	8	8	7	0	0	8	7	0	1	0	0	100.0%	87.5%
Serratia marcescens	16	16	15	0	1	16	16	0	0	0	0	100.0%	93.8%
Stenotrophomonas maltophilia	8	8	8	0	0	8	8	0	0	0	0	100.0%	100.0%
Vibrio parahaemolyticus	2	2	2	0	0	2	2	0	0	0	0	100.0%	100.0%
Total Gram-negative	**312**	**296**	**289**	**10**	**12**	**306**	**301**	**6**	**11**	**0**	**0**	**94.9%**	**92.6%**
Total	**468**	**401**	**412**	**39**	**35**	**440**	**447**	**28**	**21**	**0**	**0**	**85.7%**	**88.0%**

Traditional 510(k) Premarket Notification for Copan WASP Colibrí
510(K) SUMMARY

Specificity Study

The Specificity Study was performed to demonstrate that the Colibrí System is able to prepare targets with "off-panel" species that should provide the expected organism identity when analyzed with the bioMérieux VITEK MS and Bruker MALDI Biotyper CA System without false identifications. Isolated colonies of "off-panel" Gram-positive and Gram-negative strains that are not included in the knowledge databases of the VITEK MS and MALDI Biotyper CA have been used on the Colibrí System to prepare a total of 20 spots for each IVD analyzer. For both IVD analyzers, the study was conducted by one operator on one Colibrí System; an agreement of 100% was found between the identification results of colonies spotted by Colibrí System than those spotted using the manual method. No false positive results for "on-panel" species were obtained.

Specificity Study identification results of the Colibrí System obtained with the bioMérieux VITEK MS

Test strain	Total no. of picked colonies	Correct Single Choice (≥60% Confidence value)	Low discrimination (<60% Confidence value)	No ID	Wrong ID	% agreement* between Colibrí and expected ID
Gram-positive						
Aneurinibacillus migulanus	2	0	0	2	0	100.0%
Exiguobacterium aurantiacum	2	0	0	2	0	100.0%
Janibacter melonis	2	0	0	2	0	100.0%
Leuconostoc carnosum	2	0	0	2	0	100.0%
Leuconostoc fallax	2	0	0	2	0	100.0%
Rothia amarae	2	0	0	2	0	100.0%
Total Gram-positive	**12**	**0**	**0**	**12**	**0**	**100.0%**
Gram-negative						
Acidovorax delafieldii	2	0	0	2	0	100.0%
Burkholderia thailendensis	2	0	0	2	0	100.0%
Pectobacterium atrosepticum	2	0	0	2	0	100.0%
Pseudocitrobacter faecalis	2	0	0	2	0	100.0%
Total Gram-negative	**8**	**0**	**0**	**8**	**0**	**100.0%**
Total	**20**	**0**	**0**	**20**	**0**	**100.0%**

*Calculated as: $\frac{No.\ of\ No\ Identification\ results}{Total\ number\ of\ picked\ colonies} x100$

Specificity Study identification results of the Colibrí System obtained with the Bruker MALDI Biotyper CA System

Test strain	Total no. of picked colonies	High confidence ID Log (Score) ≥2	Low confidence ID 1.7≤ Log (Score) <2	Combined performance	No ID	Wrong ID	% agreement* between Colibrí and expected ID
Gram-positive							
Paenibacillus huminicus	2	0	0	0	2	0	100.0%
Bacillus licheniformis	2	0	0	0	2	0	100.0%
Bacillus flexus	2	0	0	0	2	0	100.0%
Bacillus infantis	2	0	0	0	2	0	100.0%
Geobacillus stearothermophilus	2	0	0	0	2	0	100.0%
Total Gram-positive	**10**	**0**	**0**	**0**	**10**	**0**	**100.0%**
Gram-negative							
Cardiobacterium hominis	2	0	0	0	2	0	100.0%
Cedecea neteri	2	0	0	0	2	0	100.0%
Brachyspira murdochii	2	0	0	0	2	0	100.0%
Gallibacterium anatis	2	0	0	0	2	0	100.0%
Novosphingobium capsulatum	2	0	0	0	2	0	100.0%
Total Gram-negative	**10**	**0**	**0**	**0**	**10**	**0**	**100.0%**
Total	**20**	**0**	**0**	**0**	**20**	**0**	**100.0%**

*Calculated as: $\frac{No.\ of\ No\ Identification\ results}{Total\ number\ of\ picked\ colonies} x100$

Reproducibility Study

The Reproducibility Study was performed to assess the repeatability of results obtained with samples processed by the automatic preparation using the Colibrí System. For this, three Colibrí Systems have been used to prepare target slides using a blinded panel of 10 common "on-panel" clinically relevant Gram-negative and Gram-positive bacteria. The test was repeated for 5 days including 3 replications per strain, performed by two operators in rotation with different levels of experience per Colibrí System for a total of 1800 spots on both IVD Analyzers.

When Copan Colibrí System was used in conjunction with the bioMérieux VITEK MS, there was 99.9% agreement (1799/1800) between the reported Good Confidence identification results and the expected identity of each colony in the Reproducibility Study. The agreement calculation includes

180 colonies of *Enterobacter cloacae* reported with Low Discrimination as *Enterobacter cloacae/Enterobacter asburiae* in accordance with the labeling for the VITEK MS analyzer.

When Copan Colibrí System was used in conjunction with the Bruker MALDI Biotyper CA, there was 88.1% agreement (1585/1800) between the reported High Confidence identification results (Log (Score) ≥ 2.00) and the expected identity of each colony in the Reproducibility Study. For Gram-positive species, 179/900 colonies (19.9%) were identified with Low Confidence (Log (Score) 1.70-1.99), compared with 1/900 colonies (0.1%) of Gram-negative species. In addition, 31/900 Gram-positive colonies (3.4%) produced no identification result compared with 4/900 Gram-negative colonies (0.4%).

The lower proportion of concordant results for Gram-positive bacteria with the Bruker MALDI Biotyper CA was noted. Consistent with the labeling for the MALDI Biotyper CA, the Copan Colibrí System Package Insert will recommend that Gram-positive species or any samples that produce a Low Confidence Identification or No Identification Result should be manually prepared using the Bruker's extended Direct Transfer Procedure (eDT), Extraction (Ext) Procedure and/or an alternative method of organism identification.

Reproducibility Study identification results of the Colibrí System obtained with the bioMérieux VITEK MS

Test strain	Total no. of picked colonies	Correct Single Choice (≥60% Confidence value)	Low discrimination (<60% Confidence value)	No ID	Wrong ID	% agreement* between Colibrí and expected ID
Gram-positive						
Enterococcus faecalis	180	180	0	0	0	100.0%
Staphylococcus aureus	180	180	0	0	0	100.0%
Staphylococcus epidermidis	180	180	0	0	0	100.0%
Staphylococcus saprophyticus	180	180	0	0	0	100.0%
Streptococcus agalactiae	180	179	0	1	0	99.4%
Total Gram-positive	**900**	**899**	**0**	**1**	**0**	**99.9%**
Gram-negative						
*Enterobacter cloacae**	180	0	180[a]	0	0	100.0%
Escherichia coli	180	180	0	0	0	100.0%
Klebsiella pneumoniae	180	180	0	0	0	100.0%
Proteus mirabilis	180	180	0	0	0	100.0%
Pseudomonas aeruginosa	180	180	0	0	0	100.0%
Total Gram-negative	**900**	**720**	**180 [a]**	**0**	**0**	**100.0%**
Total	**1800**	**1619**	**180 [a]**	**1**	**0**	**99.9% [a]**

[a]According to VITEK MS instrument, *Enterobacter cloacae* identifications are considered as a slashline result, *Enterobacter cloacae/ Enterobacter asburiae* (50%/50%). Therefore, the Low discrimination results for this strain are included in the Agreement calculation.

*Calculated as $\frac{No.\ of\ correct\ results\ with\ Good\ Confidence\ value\ (\geq 60\%)}{Total\ number\ of\ picked\ colonies} x100$

Reproducibility Study identification results of the Colibrí System obtained with the Bruker MALDI Biotyper CA System

Test strain	Total no. of picked colonies	High confidence ID Log (Score)≥2	Low confidence ID1.7≤ Log (Score)<2	Combined performance	No ID	Wrong ID	% agreement* between Colibrí and expected ID
Gram-positive							
Enterococcus faecalis	180	139	40	179	1	0	77.2%
Staphylococcus aureus	180	159	21	180	0	0	88.3%
Staphylococcus epidermidis	180	129	42	171	9	0	71.7%
Staphylococcus saprophyticus	180	143	26	169	11	0	79.4%
Streptococcus agalactiae	180	120	50	170	10	0	66.7%
Total Gram-positive	**900**	**690**	**179**	**869**	**31**	**0**	**76.7%**
Gram-negative							
Enterobacter cloacae	180	180	0	180	0	0	100.0%
Escherichia coli	180	178	1	179	1	0	98.9%
Klebsiella pneumoniae	180	180	0	180	0	0	100.0%
Proteus mirabilis	180	180	0	180	0	0	100.0%
Pseudomonas aeruginosa	180	177	0	177	3	0	98.3%
Total Gram-negative	**900**	**895**	**1**	**896**	**4**	**0**	**99.4%**
Total	**1800**	**1585**	**180**	**1765**	**35**	**0**	**88.1%**

*Calculated as $\frac{No.\ of\ correct\ results\ with\ High\ Confidence\ Log(Score)\geq 2}{Total\ number\ of\ picked\ colonies} x100$

Cross-Contamination Studies

Cross-Contamination Study was performed to demonstrate that the use of the Colibrí System does not cause false-positive results due to contamination of adjacent spots on the target slide. Alternating culture media showing isolated colonies of "on-panel" and "off-panel" Gram-positive and Gram-negative strains have been used to prepare the VITEK MS-DS and Bruker MALDI Biotyper CA System targets using the Copan Colibrí System as sample preparator.
For the bioMérieux VITEK MS, the study was conducted by one operator on one Colibrí System for a total of 572 spots. 99.3% of colonies from "on-panel species" produced the expected result

without false identifications. None of the "off-panel" organisms yielded an identification. For the Bruker MALDI Biotyper CA System, the study was conducted by one operator on two Colibrí Systems, one configured for the processing of the US IVD 48 Spot target (48 positions reusable steel target) and the other for the MBT Biotarget 96 US IVD (96 positions disposable targets) for a total of 686 spots. For "on-panel" species spotted on US IVD 48 Spot, 95% of organisms produced the expected result. For "on-panel" species spotted on MBT Biotarget 96 US IVD, 85.3% of organisms produced the expected result: nevertheless, the result is considered acceptable because the lack of identification is not due to the cross-contamination but to the limited ability of Colibrí System to provide High Confidence results for Gram-positive organisms. None of the "off-panel" organisms yielded an identification. This is consistent with observations in other analytical studies using the Colibrí System in conjunction with the Bruker MALDI Biotyper CA to identify Gram-positive organisms and is mitigated by the requirement for additional testing that is noted in the device labeling.

Cross-Contamination identification results of the Colibrí System obtained with the bioMérieux VITEK MS for "on-panel" species

Test strain	Total no. of spots	Correct Single Choice (≥60% Confidence value)	Low discrimination (<60% Confidence value)	No ID	Wrong ID	% colonies providing expected result*
Gram-positive						
Enterococcus faecalis	46	46	0	0	0	
Staphylococcus aureus	48	48	0	0	0	
Streptococcus agalactiae	48	46	0	2	0	
Total Gram positive	**142**	**140**	**0**	**2**	**0**	**98.6%**
Gram-negative						
Escherichia coli	48	48	0	0	0	
Klebsiella pneumoniae	48	48	0	0	0	
Pseudomonas aeruginosa	48	48	0	0	0	
Total Gram negative	**144**	**144**	**0**	**0**	**0**	**100%**
Total	**286**	**284**	**0**	**2**	**0**	**99.3%**

*Calculated as $\frac{No.of\ correct\ results\ with\ Confidence\ Value\ \geq 60}{Total\ number\ of\ picked\ colonies} x100$

Traditional 510(k) Premarket Notification for Copan WASP Colibrí
510(K) SUMMARY

Cross-Contamination identification results of the Colibrí System obtained with the bioMérieux VITEK MS for "off-panel" species

Test strain	Total no. of spots	Correct Single Choice (≥60% Confidence value)	Low discrimination (<60% Confidence value)	No ID	Wrong ID	% colonies providing expected result*
Aneurinibacillus migulanus	48	0	0	48	0	
Leuconostoc carnosum	48	0	0	48	0	
Rothia amarae	46	0	0	46	0	
Acidovorax delafieldii	48	0	0	48	0	
Burkholderia thailandensis	48	0	0	48	0	
Pseudocitrobacter faecalis	48	0	0	48	0	
Total	**286**	**0**	**0**	**286**	**0**	**100%**

*Calculated as $\frac{No.\ of\ No\ Identification\ Results}{Total\ number\ of\ picked\ colonies} x100$

Cross-Contamination identification results of the Colibrí System obtained with the Bruker MALDI Biotyper CA on US IVD 48 Spot target for "on-panel" species

Test strain	Total no. of spots	High confidence ID Log (Score)≥2	Low confidence ID 1.7≤ Log (Score)<2	Combined performance	No ID	Wrong ID	% colonies providing expected result*
Gram-positive							
Enterococcus faecalis	24	19	5	24	0	0	
Staphylococcus aureus	48	48	0	48	0	0	
Streptococcus agalactiae	24	20	4	24	0	0	
Total Gram-positive	**96**	**87**	**9**	**96**	**0**	**0**	**90.6%**
Gram-negative							
Acinobacter baumannii	24	23	1	24	0	0	
Escherichia coli	56	56	0	56	0	0	
Klebsiella pneumoniae	24	24	0	24	0	0	
Total Gram-negative	**104**	**103**	**1**	**104**	**0**	**0**	**99.0%**
Total	**200**	**190**	**10**	**200**	**0**	**0**	**95.0%**

**Calculated as $\frac{No.\ of\ correct\ results\ with\ High\ Confidence\ Log(Score)\geq 2}{Total\ number\ of\ picked\ colonies} x100$

Cross-Contamination identification results of the Colibrí System obtained with the Bruker MALDI Biotyper CA on US IVD 48 Spot target for "off-panel" species

Test strain	Total no. of spots	High confidence ID Log (Score)≥2	Low confidence ID 1.7≤ Log (Score)<2	Combined performance	No ID	Wrong ID	% colonies providing expected result*
Bacillus flexus	48	0	0	0	48	0	
Bacillus infantis	24	0	0	0	24	0	
Bacillus licheniformis	24	0	0	0	24	0	
Cedecea neteri	56	0	0	0	56	0	
Gallibacterium anatis	24	0	0	0	24	0	
Novosphingobium capsulatum	24	0	0	0	24	0	
Total	**200**	**0**	**0**	**0**	**200**	**0**	**100%**

*Calculated as $\frac{No.\ of\ No\ Identification\ results}{Total\ number\ of\ picked\ colonies} x100$

Cross-Contamination identification results of the Colibrí System obtained with the Bruker MALDI Biotyper CA on MBT Biotarget 96 US IVD for "on-panel" species

Test strain	Total no. of spots	High confidence ID Log (Score)≥2	Low confidence ID 1.7≤ Log (Score)<2	Combined performance	No ID	Wrong ID	% colonies providing expected result*
Gram-positive							
Enterococcus faecalis	24	20	1	21	3	0	
Staphylococcus aureus	24	22	2	24	0	0	
Streptococcus agalactiae	23	10	8	18	5	0	
Total Gram-positive	**71**	**52**	**11**	**63**	**8**	**0**	**73.2%**
Gram-negative							
Acinobacter baumannii	24	23	0	23	1	0	
Escherichia coli	24	24	0	24	0	0	
Klebsiella pneumoniae	24	23	0	23	1	0	
Total Gram-negative	**72**	**70**	**0**	**70**	**2**	**0**	**97.2%**
Total	**143**	**122**	**11**	**133**	**10**	**0**	**85.3%**

*Calculated as $\frac{No.\ of\ correct\ results\ with\ High\ Confidence\ Log(Score)\geq 2}{Total\ number\ of\ picked\ colonies} x100$

Cross-Contamination identification results of the Colibrí System obtained with the Bruker MALDI Biotyper CA on MBT Biotarget 96 US IVD for "off-panel" species

Test strain	Total no. of spots	High confidence ID Log (Score)≥2	Low confidence ID 1.7≤ Log (Score)<2	Combined performance	No ID	Wrong ID	% colonies providing expected result*
Bacillus flexus	24	0	0	0	24	0	
Bacillus infantis	24	0	0	0	24	0	
Bacillus licheniformis	23	0	0	0	23	0	
Cedecea neteri	24	0	0	0	24	0	
Gallibacterium anatis	24	0	0	0	24	0	
Novosphingobium capsulatum	24	0	0	0	24	0	
Total	**143**	**0**	**0**	**0**	**143**	**0**	**100%**

*Calculated as $\frac{No.\ of\ No\ Identification\ results}{Total\ number\ of\ picked\ colonies} x100$

Colony Stability Study

Colony Stability Study was performed to demonstrate the ability of the Colibrí System to prepare target slides from cultures of different ages. Isolated colonies of "on-panel" and Gram-positive and Gram-negative strains have been grown on different culture plates incubated at different incubation times including the lower and the upper incubation time specified in the labeling for the two IVD analyzers. The study conducted in conjunction with the Bruker MALDI Biotyper CA System was performed on plates incubated at the minimum and at maximum incubation time with additional of 12 hours post incubation time at room temperature. For both IVD analyzers the study was conducted by one operator on one Colibrí System.

For the bioMérieux VITEK MS, a total of 576 spots were prepared, and 99.8% of samples produced the expected identification at each time point for all agar media plates under evaluation. No false identification result was provided.

For the Bruker MALDI Biotyper CA System, a total of 1440 spots were prepared: a general good agreement with the expected results for Gram-negative species (i.e., the expected organism identity was reported with a High Confidence Log(Score) value) was found, irrespective of the culture medium or duration of incubation, whereas lower agreement was observed with Gram-positive species. Nevertheless, no incorrect identification results were reported for any of the isolates included in the study and therefore colony age was not shown to affect the accuracy organism identification. For Bordetella pertussis on Bordet Gengou Agar, holding cultures at ambient temperature for 12 hours after incubation for 7 days at 35 ± 2°C resulted in a decrease in the proportion of High Confidence Log(scores) obtained. This is noted in the device labeling.

Colony Stability identification results of the Colibrí System obtained with the bioMérieux VITEK MS

Culture Medium	N° spot per culture medium	Culture Medium incubation time	ID % Agreement at each Culture Medium incubation time*
Columbia Agar + 5% sheep blood	192	18 h	100%
		24h	100%
		48 h	100%
		72 h	100%
MacConkey Agar	144	18 h	100%
		24 h	100%
		72 h	100%
Trypticase Soy Agar + 5% sheep blood	144	18 h	100%
		24 h	100%
		72 h	97.9%
Chocolate Agar	96	18 h	100%
		48 h	100%

*Calculated as $\frac{No.\ of\ correct\ results\ with\ Good\ Confidence\ value\ (\geq 60\%)}{Total\ number\ of\ picked\ colonies} x100$

Colony Stability identification results of the Colibrí System obtained with the MALDI Biotyper CA on MBT Biotarget 96 US IVD for "on-panel" species

Culture Medium	N° spot per culture medium	Culture Medium incubation time	ID % Agreement at different incubation times*	ID % Agreement at Culture Medium different incubation time + 12h post-incubation at RT*
Columbia Agar + 5% sheep blood	288	18 h	93.8%	95.8%
		24 h	91.7%	93.8%
		48 h	87.5%	89.6%
MacConkey Agar	288	18 h	97.9%	100%
		24 h	100%	95.8%
		48 h	100%	100%
Trypticase Soy Agar + 5% sheep blood	288	18 h	79.2%	79.2%
		24 h	83.3%	83.3%
		48 h	87.5%	91.7%
Chocolate Agar	192	18 h	100%	100%

Culture Medium	N° spot per culture medium	Culture Medium incubation time	ID % Agreement at different incubation times*	ID % Agreement at Culture Medium different incubation time + 12h post-incubation at RT*
		48 h	100%	93.8%
Columbia Agar + 5% sheep blood supplemented of colistin and nalidixic acid	192	18 h	87.5%	91.7%
		48 h	87.5%	85.4%
Bordet Gengou + 15% sheep blood	192	5 days	100%	100%
		7 days	97.9%	68.7%

*Calculated as $\frac{No.\ of\ correct\ results\ with\ High\ Confidence\ Log(Score) \geq 2}{Total\ number\ of\ picked\ colonies} x100$

Spot Stability Prior To and After Matrix Deposition

The spot stability prior to and after matrix application study was performed evaluate the stability of spots prepared by the Copan Colibrí System before matrix application and the stability of target spots before MALDI-TOF MS analysis. Spot stability was evaluated comparing the identification performance between the Standard Deposition Mode (SDM – application of matrix immediately after the colony spotting) and the Delayed Deposition Mode (DDM - matrix application after 60 minutes after the colony spotting) and when testing was delayed for 24-, 48- or 72-hours following matrix deposition. Target stability was investigated by holding the target at room temperature in ambient air or on the deck of the Colibrí Preparation Station for the maximum incubation time indicated by the respective MALDI-TOF MS analyzer before analysis. For each condition, a complete target was spotted randomly alternating Gram-positive and Gram-negative colonies grown on Trypticase Soy Agar + 5% sheep blood.
For Bruker MALDI Biotyper CA System the evaluation was performed for both validated targets, MBT Biotarget 96 US IVD (96 positions disposable targets) and US IVD 48 Spot target (48 positions reusable steel target).
For the bioMérieux VITEK MS, the colonies spotted by Colibrí System are stable up to 60 minutes without matrix and, after preparation, targets can be stored for 48h at room temperature when held on the Colibrí deck and for 72 h when held in the original box, since the identification performance is not different to the performance in standard conditions.

For MALDI Biotyper CA System identification results show that colonies spotted by Colibrí System on MBT Biotarget 96 US IVD and US IVD 48 Spot targets are stable up to 60 minutes without matrix and for 24h at room temperature after matrix addition when held both on the Colibrí deck and on the Lab bench. Lower agreement with the expected results was observed with Gram-positive species using the 96-spot disposable target format, which is noted in the device labeling.

The Copan Colibrí device labeling recommends that prepared targets are tested within 24 hours for the Bruker MALDI Biotyper CA and within 48 hours for the bioMérieux VITEK MS.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the Colibrí System, consisting of the Vision System and Preparation Station. The system complies with the IEC 61010-1: 2010, IEC 61010-2-081: 2015, IEC 61010-2-101: 2015 standards for safety and the IEC 61326-1: 2012, IEC 61326-2-6: 2012 and IEC 60601-1-2:2014 standards for EMC; test reports are included.

Laser Product

The Colibrí System complies with the IEC 60825-1: 2007 standard; test report is included.

Software Verification and Validation Testing

Software verification and validation testing were conducted according to the internal Standard Operative Procedure in agreement with IEC 62304 Edition 1.1 2015-06 Consolidate version. Documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005. The software for the Device was considered as a "Moderate" level of concern, since a failure or latent design flaw could directly or indirectly through incorrect or delayed information or through the action of a care provider result in minor injury to the patient or operator.

Usability Validation

Usability has been addressed for Colibrí System following recommendations in the "Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016)" and in agreement with "IEC 62366-1:2015-02 Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices [Including CORRIGENDUM 1 (2016)]".

The results of usability validation provided evidence that all the measurements implemented to prevent use errors, regarding the device design, labeling and training, are effective and the device can be used in a safe and effective way, establishing that all the risks included in the Risk Analysis have been mitigated and there are no Unacceptable residual risks.

VIII NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY & CONCLUSIONS

Conclusions:

All the necessary safety tests were performed and documented. We have verified and validated that

the Copan Colibrí System meets its functional specifications and performance requirements, and complies with applicable international standards IEC 61010-1, IEC 6010-2:101, IEC 61010-2:081, IEC 60825-1, IEC 61326-1, IEC 61326-2:6, IEC 60601-1-2:2014, CLSI M58, IEC 62304 and IEC 62366-1.

The analytical study results demonstrated that the Colibrí System when used in conjunction with its parental device is as safe, as effective, and performs as well as the predicate device. The minor differences between the devices do not adversely affect safety and effectiveness. The used methodology (direct colony suspension) and claimed prerequisites for sample preparation are in line with the IVD analyzer manufacturer IFU and with the relevant CLSI M58 guideline (Methods for the Identification of Cultured Microorganisms Using Matrix-Assisted Laser Desorption/Ionization Time-of-Flight Mass Spectrometry).