December 27, 2023

Copan WASP S.r.l.
Chiara Congiu
Regulatory Affairs Manager
Via A. Grandi, 32
Brescia, Brescia 25125
Italy

Re: K232756
Trade/Device Name: Colibrí
Regulation Number: 21 CFR 866.1645
Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System
Regulatory Class: Class II
Product Code: LON, QQV, QBN
Dated: September 8, 2023
Received: September 8, 2023

Dear Chiara Congiu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

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

Sincerely,

Ribhi Shawar -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K232756

Device Name
Colibrí

Indications for Use *(Describe)*
The Colibrí is an automated in vitro diagnostic specimen preparation system for use with WASPLab to prepare MALDI-TOF targets for the bioMérieux VITEK MS systems or Bruker MALDI Biotyper CA mass spectrometry systems for qualitative identification and microbial suspension for the bioMérieux VITEK 2 systems or Beckman Coulter MicroScan WalkAway Antimicrobial Susceptibility Testing (AST) systems for qualitative testing of isolated colonies of gram-negative and gram-positive bacterial species grown on solid culture media.
The Colibrí is an 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 for bacterial identification and microbial suspension at known concentration for Antimicrobial Susceptibility Testing and purity assessment.
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.
Bacterial suspensions for AST and purity plates are identified by barcode label.
The Colibrí 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 has not been validated for use in the identification or processing of yeast species, molds, Nocardia, or mycobacteria.

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.

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	Chiara Congiu Copan WASP Srl Via A. Grandi 32 25125 Brescia, Italy +39 338 6904942 copan.regulatory@copangroup.com
Establishment Registration Number:	3009288740
Date Prepared:	September 08, 2023

II. Device Name

Proprietary Name	Colibrí
Common/Usual Name	Colibrí
Classification Name	Clinical mass spectrometry microorganism identification and differentiation system (21 CFR 866.3378) Fully automated short-term incubation cycle antimicrobial susceptibility system (21 CFR 866.1645)
Device Class	II
Product Code	QQV, QBN, LON
Panel	Microbiology

Copan WASP Colibrí™ - 510(k) Summary

III. Legally Marketed Predicate Device

Device Name	Colibrí
510(K) Number	K223245

No reference Devices were used in this submission.

IV. Device Description

The Colibrí is an instrument which automates the picking of selected colonies from plated media and prepares MALDI target slides for the bioMérieux VITEK MS systems or the Bruker MALDI Biotyper CA systems 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 Colibrí automates the preparation of microbial suspensions at known concentration for bioMérieux VITEK 2 systems and Beckman Coulter MicroScan WalkAway systems that are used in clinical laboratories for AST analyses. Moreover, the Colibrí is used for Purity Plates preparation for purity assessments.

The Colibrí includes the following components:

- Colibrí instrument and software with on-board pipetting system and nephelometer
- Colibrí Primary Tubes
- Colibrí Spreader
- Colibrí Daily Verification kit.

Colibri is designed to be used in conjunction with the WASPLab device for culture plate incubation and image analysis. After appropriate plate incubation, the operator selects the colonies from a digital image of culture media plate streaked with microbiological human specimen, available through WebApp software, the WASPLab User Interface.

The operator assigns the automatic ID or AST tasks to the isolated colonies to be processed. Then, the operator loads the plates in the Colibrí where colonies are automatically picked, spotted on the target slide and overlayed with the matrix or suspended into the dedicated solution for the preparation of the microbial suspension for AST purposes (Secondary Tube).

When used in conjunction with the bioMérieux VITEK MS systems, the Colibrí 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 systems, the Colibrí 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.

When used in conjunction with the bioMérieux VITEK 2 systems or the Beckman Coulter MicroScan WalkAway systems, the Colibrí can prepare the microbial suspension at the proper concentration by direct colony suspension method. The onboard nephelometer allows the preparation of Secondary Tubes (AST suspensions) at the correct concentration and the Colibrí Spreader is used for Purity Plates preparation.

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.

The traceability of prepared Secondary Tube and Purity Plates is maintained by dedicated labels applications.

Colibrí requires four different calibrations, one on the nephelometer, three on the cameras. 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. The Set-up calibration of nephelometer and camera units are performed during the device initial setup. Auto-calibration is performed at the end of the initial set-up and periodically during the preventive maintenance to check that all the mechanical references can be found inside the positioning tolerances, that the I/Os are responsive. Runtime calibration is performed during the normal usage to automatically check the proper functioning of the Colibrí.

Colibrí requires a daily nephelometer verification to check the proper reading of suspensions at different turbidity values.

V. Intended Use / Indications For Use

The Colibrí is an automated in vitro diagnostic specimen preparation system for use with WASPLab to prepare MALDI-TOF targets for the bioMérieux VITEK MS systems or Bruker MALDI Biotyper CA mass spectrometry systems for qualitative identification and microbial suspension for the bioMérieux VITEK 2 systems or Beckman Coulter MicroScan WalkAway Antimicrobial Susceptibility Testing (AST) systems for qualitative testing of isolated colonies of gram-negative and gram-positive bacterial species grown on solid culture media.

The Colibrí is an 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 for bacterial identification and microbial suspension at known concentration for Antimicrobial Susceptibility Testing and purity assessment.

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.

Bacterial suspensions for AST and purity plates are identified by barcode label.

Copan WASP Colibrí™ - 510(k) Summary

The Colibrí 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 has not been validated for use in the identification or processing of yeast species, molds, Nocardia, or mycobacteria.

VI. Comparison to Predicate

According to its intended use, Colibrí supports the performance of the connected IVD Analyzers by facilitating sample preparation for Gram-Negative and Gram-Positive bacteria ID or AST according to their intended use.

This submission aims to demonstrate the suitability of AST microbial suspensions prepared by Colibrí for processing with MicroScan WalkAway analyzers.

Similarities		
Item	**New Device**	**Predicate Device**
Device Name (K number)	**Colibrí**	**Colibrí (K223245)**
Device Classification	Class II (special controls)	Class II (special controls)
Regulation Number	21 CFR 866.3378 and 21 CFR 866.1645	21 CFR 866.3378 and 21 CFR 866.1645
Product Code	QQV, Automated System For Sample Preparation And Identification Of Microorganisms From Cultured Isolates By Mass Spectrometry QBN, Mass Spectrometry, Maldi Tof, Microorganism Identification, Cultured Isolates LON, System, Test, Automated, Antimicrobial Susceptibility, Short Incubation	QQV, Automated System For Sample Preparation And Identification Of Microorganisms From Cultured Isolates By Mass Spectrometry QBN, Mass Spectrometry, Maldi Tof, Microorganism Identification, Cultured Isolates LON, System, Test, Automated, Antimicrobial Susceptibility, Short Incubation
Indications for Use	The Colibrí is an automated in vitro diagnostic specimen preparation system for use with WASPLab to prepare MALDI-TOF targets for the bioMérieux VITEK MS systems or Bruker MALDI Biotyper CA mass spectrometry systems for qualitative identification and microbial suspension for the bioMérieux VITEK 2 systems or Beckman Coulter MicroScan WalkAway Antimicrobial Susceptibility Testing (AST) systems for qualitative testing of isolated colonies of gram-negative and gram-positive bacterial species grown on solid culture media. The Colibrí is an 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 for bacterial identification and microbial suspension at known concentration for Antimicrobial Susceptibility Testing and purity assessment. 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. Bacterial suspensions for AST and purity plates are identified by barcode label. The Colibrí is intended for use by trained healthcare professionals in clinical laboratories	The Colibrí™ is an automated in vitro diagnostic specimen preparation system for use with WASPLab® to prepare MALDI-TOF targets for the bioMérieux VITEK® MS or Bruker MALDI Biotyper® CA mass spectrometry systems for qualitative identification and microbial suspension for the bioMérieux VITEK® 2 Antimicrobial Susceptibility Testing (AST) system for qualitative testing of isolated colonies of gram-negative and gram-positive bacterial species grown on solid culture media. The Colibrí™ is an 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 for bacterial identification and microbial suspension at known concentration for Antimicrobial Susceptibility Testing and purity assessment. 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. Bacterial suspensions for AST and purity plates are identified by barcode label. The Colibrí™ is intended for use by trained healthcare professionals in clinical laboratories in conjunction with other clinical and laboratory

Copan WASP Colibrí™ - 510(k) Summary

Similarities		
Item	**New Device**	**Predicate Device**
Device Name (K number)	**Colibrí**	**Colibrí (K223245)**
	in conjunction with other clinical and laboratory findings, including Gram staining, to aid in the diagnosis of bacterial infections. The Colibrí has not been validated for use in the identification or processing of yeast species, molds, Nocardia, or mycobacteria.	findings, including Gram staining, to aid in the diagnosis of bacterial infections. The Colibrí™ has not been validated for use in the identification or processing of yeast species, molds, Nocardia, or mycobacteria.
Method of testing	Direct testing from isolated colonies for ID purposes in conjunction with bioMérieux VITEK MS systems or Bruker MALDI Biotyper CA systems. Direct testing from isolated colonies for AST purposes in conjunction with bioMérieux VITEK 2 systems or Beckman Coulter MicroScan WalkAway systems.	Direct testing from isolated colonies for ID purposes in conjunction with bioMérieux VITEK MS systems or Bruker MALDI Biotyper CA systems. Direct testing from isolated colonies for AST purposes in conjunction with bioMérieux VITEK 2 systems.
Sample/Media Type	Isolated bacterial colonies from any patient source grown on plates included in K193138, K220546 and K223245.	Same
Plate management	Automatic image capturing management and manual loading into instrument for picking activities.	Same
Colonies selection	The colony to be picked is selected by an operator on a digital plate using a Graphical User Interface on a dedicated workstation.	Same
Method of Colony Picking	Automatic picking of colonies using pipette tips.	Same
ID Target preparation	When connected with VITEK MS systems, a portion of microbial colony from an agar plate is automatically spotted on a VITEK MS-DS target slide (VITEK MS DS Target Slides, 48 positions disposable plastic targets) by using the pipetting system. 1µL of matrix is automatically applied to the spot using the pipetting system. The dried target slide is then manually loaded into the VITEK MS system. When connected with MALDI Biotyper CA systems, a portion of microbial colony from an agar plate is automatically spotted on a Bruker Target Plate (IVD 48 Spot Target plate or MBT Biotarget 96 US IVD) by using the pipetting system. 1µL of matrix is automatically applied to the spot using the pipetting system. The dried target slide is then manually loaded into the MALDI Biotyper CA systems.	Same
AST Suspension Preparation for VITEK 2	Using a pipetting system, a predefined number of morphologically similar colonies are transferred into Primary Tube containing saline solution (0.45% NaCl Saline Solution pH 4.5 to 7.0). A homogenous heavy suspension of organisms is prepared and checked by using onboard Colibrí nephelometer. In the Secondary Tube containing 3.0mL of the same saline solution, a variable aliquot of the heavy suspension is automatically transferred to obtain the final microbial concentration according to IVD package insert indications. The suspensions prepared by Colibrí must be tested in MANUAL MODE on the VITEK 2 systems.	Same
Calibration	Colibrí requires four different calibrations, one on the nephelometer, three on the cameras.	Same

Similarities		
Item	**New Device**	**Predicate Device**
Device Name (K number)	**Colibrí**	**Colibrí (K223245)**
	None of these calibration activities require user intervention.	
Preparatory activities	Nephelometer verification by check using Daily verification Kit.	Same
Quality control	Completely dependent on next-step IVD analyzers.	Same

Differences		
Item	**New Device**	**Predicate Device**
Device Name (K number)	**Colibrí**	**Colibrí (K223245)**
AST Suspension Preparation for Beckman Coulter MicroScan WalkAway	Using a pipetting system, a predefined number of morphologically similar colonies are transferred into Primary Tube containing water or saline solution (0.9% NaCl). A homogenous heavy suspension of organisms is prepared and checked by using an on-board Colibrí nephelometer. In the Secondary Tube containing 25 ml of MicroScan Inoculum Water with PLURONIC or 25 ml of Mueller-Hinton Broth with 3% lysed horse blood, a variable aliquot of the heavy suspension is automatically transferred to obtain the final microbial concentration according to IVD package insert indications. The suspension prepared by Colibrí must be used to rehydrate MicroScan AST panels.	Not present

These differences do not affect substantial equivalence of Colibrí and the Predicate Device.

VII. Performance Data

The performance studies which demonstrate the ability of the predicate device Colibrí to prepare MALDI-TOF targets and microbial suspensions for VITEK 2 have been conducted under K193138, K220546 and K223245.

Please, refer to the Decision Summary for K193138 for the following performance studies on the MALDI-TOF targets preparation:

- Precision/Reproducibility
- Colony Picking Accuracy
- Accuracy of Bacterial Identification
- Positional Accuracy
- Carry-Over
- Colony Stability
- Spot Stability

Please, refer to the Decision Summary for K220546 for the following performance studies on the microbial suspension preparation for AST:

- Precision/Reproducibility of results for VITEK 2
- Colony Picking Accuracy

Copan WASP Colibrí™ - 510(k) Summary

- Microbial Suspension Accuracy for VITEK 2
- Accuracy of AST Results for VITEK 2
- Carry-Over
- Pipettor Trueness and Precision
- Accuracy of the Onboard Nephelometer
- *E. coli* Suspensions Preparation Verification Study
- Purity Plate Growth
- Reagent Hold Time

Please, refer to the Decision Summary for K223245 for the validation of the full workflow of Colibri in conjunction with the WASPLab.

Analytical Studies

The Analytical studies performed with the Colibrí support its use for the preparation of microbial suspension used in conjunction with the MicroScan WalkAway AST analyzer. The Analytical studies demonstrated that microbial suspensions prepared from isolated colonies by the Colibrí can be used to hydrate MicroScan panels for the determination of susceptibility of organisms to certain drugs included on the panels. The used methodology (direct colony suspension) and claimed prerequisites for sample preparation are in line with the IVD analyzer manufacturer IFU.

Preparation of Microbial Suspensions for AST

The accuracy of the inoculum density in the Secondary Tubes was determined by viable cell count of the microbial suspensions prepared by three Colibrí instruments and compared to the acceptance range 3-7 x 10^5 CFU/mL for *E. coli* ATCC 25922[1] and 2-8 x 10^5 CFU/mL[2] for other bacteria.

The percentage of prepared suspension with microbial concentration within the acceptable limits was 98.5% and has been compared between instruments with χ^2-test, resulting in no statistically significant difference among the instruments (p-value = 0.34). The results provided evidence that the microbial concentration of AST suspensions prepared by Colibrí is accurate.

Table 1: Percentage suspensions with acceptable microbial concentration, stratified per microorganism and instrument

Microorganism	Avg. Calculated concentration (CFU/mL)	Expected concentration (CFU/mL)	Colibrí #1	Colibrí #2	Colibrí #3	Overall
Escherichia coli	4.8 x 10^5	3-7 x 10^5	12/12	12/12	12/12	36/36 (100%)

1 Guidance for Industry and FDA - Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems

2 CLSI guideline - M07 Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically, 11th Edition

Microorganism	Avg. Calculated concentration (CFU/mL)	Expected concentration (CFU/mL)	Colibrí #1	Colibrí #2	Colibrí #3	Overall
Pseudomonas aeruginosa	2.9 x 10^5	2-8 x 10^5	10/10	9/10	10/10	29/30 (96.7%)
Staphylococcus aureus	5.7 x 10^5	2-8 x 10^5	13/14	14/14	14/14	41/42 (97.6%)
Enterococcus faecalis	4.2 x 10^5	2-8 x 10^5	10/10	10/10	10/10	30/30 (100%)
Total	*4.5 x 10^5*	*2-8 x 10^5*	*43/44 (97.7%)*	*43/44 (97.7%)*	*44/44 (100%)*	*130/132 (98.5%)*

AST Challenge Test

The accuracy of MICs obtained by MicroScan WalkAway with microbial suspensions prepared by Colibrí from isolated colonies was evaluated using representative isolates of different species of *Enterobacterales* (n=50), *Staphylococcus* (n=20), *Streptococcus* (n=12), *Enterococcus* (n=18) and non-fermenters (n=10). The strains included in this study were both susceptible and resistant strains, exhibiting a range of on-scale MIC values toward at least 4 antibiotics representative for the major classes of drugs. Each strain was grown on Trypticase Soy Agar + 5% Sheep Blood or MacConkey Agar (only *Enterobacterales* and non-fermenters) at specific incubation times and then processed by three Colibrí operated by three different technicians. Manual suspension preparation was used as comparative method.

Microbial suspensions were processed by the MicroScan WalkAway using the appropriate antibiotic panel in **Table 2**.

Table 2: MicroScan Panels Tested in AST Challenge Study

MicroScan Panel	Indicated Organisms Groups	Antimicrobial Agents
MSP6	*Streptococcus* spp.	Ampicillin Cefepime Cefotaxime Ceftriaxone Clarithromycin Clindamycin Daptomycin Erythromycin Levofloxacin Linezolid Meropenem Penicillin G Tetracycline Vancomycin

Copan WASP Colibrí™ - 510(k) Summary

MicroScan Panel	Indicated Organisms Groups	Antimicrobial Agents
NM-NF50	Enterobacterales, Non-fermenters	Amikacin Gentamicin Tobramycin Cefepime Ceftazidime Cefotaxime Meropenem Imipenem Ampicillin/Sulbactam Piperacillin/Tazobactam Ticarcillin/K Clavulanate Aztreonam Levofloxacin Ciprofloxacin Minocycline Tetracycline Trimethoprim/Sulfamethoxazole
PM-E37	*Enterococcus* spp., *Staphylococcus* spp.	Ampicillin Ciprofloxacin Clindamycin Daptomycin Erythromycin Levofloxacin Linezolid Minocycline Moxifloxacin Nitrofurantoin Penicillin G Tetracycline Tigecycline Vancomycin

The SIR category was reported according to the FDA-Recognized Antimicrobial Susceptibility Test Interpretive Criteria. Essential Agreement (EA) of the MICs and Category Agreement (CA) were calculated in comparison with the manual result. The discrepant SIR results were categorized as Very Major discrepancy (vmj), Major discrepancy (maj) and Minor discrepancy (min).

MICs obtained using Colibrí for microbial suspensions preparation showed very high agreement with the manual preparation for all the microorganisms group; overall, 1232/1232 evaluable MIC results were within 1 two-fold dilution of the reference result and 4187/4254 SIR categorizations were in agreement. The overall Essential Agreement of the evaluable MIC results was 100% and the Category Agreement was 98.4%.

Table 3: AST Challenge Study summary of results, stratified by MicroScan panel

Copan WASP Colibrí™ - 510(k) Summary

MicroScan panel	Organism Group	Total tested	# EA	% EA	Total Evaluable	# EA of Evaluable	% EA of Evaluable	Total cat.	# CA	% CA	# S	# R	# vmj	# maj	# min
NM-NF50	*Enterobacterales*	2454	2454	100%	577	577	100%	2352	2304	98.0%	1197	996	0	0	48
NM-NF50	Non-fermenters	294	294	100%	165	165	100%	291	282	96.9%	126	120	0	0	9
PM-E37	*Staphylococcus*	690	690	100%	157	157	100%	663	656	98.9%	465	159	0	0	7
PM-E37	*Enterococcus*	525	525	100%	258	258	100%	519	516	99.4%	354	102	0	0	3
MSP6	*Streptococcus*	429	429	100%	75	75	100%	429	429	100%	381	39	0	0	0

Reproducibility Study

The Reproducibility Study was performed to demonstrate consistency of AST results given by Beckman Coulter MicroScan WalkAway system on microbial suspensions prepared by different Colibrí instruments in different test days.

Culture media showing isolated colonies of 9 gram-positive and 9 gram-negative strains were processed on 3 Colibrí over 3 days to prepare microbial suspensions that were tested for purity and loaded in the appropriate antibiotic panel following the MicroScan instructions for use. Each condition was tested in triplicate for a total number of 27 replicates for each combination strain-antimicrobial agent.

The reported MIC values were used to calculate within-instrument and between-instruments reproducibility. Reproducibility was calculated as the total number of results that were within one doubling dilution of the mode result divided by total number of results. Off-scale results that were one doubling dilution from the mode were considered reproducible for best-case reproducibility calculations but considered not reproducible for worst-case calculations.

Best-case reproducibility was ≥95% and worst-case reproducibility was ≥89% for all antimicrobial agents tested across all panels with microbial suspensions prepared from isolated colonies by each instrument. The reproducibility results are acceptable.

Table 4: Summary of reproducibility results –stratified by MicroScan panel

MicroScan Panel	Colibrí	Best Case[a] (%)	Worst Case[b] (%)
MSP6	Instrument 1	117/117 (100%)	113/117 (96.6%)
	Instrument 2	117/117 (100%)	110/117 (94.0%)
	Instrument 3	117/117 (100%)	108/117 (92.3%)
	Combined	351/351 (100%)	331/351 (94.3%)
NM-NF50	Instrument 1	459/459 (100%)	453/459 (98.7%)
	Instrument 2	458/459 (99.8%)	453/459 (99.7%)
	Instrument 3	459/459 (100%)	452/459 (98.5%)
	Combined	1376/1377 (99.9%)	1358/1377 (98.6%)
PM-E37	Instrument 1	297/297 (100%)	297/297 (100%)
	Instrument 2	297/297 (100%)	295/297 (99.3%)
	Instrument 3	297/297 (100%)	297/297 (100%)

Copan WASP Colibrí™ - 510(k) Summary

MicroScan Panel	Colibrí	Best Case[a] (%)	Worst Case[b] (%)
	Combined	891/891 (100%)	889/891 (99.8%)

[a]Calculated assuming the off-scale results are within one well from the mode.
[b]Calculated assuming the off-scale results are greater than one well from the mode.

Sample preparation for Quality Control

The study was performed to demonstrate the reproducibility of MIC results for AST Quality Control organisms using the Colibrí as suspension preparator. CLSI-recommended reference strains *Escherichia coli* ATCC 25922, *Pseudomonas aeruginosa* ATCC 27853, *Staphylococcus aureus* ATCC 29213 and *Enterococcus faecalis* ATCC 29212 were grown on trypticase soy agar + 5% sheep blood.

The sample preparation for Quality Control was conducted daily at the beginning of the working session on each instrument involved in the Analytical Studies. All instruments were used to prepare bacterial suspensions then tested using the appropriate AST panel. MIC values for each drug/organism combination were compared to the established ranges reported in the MicroScan panels labeling[3][4][5], resulting in 100% acceptable MIC values. Purity of all the suspensions was confirmed by Purity Plates prepared by Colibrí. The summary of results is in the table below.

Table 5: List of QC organisms and antimicrobial agent tested

QC organism	Antimicrobial agent	QC range (CLSI M100[6])	On panel values (panel IFU)	No. MIC within QC range
Escherichia coli ATCC 25922	Amikacin	0.5 - 4	≤4 - 8	36/36 (100%)
	Ampicillin/Sulbactam	2/1 - 8/4	≤4/2	36/36 (100%)
	Aztreonam	0.06 - 0.25	≤0.5	36/36 (100%)
	Ceftazidime	0.06 - 0.5	≤1	36/36 (100%)
	Cefotaxime	0.03 - 0.12	≤4	36/36 (100%)
	Ciprofloxacin	0.004 - 0.016	≤0.12	36/36 (100%)
	Cefepime	0.016 - 0.12	≤1	36/36 (100%)
	Gentamicin	0.25 - 1	≤1 - 2	36/36 (100%)
	Imipenem	0.06 - 0.5	≤0.5	36/36 (100%)

[3] C29871-AD MicroScan Gram Positive Procedural Manual, Multi-regional PU-06 panels
[4] C29884-AB MicroScan MICroSTREP plus 6 Procedural Manual, Multi-regional
[5] C80530-AB MicroScan Gram Negative Procedural Manual, Multi-regional LabPro ≥V5.00 (11-digit biotype)
[6] CLSI guideline M100. 33rd ed Performance Standard for Antimicrobial Susceptibility Testing. Wayne, PA: Clinical and Laboratory Standards Institute, 2023.

Copan WASP Colibrí™ - 510(k) Summary

QC organism	Antimicrobial agent	QC range (CLSI M100[6])	On panel values (panel IFU)	No. MIC within QC range
	Levofloxacin	0.008 - 0.06	≤0.5	36/36 (100%)
	Meropenem	0.008 - 0.06	≤0.12	36/36 (100%)
	Minocycline	0.25 - 1	≤2	36/36 (100%)
	Piperacillin/Tazobactam	1/4 - 8/4	≤8/4	36/36 (100%)
	Tetracycline	0.5 - 2	≤2	36/36 (100%)
	Ticarcillin/K Clavulanate	4/2 - 16/2	≤16/2	36/36 (100%)
	Tobramycin	0.25 - 1	≤2	36/36 (100%)
	Trimethoprim/Sulfamethoxazole	≤0.5/9.5	≤1/19	36/36 (100%)
Staphylococcus aureus ATCC 29213	Ciprofloxacin	0.12 - 0.5	≤0.5	42/42 (100%)
	Clindamycin	0.06 - 0.25	≤0.25	42/42 (100%)
	Daptomycin	0.12 - 1	≤0.25 - 1	42/42 (100%)
	Erythromycin	0.25 - 1	≤0.25 - 1	42/42 (100%)
	Levofloxacin	0.06 - 0.5	≤1	42/42 (100%)
	Linezolid	1 - 4	≤1 - 4	42/42 (100%)
	Minocycline	0.06 - 0.5	≤1	42/42 (100%)
	Moxifloxacin	0.016 - 0.12	≤0.25	42/42 (100%)
	Nitrofurantoin	8 - 32	≤32	42/42 (100%)
	Penicillin G	0.25 - 2	0.25 - >8	42/42 (100%)
	Tetracycline	0.12 - 1	≤1	42/42 (100%)
	Tigecycline	0.03 - 0.25	≤0.25	42/42 (100%)
	Vancomycin	0.5 - 2	0.5 - 2	42/42 (100%)
Pseudomonas aeruginosa ATCC 27853	Amikacin	1 - 4	≤4 - 8	30/30 (100%)
	Aztreonam	2 - 8	2 - 8	30/30 (100%)
	Cefepime	0.5 - 4	≤1 - 4	30/30 (100%)
	Cefotaxime	8 - 32	8 - 32	30/30 (100%)
	Ceftazidime	1 - 4	≤1 - 4	30/30 (100%)
	Ciprofloxacin	0.12 - 1	≤0.12 - 1	30/30 (100%)
	Gentamicin	0.5 - 2	≤1 - 4	30/30 (100%)
	Imipenem	1 - 4	1 - 4	30/30 (100%)

QC organism	Antimicrobial agent	QC range (CLSI M100[6])	On panel values (panel IFU)	No. MIC within QC range
	Levofloxacin	0.5 - 4	≤0.5 - 4	30/30 (100%)
	Meropenem	0.12 - 1	≤0.12 - 1	30/30 (100%)
	Piperacillin/Tazobactam	1/4 - 8/4	≤8/4	30/30 (100%)
	Tetracycline	8 - 32	8 - >8	30/30 (100%)
	Ticarcillin/K Clavulanate	8/2 - 32/2	≤16/2 - 32/2	30/30 (100%)
	Tobramycin	0.25 - 1	≤2	30/30 (100%)
Enterococcus faecalis ATCC 29212	Ampicillin	0.5 - 2	≤1	30/30 (100%)
	Ciprofloxacin	0.25 - 2	≤0.5 - 1	30/30 (100%)
	Daptomycin	1 - 4	1 - 4	30/30 (100%)
	Erythromycin	1 - 4	1 - 4	30/30 (100%)
	Levofloxacin	0.25 - 2	≤1 - 2	30/30 (100%)
	Linezolid	1 - 4	≤1 - 4	30/30 (100%)
	Moxifloxacin	0.06 - 0.5	≤0.25 - 0.5	30/30 (100%)
	Nitrofurantoin	4 - 16	≤32	30/30 (100%)
	Penicillin G	1 - 4	0.5 - 2	30/30 (100%)
	Tetracycline	8 - 32	4 - >8	30/30 (100%)
	Tigecycline	0.03 - 0.12	≤0.25	30/30 (100%)
	Vancomycin	1 - 4	1 - 4	30/30 (100%)

*Due to MicroScan panel design, the full QC range was not available for all organism/drug combinations. For the drugs where the concentrations on the MicroScan panel do not cover the full CLSI/FDA-recommended QC range, the reported value was taken as an indication of acceptable QC.

Purity Plates Evaluation

All the microbial suspensions prepared during the analytical studies were tested for purity by Purity Plate preparation using Colibrí. The purity assessment was performed to demonstrate the absence of cross contamination during the preparation of Secondary Tubes and the efficiency of the on-board incinerator in sterilizing the spreader. A total of 453 Purity Plates were prepared resulting in 100% acceptable plates without evidence of growth of other organisms than the target one.

Study	Number of Purity Plates showing monomicrobial growth	Number of Purity Plates tested	Percentage of Purity Plates showing monomicrobial Growth
AST Challenge	150	150	100%
AST Reproducibility	162	162	100%
Quality Control	141	141	100%
Total	453	453	100%

VIII. Non-Clinical and/or Clinical Tests Summary & Conclusions

Conclusions:

The predicate device (existing device) and the new device both utilize the same technology for the preparation of the MALDI-TOF targets and the AST microbial suspensions.

The Analytical Studies results demonstrated that the Colibrí when used in conjunction with MicroScan WalkAway device is as safe, as effective, and performs equivalently to the predicate device. The minor differences between the devices do not adversely affect safety and effectiveness. The used methodology and claimed prerequisites for sample preparation are in line with the IVD analyzer manufacturer IFU and with the relevant CLSI guidance. Analytical study result summaries have been updated in the package insert to harmonize data presentation between the MicroScan WalkAway and bioMérieux VITEK 2 AST systems.