October 5, 2022

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

Re: K220546
Trade/Device Name: Colibrí System
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: February 18, 2022
Received: February 25, 2022

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 (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,

For: Uwe Scherf, Ph.D.
Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
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)*
K220546

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 and with 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™ 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 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™ 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 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.

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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	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:	February 18, 2022

II. Device Name

Proprietary Name	Colibrí System
Common/Usual Name	Colibrí System
Classification Name	Fully automated short-term incubation cycle antimicrobial susceptibility system (21 CFR 866. 1645) Clinical mass spectrometry microorganism identification and differentiation system (21 CFR 866.3378) [Cleared, K193138]
Device Class	II
Product Code	LON QQV, QBN [Cleared, K193138]
Panel	Microbiology

III. Legally Marketed Predicate Device

Device Name	VITEK 2 Gram Negative Imipenem & VITEK 2 Systems (PC) 5.02 Software
510(K) Number	K103752

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 MS and antimicrobial susceptibility testing (AST) analyzers automating various manual steps in the workflow for the preparation of samples for the identification of isolated colonies and for AST of isolated colonies of gram-negative and gram-positive bacterial species grown on solid culture media.

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 (ID) of organisms grown on plated media by Matrix-Assisted Laser Desorption/Ionization Time-of Flight Mass Spectrometry (MALDI-TOF MS). The Colibrí System automates the preparation of microbial suspensions at known concentration for bioMérieux VITEK 2 System that is used in clinical laboratories for AST analyses. Moreover, the Colibrí System is used for Purity Plates preparation for purity assessments.

The Colibrí System comprises the Colibrí Vision System and Colibrí Preparation Station hardware modules and pipette tips, Primary Tubes, Spreader and nephelometer Verification Kit 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 or AST 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 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, 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.

When used in conjunction with the bioMérieux VITEK 2, the Colibrí System 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 System 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 positioned on the Colibrí Vision System and on the Colibrí Preparation Station 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, 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.

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

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 and with 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 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 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 analyzer.

Bacterial suspensions for AST and Purity Plates are identified by barcode label.

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 the identification or processing of yeast species, molds, Nocardia, or mycobacteria.

VI. Comparison to Predicate

Colibrí System is designed to automatize the standard manual workflow for the preparation of microbial suspension for AST via direct colony suspension method and purity assessment decreasing the risk of cross-contamination among colonies grown on the culture plate, the risk of scratching from the media plate surface and the risk to use AST suspensions at improper concentration. Specifically, the Colibrí Vision System aids the operator in selecting single, well-isolated colonies. The Colibrí Preparation Station allows the automatic picking of the preselected colonies and their suspension into the saline solution of the Primary Tube. The Primary Tube turbidity is checked by the on-board nephelometer to assure it is in the proper working range, allowing the preparation of a Secondary Tube at a precise concentration. The Colibrí Preparation Station labels the Secondary Tube and the Purity Plate, optionally prepared, for traceability.

With reference to the sample preparation workflow for AST testing, comparison with the Predicate Device is provided in the following tables:

<table>
<tr><th colspan="3">Similarities</th></tr>
<tr><th>Item</th><th>New Device</th><th>Predicate Device</th></tr>
<tr><td>Device Name
(K number)</td><td>Colibrí System
(K220546)</td><td>VITEK 2 Gram Negative Imipenem & VITEK 2 Systems (PC) 5.02 Software
(K103752)</td></tr>
<tr><td>Device Classification</td><td>Class II (special controls)</td><td>Class II (special controls)</td></tr>
<tr><td>Regulation Number</td><td>21 CFR 866.1645 Fully automated short-term incubation cycle antimicrobial susceptibility system</td><td>21 CFR 866.1645 Fully automated short-term incubation cycle antimicrobial susceptibility system</td></tr>
<tr><td>Product Code</td><td>LON System, Test, Automated, Antimicrobial Susceptibility, Short Incubation</td><td>LON System, Test, Automated, Antimicrobial Susceptibility, Short Incubation</td></tr>
<tr><td>Indications for Use</td><td>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 and with 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 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 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 analyzer.
Bacterial suspensions for AST and Purity Plates are identified by barcode label.
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</td><td>VITEK 2 GN Imipenem is designed for antimicrobial susceptibility testing of Gram-Negative bacilli. VITEK 2 GN Imipenem is a quantitative test intended for use with the VITEK 2 and VITEK 2 Compact Systems using VITEK 2 Systems 5.02 Software as a laboratory aid in the determination of in vitro susceptibility to antimicrobial agents. Imipenem has been shown to be
active both in vitro and in clinical infections against most strains of the following microorganisms according to the FDA label for the antimicrobial.

Active in vitro and in clinical infections:
<table><tr><td>Acinetobacter spp.</td><td>Morganella morganii</td></tr><tr><td>Citrobacter spp.</td><td>Proteus vulgaris</td></tr><tr><td>Enterobacter aerogenes</td><td>Providencia rettgeri</td></tr><tr><td>Escherichia coli</td><td>Pseudomonas aeruginosa</td></tr><tr><td>Klebsiella spp.</td><td>Serratia marcescens</td></tr></table>
Active in vitro but clinical significance unknown:
<table><tr><td>Providencia stuartii</td></tr></table>
The VITEK 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK 2</td></tr>
</table>

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

Similarities		
Item	**New Device**	**Predicate Device**
Device Name (K number)	**Colibrí System (K220546)**	**VITEK 2 Gram Negative Imipenem & VITEK 2 Systems (PC) 5.02 Software (K103752)**
	diagnosis of bacterial infections. The Colibrí System has not been validated for use in the identification or processing of yeast species, molds, Nocardia or mycobacteria.	System for the automated quantitative or qualitative susceptibility testing of isolated colonies for the most clinically significant aerobic Gram-Negative bacilli, *Staphylococcus spp., Enterococcus spp., Streptococcus agalactiae, S. pneumoniae* and clinically significant yeast. The VITEK 2 Systems (PC) 5.02 Software is intended for use with VITEK 2 and VITEK 2 Compact Systems.
Method of testing	Direct testing from isolated colonies.	Direct testing from isolated colonies.
Sample/Media Type	Isolated bacterial colonies from any patient source. Acceptable media: 1. Trypticase soy agar with 5% sheep blood 2. MacConkey agar 3. Columbia blood agar with 5% sheep blood as whole plate or bi-plate	Isolated bacterial colonies from any patient source. Acceptable media: 1. Trypticase soy agar with 5% sheep blood 2. MacConkey agar 3. Columbia blood agar with 5% sheep blood
Solution for Suspension Preparation	Aqueous 0.45% NaCl Saline Solution (pH 4.5 to 7.0) 3mL volume in the Secondary Tube	Aqueous 0.45% NaCl Saline Solution (pH 4.5 to 7.0) 3mL volume in the Secondary Tube
Inoculum density check	The accuracy of the inoculum preparation is verified by an on-boarding nephelometer.	The accuracy of the inoculum preparation is verified by a nephelometer.
Quality control	Suspension of reference strains to be used as quality control should be prepared manually according to the instruction for use of the used VITEK 2 card.	Suspension of reference strains to be used as quality control should be prepared manually according to the instruction for use of the used VITEK 2 card.
AST results interpretation	MIC and categorization of results are provided by VITEK 2.	MIC and categorization of results are provided by VITEK 2.

Differences		
Item	**New Device**	**Predicate Device**
Device Name (K number)	**Colibrí System (K220546)**	**VITEK 2 Gram Negative Imipenem & VITEK 2 Systems (PC) 5.02 Software (K103752)**
Colony Selection	The colony to be picked is selected by an operator on a digital plate using the Graphical User Interface of a Vision System.	The colony to be picked be picked is manually selected by an operator on a real plate through the visual inspection.
Media Type	Colibrí System is not validated for ChromID CPS	Acceptable media: 1. ChromID CPS
Method of Colony Picking	Colibrí System has been validated for automatic picking of colonies using a sterile pipette tip.	The colonies to be picked are manually transferred using a sterile stick or swab.
Sample Traceability	On each Secondary Tube prepared by the Colibrí System, a barcode label is applied including following data: the sample identification, the hour of the preparation and the Gram classification associated to the processed isolate. Label data are used for sample traceability for further processing on the VITEK 2.	The sample identification is recorded directly in the Cassette Docking Station software manually or scanning the barcode of the culture media plate from which the colonies were collected during the preparation of the microbial suspension.
Method of AST suspension preparation	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 on-	Using a sterile stick or swab, a sufficient number of morphologically similar colonies are transferred to a saline tube (0.45% NaCl, Saline Solution pH 4.5 to 7.0). A homogenous suspension with a density equivalent to the 0.5 McFarland is prepared and checked with the

Differences		
Item	**New Device**	**Predicate Device**
Device Name (K number)	**Colibrí System (K220546)**	**VITEK 2 Gram Negative Imipenem & VITEK 2 Systems (PC) 5.02 Software (K103752)**
	board 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 System must be tested in MANUAL MODE on the VITEK 2.	nephelometer. In a second tube containing 3.0mL of saline, a predetermined aliquot of 0.5 McFarland is transferred according to IVD package insert indications (MANUAL MODE). Alternatively, the 0.5 McFarland suspension is loaded on the VITEK 2 that automatically prepares the Secondary Tube at proper concentration (AUTO DILUTION MODE).

These differences do not affect substantial equivalence of Colibrí System and the Predicate Device. Both Systems are intended for the AST 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 Analytical studies performed with the Colibrí System support its use for the preparation of microbial suspension used in conjunction with the bioMérieux VITEK 2 AST analyzer. The Analytical studies demonstrated that the Device can automatically prepare the microbial suspensions at appropriate concentrations, starting from gram-negative and ram-positive bacterial colonies grown on solid culture media, which can be used to hydrate VITEK 2 cards for the determination of susceptibility of organisms to certain drugs. The used methodology (direct colony suspension) and claimed prerequisites for sample preparation are in line with the IVD analyzer manufacturer IFU.

Nephelometer Calibration Verification

To verify the accuracy of the onboard Colibrí System nephelometer in preparing microbial suspensions at specific concentrations within the calibration range, isolated colonies of *E. coli* (ATCC 25922) grown on non-selective medium were used to manually prepare suspensions at determined concentrations (0.25, 0.5, 1.0, 2.0, 3.0 McFarland), representing the calibration points. For each concentration, 20 suspensions were prepared from three operators in rotation, and the process was repeated on 3 Colibrí Systems calibrated with 3 different lots of suspensions at known concentrations. For each suspension, ten-fold dilutions were prepared and plated in triplicate; to perform viable cell count to calculate the initial tube concentration.

A total of 300 suspensions were prepared: overall, 100% of suspensions contained the correct concentration of bacteria considering that a 0.5 McFarland suspension of *E. coli* has a nominal microbial content of 1-2 × 10^8 CFU/mL[1]. The study demonstrated acceptable accuracy.

Pipettor Trueness and Precision

The accuracy and reproducibility of the on-board Colibrí System pipettor was determined gravimetrically. Appropriate vessels were weighted before and after the dispensations of four volumes (50µL, 100 µL, 500µL, 900µL) representing the 5%, 10%, 50% and 90% of the nominal volume of the tip used for the AST preparation. Three Colibrí System pipettors were included in the examination: for each volume, 10 measurements were performed using saline solution (aqueous 0.45%, pH 4.5 to 7.0) and the trueness and reproducibility were calculated. As expected, trueness and reproducibility vary according to the volume under testing but always within the acceptance criteria.

***E. coli* Suspensions Preparation Verification Study**

To assess the ability of the Colibrí System to prepare and manage Primary Tubes at various concentrations, isolated colonies of the *E. coli* ATCC® 25922 were used to automatically prepare Primary Tubes at various turbidities.

A variable number of colonies was selected on the plates images to create different suspensions at increasing turbidity values. Three Colibrí Systems run by three different operators were included in the test.

All the Primary Tubes were correctly managed by Colibrí System according to the turbidity value.

100% suspensions over the entire working range contained the expected number of colonies, estimated considering that the 0.5 McFarland has a nominal content of 1-2 × 10^8 CFU/mL for *E. coli*[1].

Validation of Colony Picking and Preparation of Microbial Suspensions for AST

The accuracy of colony picking and preparation of the microbial suspension was demonstrated by purity check and bacterial concentration determination of the Primary Tubes.

Three Colibrí Systems were used to prepare Primary Tubes, Secondary Tubes and the respective subculture (Purity Plate) from isolated colonies of 6 bacterial species (3 Gram-Negative and 3 Gram-Positive) grown in 2 polymicrobial mixtures on different types of culture medium in whole and bi-plates at various incubation time. To confirm nephelometer accuracy, bacterial concentration of the Primary Tube was determined by viable cell count and compared to the theorical concentration, estimated considering that the 0.5 McFarland has a nominal content of 1-2 × 10^8 CFU/mL for *E. coli*[1].

[1] CLSI guideline M07. 11th ed Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically. Wayne, PA: Clinical and Laboratory Standards Institute, 2018.

100% of colonies designated by the operator were picked correctly by the Colibrí System both on whole plates and bi-plates and 100% of Purity Plates showed no evidence of microbial contamination, demonstrating that the Colibrí System accurately picks microbial colonies, without contamination from other microorganisms grown on the same culture plate.

The percentage of prepared suspension with microbial concentration within the acceptable limits was 99.2% and, for each instrument, the result was always >98%. The percentage suspension within acceptable limits has been compared between each instrument with χ^2-test, resulting in no statistically significant difference among the instruments. The results provided evidence that the microbial concentration is accurately measured by the Colibrí nephelometer through its turbidity.

AST Challenge Test

The accuracy of MICs obtained by bioMérieux VITEK 2 using Colibrí System for microbial suspensions preparation was evaluated using representative isolates of different species of *Enterobacterales* (n=62), *Staphylococcus* (n=16), *Streptococcus* (n=30), *Enterococcus* (n=16) and non-fermenters (n=32). 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 different agar media (Trypticase Soy Agar + 5% Sheep Blood, MacConkey Agar and Columbia agar + 5% sheep blood) at specific incubation times and then processed on three Colibrí System in comparison with the manual preparation.

Microbial suspensions were prepared by Colibrí Preparation Station and processed by the bioMérieux VITEK 2 using the appropriate antibiotic panel. The MICs obtained by bioMérieux VITEK 2 using Colibrí System were compared to the MICs obtained by bioMérieux VITEK 2 using manual sample preparation and 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. The discrepant SIR results were categorized as Very Major Category Error, Major Category Error and Minor Category Error.

AST Challenge Study summary of results, antimicrobial agent

Agent	Organism group	Total tested	# EA	% EA	Total Evaluable	# EA of Evaluable	% EA of Evaluable	Total cat.	# CA	% CA	# S	# R	# vmj	# maj	# min
Amikacin	*Enterobacterales*	186	186	100%	81	81	100%	186	182	97.8%	141	39	0	0	4
	Non-fermenters	81	81	100%	39	39	100%	81	79	97.5%	66	6	0	0	2
Ampicillin	*Enterococcus*	48	48	100%	4	4	100%	48	48	100%	36	12	0	0	0
	Streptococcus	90	90	100%	0	0	N/A	90	90	100%	90	0	0	0	0
Ampicillin / Sulbactam	*Enterobacterales*	111	111	100%	9	9	100%	111	111	100%	21	90	0	0	0
	Non-fermenters	24	24	100%	5	5	100%	24	23	95.8%	15	6	0	0	1
Aztreonam	*Enterobacterales*	186	185	99.5%	54	54	100%	186	185	99.5%	57	123	0	0	1
Cefepime	*Enterobacterales*	186	186	100%	58	58	100%	186	185	99.5%	93	54	0	0	1
	Non-fermenters	81	81	100%	50	50	100%	81	80	98.8%	48	33	0	1	0
Cefotaxime	*Streptococcus*	90	90	100%	0	0	N/A	90	90	100%	90	0	0	0	0
Cefoxitin	*Enterobacterales*	186	186	100%	42	42	100%	186	184	98.9%	36	132	0	0	2
Ceftazidime	*Enterobacterales*	180	180	100%	43	43	100%	180	179	99.4%	33	132	0	0	1
	Non-fermenters	105	105	100%	68	68	100%	105	105	100%	57	36	0	0	0
Ceftriaxone	*Enterobacterales*	186	185	99.5%	31	30	96.8%	186	185	99.5%	36	144	0	0	1
	Streptococcus	90	90	100%	0	0	N/A	90	90	100%	90	0	0	0	0
Ciprofloxacin	Non-fermenters	81	81	100%	28	28	100%	81	80	98.8%	51	18	0	0	1
	Staphylococcus	48	48	100%	6	6	100%	48	48	100%	33	12	0	0	0
	Enterococcus	48	48	100%	30	30	100%	48	47	97.9%	27	12	0	0	1
Clindamycin	*Streptococcus*	90	90	100%	2	2	100%	90	89	98.9%	54	33	0	0	1
Ertapenem	*Enterobacterales*	186	186	100%	22	22	100%	186	184	98.9%	102	81	0	0	2
Erythromycin	*Staphylococcus*	48	48	100%	9	9	100%	48	47	97.9%	21	24	0	0	1
	Enterococcus	48	48	100%	15	15	100%	48	48	100%	6	30	0	0	0
	Streptococcus	90	90	100%	29	29	100%	90	90	100%	54	36	0	0	0

Traditional 510(k) Premarket Notification for Copan WASP Colibrí™

510(K) SUMMARY

Agent	Organism group	Total tested	# EA	% EA	Total Evaluable	# EA of Evaluable	% EA of Evaluable	Total cat.	# CA	% CA	# S	# R	# vmj	# maj	# min
Gentamicin	*Enterobacterales*	186	186	100%	40	40	100%	186	185	99.5%	108	66	0	0	1
	Non-fermenters	81	81	100%	27	27	100%	81	81	100%	54	21	0	0	0
	Staphylococcus	48	48	100%	6	6	100%	48	48	100%	27	21	0	0	0
Imipenem	Non-fermenters	105	104	99.0%	54	54	100%	105	105	100%	72	33	0	0	0
Levofloxacin	*Enterobacterales*	186	186	100%	47	47	100%	186	183	98.4%	69	99	0	0	3
	Non-fermenters	81	81	100%	63	63	100%	81	79	97.5%	42	27	0	0	2
	Staphylococcus	33	33	100%	14	14	100%	33	32	97.0%	27	6	0	0	1
	Enterococcus	48	48	100%	41	41	100%	48	47	97.9%	27	6	0	0	1
	Streptococcus	90	90	100%	90	90	100%	90	90	100%	87	0	0	0	0
Linezolid	*Staphylococcus*	48	48	100%	48	48	100%	48	48	100%	48	0	0	0	0
	Enterococcus	48	48	100%	48	48	100%	48	47	97.9%	45	0	0	0	1
	Streptococcus	90	90	100%	0	0	N/A	90	90	100%	90	0	0	0	0
Meropenem	*Enterobacterales*	186	186	100%	26	26	100%	186	184	98.9%	111	72	0	0	2
	Non-fermenters	105	105	100%	64	64	100%	105	105	100%	72	27	0	0	0
Moxifloxacin	*Staphylococcus*	48	48	100%	12	12	100%	48	48	100%	39	6	0	0	0
Nitrofurantoin	*Enterobacterales*	186	186	100%	134	134	100%	186	184	98.9%	51	90	0	0	2
	Staphylococcus	48	48	100%	2	2	100%	48	48	100%	48	0	0	0	0
	Enterococcus	48	48	100%	27	27	100%	48	47	97.9%	24	15	0	0	1
Oxacillin	*Staphylococcus*	48	48	100%	13	13	100%	48	48	100%	21	27	0	0	0
Penicillin (Benzyl-penicillin)	*Enterococcus*	48	48	100%	38	38	100%	48	48	100%	33	15	0	0	0
	Streptococcus	90	90	100%	25	25	100%	90	90	100%	90	0	0	0	0
	Staphylococcus	48	48	100%	11	11	100%	48	48	100%	12	36	0	0	0
Piperacillin / Tazobactam	*Enterobacterales*	177	177	100%	29	29	100%	177	176	99.4%	60	111	0	0	1
	Non-fermenters	105	105	100%	52	52	100%	105	103	98.1%	57	30	0	0	2
Quinupristin / Dalfopristin	*Staphylococcus*	48	48	100%	16	16	100%	48	48	100%	45	3	0	0	0

Traditional 510(k) Premarket Notification for Copan WASP Colibrí™

510(K) SUMMARY

Agent	Organism group	Total tested	# EA	% EA	Total Evaluable	# EA of Evaluable	% EA of Evaluable	Total cat.	# CA	% CA	# S	# R	# vmj	# maj	# min
Tetracycline	*Enterobacterales*	186	186	100%	54	54	100%	186	184	98.9%	90	87	0	0	2
	Staphylococcus	48	48	100%	7	7	100%	48	48	100%	30	18	0	0	0
	Enterococcus	48	48	100%	0	0	N/A	48	48	100%	15	33	0	0	0
	Streptococcus	42	42	100%	0	0	N/A	42	42	100%	39	3	0	0	0
Tigecycline	*Enterobacterales*	186	186	100%	104	104	100%	186	183	98.4%	144	18	0	0	3
	Staphylococcus	33	33	100%	0	0	N/A	33	33	100%	33	0	0	0	0
	Enterococcus	21	21	100%	0	0	N/A	21	21	100%	21	0	0	0	0
	Streptococcus	90	90	100%	2	2	100%	90	90	100%	90	0	0	0	0
Tobramycin	*Enterobacterales*	186	186	100%	42	42	100%	186	185	99.5%	51	108	0	0	1
	Non-fermenters	81	81	100%	1	1	100%	81	80	98.8%	57	24	0	0	1
Trimethoprim / Sulfamethoxazole	*Enterobacterales*	186	186	100%	3	3	100%	186	186	100%	63	123	0	0	0
Vancomycin	*Staphylococcus*	48	48	100%	35	35	100%	48	48	100%	45	0	0	0	0
	Enterococcus	48	48	100%	18	18	100%	48	48	100%	30	18	0	0	0
	Streptococcus	90	89	98.9%	65	65	100%	90	90	100%	90	0	0	0	0

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

AST Challenge Study summary of results, organism group

Group	Incub. time	Total tested	# EA	% EA	Total Evaluable	# EA of Evaluable	% EA of Evaluable	Total cat.	# CA	% CA	# S	# R	# vmj	# maj	# min
Enterobacterales	14 h	1383	1382	99.9%	361	361	100%	1383	1373	99.3%	561	735	0	0	10
	24 h	1689	1688	99.9%	458	457	99.8%	1689	1672	99.0%	705	834	0	0	17
Non-fermenters	14 h	420	420	100%	200	200	100%	420	416	99.0%	252	126	0	0	4
	24 h	510	509	99.8%	251	251	100%	510	504	98.8%	339	135	0	1	5
Staphylococcus	18 h	594	594	100%	179	179	100%	594	592	99.7%	429	153	0	0	2
Enterococcus	18 h	453	453	100%	221	221	100%	453	449	99.1%	264	141	0	0	4
Streptococcus	18 h	942	941	99.9%	213	213	100%	942	941	99.9%	864	72	0	0	1

MICs obtained using Colibrí System for microbial suspensions preparation showed very high agreement with the manual preparation for all the microorganisms group; overall, 1882/1883 evaluable MIC results were within one doubling dilution of the comparator method result and 5947/5991SIR categorizations were in agreement. The overall Essential Agreement of the evaluable MIC results was > 99.9% and the Category Agreement was 99.3%.

Reproducibility Study

The Reproducibility Study was performed to demonstrate consistency of AST results given by bioMérieux VITEK 2 on microbial suspensions prepared by different Colibrí Systems in different test days.

Culture media showing isolated colonies of different Gram-Positive and Gram-Negative strains were processed on three Colibrí Systems run by three operators over 3 days. Each microorganism was tested with the appropriate antibiotic panel following the analyzer's instructions for use. Each condition was tested in triplicate for a total number of 81 replicates for each combination strain-antimicrobial agent.

The MIC results were considered reproducible if they fell within one doubling dilution from the modal value of each combination strain-antimicrobial agent

The results were reproducible for each antimicrobial agent between instruments, operators and days.

Summary of reproducibility results – Gram-negatives Organisms Stratified by Antibiotic

Antibiotic	Colibrí System	Best case[a] (%)	Worst case[b] (%)
Ampicillin-Sulbactam	Instrument 1	27/27 (100%)	27/27 (100%)
	Instrument 2	27/27 (100%)	27/27 (100%)
	Instrument 3	27/27 (100%)	27/27 (100%)
	Combined	*81/81 (100%)*	*81/81 (100%)*
Piperacillin/ Tazobactam	Instrument 1	134/135 (99.3%)	133/135 (98.5%)
	Instrument 2	133/135 (98.5%)	132/135 (97.8%)
	Instrument 3	135/135 (100%)	133/135 (98.5%)
	Combined	*402/405 (99.3%)*	*398/405 (98.3%)*
Cefoxitin	Instrument 1	81/81 (100%)	79/81 (97.5%)
	Instrument 2	81/81 (100%)	80/81 (98.8%)
	Instrument 3	80/81 (98.8%)	79/81 (97.5%)
	Combined	*242/243 (99.6%)*	*238/243 (97.9%)*
Ceftazidime	Instrument 1	187/189 (98.9%)	186/189 (98.4%)
	Instrument 2	189/189 (100%)	189/189 (100%)
	Instrument 3	188/189 (99.5%)	188/189 (99.5%)
	Combined	*564/567 (99.5%)*	*563/567 (99.3%)*
Ceftriaxone	Instrument 1	27/27 (100%)	27/27 (100%)
	Instrument 2	27/27 (100%)	27/27 (100%)
	Instrument 3	27/27 (100%)	27/27 (100%)
	Combined	*81/81 (100%)*	*81/81 (100%)*
Cefepime	Instrument 1	162/162 (100%)	162/162 (100%)
	Instrument 2	162/162 (100%)	162/162 (100%)

Antibiotic	Colibrí System	Best case[a] (%)	Worst case[b] (%)
	Instrument 3	162/162 (100%)	162/162 (100%)
	Combined	*486/486 (100%)*	*486/486 (100%)*
Aztreonam	Instrument 1	81/81 (100%)	81/81 (100%)
	Instrument 2	81/81 (100%)	81/81 (100%)
	Instrument 3	81/81 (100%)	81/81 (100%)
	Combined	*243/243 (100%)*	*243/243 (100%)*
Meropenem	Instrument 1	108/108 (100%)	108/108 (100%)
	Instrument 2	108/108 (100%)	108/108 (100%)
	Instrument 3	108/108 (100%)	108/108 (100%)
	Combined	*324/324 (100%)*	*324/324 (100%)*
Amikacin	Instrument 1	189/189 (100%)	189/189 (100%)
	Instrument 2	189/189 (100%)	189/189 (100%)
	Instrument 3	188/189 (99.5%)	188/189 (99.5%)
	Combined	*566/567 (99.8%)*	*566/567 (99.8%)*
Gentamicin	Instrument 1	81/81 (100%)	81/81 (100%)
	Instrument 2	81/81 (100%)	81/81 (100%)
	Instrument 3	81/81 (100%)	81/81 (100%)
	Combined	*243/243 (100%)*	*243/243 (100%)*
Tobramycin	Instrument 1	27/27 (100%)	26/27 (96.3%)
	Instrument 2	27/27 (100%)	27/27 (100%)
	Instrument 3	27/27 (100%)	26/27 (96.3%)
	Combined	*81/81 (100%)*	*79/81 (97.5%)*
Levofloxacin	Instrument 1	81/81 (100%)	81/81 (100%)
	Instrument 2	80/81 (98.8%)	80/81 (98.8%)
	Instrument 3	80/81 (98.8%)	80/81 (98.8%)
	Combined	*241/243 (99.2%)*	*241/243 (99.2%)*
Tetracycline	Instrument 1	54/54 (100%)	54/54 (100%)
	Instrument 2	54/54 (100%)	54/54 (100%)
	Instrument 3	54/54 (100%)	54/54 (100%)
	Combined	*162/162 (100%)*	*162/162 (100%)*
Tigecycline	Instrument 1	81/81 (100%)	80/81 (98.8%)
	Instrument 2	81/81 (100%)	80/81 (98.8%)
	Instrument 3	81/81 (100%)	80/81 (98.8%)
	Combined	*243/243 (100%)*	*240/243 (98.8%)*
Nitrofurantoin	Instrument 1	135/135 (100%)	135/135 (100%)
	Instrument 2	135/135 (100%)	134/135 (99.3%)
	Instrument 3	134/135 (99.3%)	134/135 (99.3%)
	Combined	*404/405 (99.8%)*	*403/405 (99.5%)*
Imipenem	Instrument 1	27/27 (100%)	27/27 (100%)
	Instrument 2	27/27 (100%)	27/27 (100%)
	Instrument 3	27/27 (100%)	27/27 (100%)
	Combined	*81/81 (100%)*	*81/81 (100%)*
Ciprofloxacin	Instrument 1	27/27 (100%)	27/27 (100%)
	Instrument 2	27/27 (100%)	26/27 (96.3%)
	Instrument 3	27/27 (100%)	27/27 (100%)
	Combined	*81/81 (100%)*	*80/81 (98.8%)*

[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.

Summary of reproducibility results – Gram-positives Organisms Stratified by Antibiotic

Antibiotic	Colibrí System	Best case (%)	Worst case (%)
Levofloxacin	Instrument 1	243/243 (100%)	243/243 (100%)
	Instrument 2	241/243 (99.2%)	241/243 (99.2%)
	Instrument 3	241/243 (99.2%)	241/243 (99.2%)
	Combined	*725/729 (99.5%)*	*725/729 (99.5%)*
Tetracycline	Instrument 1	27/27 (100%)	27/27 (100%)
	Instrument 2	27/27 (100%)	26/27 (96.3%)
	Instrument 3	27/27 (100%)	27/27 (100%)
	Combined	*81/81 (100%)*	*80/81 (98.8%)*
Tigecycline	Instrument 1	27/27 (100%)	27/27 (100%)
	Instrument 2	27/27 (100%)	27/27 (100%)
	Instrument 3	27/27 (100%)	27/27 (100%)
	Combined	*81/81 (100%)*	*81/81 (100%)*
Nitrofurantoin	Instrument 1	54/54 (100%)	54/54 (100%)
	Instrument 2	54/54 (100%)	54/54 (100%)
	Instrument 3	54/54 (100%)	54/54 (100%)
	Combined	*162/162 (100%)*	*162/162 (100%)*
Ciprofloxacin	Instrument 1	81/81 (100%)	81/81 (100%)
	Instrument 2	81/81 (100%)	81/81 (100%)
	Instrument 3	81/81 (100%)	81/81 (100%)
	Combined	*243/243 (100%)*	*243/243 (100%)*
Penicillin (Benzylpenicillin)	Instrument 1	162/162 (100%)	160/162 (98.8%)
	Instrument 2	162/162 (100%)	159/162 (98.1%)
	Instrument 3	161/162 (99.4%)	159/162 (98.1%)
	Combined	*485/486 (99.8%)*	*478/486 (98.4%)*
Ampicillin	Instrument 1	27/27 (100%)	27/27 (100%)
	Instrument 2	27/27 (100%)	27/27 (100%)
	Instrument 3	27/27 (100%)	27/27 (100%)
	Combined	*81/81 (100%)*	*81/81 (100%)*
Oxacillin	Instrument 1	27/27 (100%)	27/27 (100%)
	Instrument 2	27/27 (100%)	26/27 (96.3%)
	Instrument 3	27/27 (100%)	26/27 (96.3%)
	Combined	*81/81 (100%)*	*79/81 (97.5%)*
Erythromycin	Instrument 1	108/108 (100%)	107/108 (99.1%)
	Instrument 2	108/108 (100%)	108/108 (100%)
	Instrument 3	108/108 (100%)	107/108 (99.1%)
	Combined	*324/324 (100%)*	*322/324 (99.4%)*
Quinupristin/ Dalfopristin	Instrument 1	54/54 (100%)	52/54 (96.3%)
	Instrument 2	54/54 (100%)	53/54 (98.1%)
	Instrument 3	54/54 (100%)	54/54 (100%)
	Combined	*162/162 (100%)*	*159/162 (98.1%)*
Linezolid	Instrument 1	108/108 (100%)	108/108 (100%)
	Instrument 2	108/108 (100%)	108/108 (100%)
	Instrument 3	108/108 (100%)	108/108 (100%)
	Combined	*324/324 (100%)*	*324/324 (100%)*
Vancomycin	Instrument 1	189/189 (100%)	188/189 (99.5%)
	Instrument 2	189/189 (100%)	188/189 (99.5%)

Antibiotic	Colibrí System	Best case (%)	Worst case (%)
	Instrument 3	189/189 (100%)	188/189 (99.5%)
	Combined	*567/567 (99.2%)*	*564/567 (99.5%)*

[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.

Purity Plate Growth

In total, 2,364 purity plates have been prepared by different Colibrí™ Preparation Station throughout the analytical studies used to support the AST microbial suspension function of the Colibrí System, starting from Secondary Tubes of VITEK® 2, inoculated with various microbial strains. All the purity plates (2364/2364, 100%) were correctly processed and provided evidence of absence of microbial contamination of the Secondary Tubes, demonstrating that Colibrí™ Preparation Station is able to prepare monomicrobial suspensions by picking precisely the designated colonies from the culture plates and to prevent the cross-contamination between the specimens.

Sample preparation for Quality Control

The study was performed to demonstrate the reproducibility of MIC results for AST Quality Control organisms listed in CLSI M100 using the Colibrí System as suspension preparator.

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 AST analyzer labeling, resulting in 100% in-range MIC values. Purity of all the suspensions was confirmed by Purity Plates prepared by Colibrí System. The summary of results is in the table below.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Colibrí System, consisting of Colibrí Vision System and Colibrí 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

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, labelling 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 61010-2:101, IEC 61010-2:081, IEC 60825-1, IEC 61326-1, IEC 61326-2:6, IEC 60601-1-2:2014, CLSI M100, CLSI M52, CLSI M52, IEC 62304 and IEC 62366-1.

The Analytical Studies results demonstrated that the Colibrí System when used in conjunction with its parental devices 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 guidance.