March 20, 2023

Copan WASP Srl
Chiara Congiu
Regulatory Affairs
Via A. Grandi, 32
Brescia, Brescia 25125
Italy

Re: K223245
Trade/Device Name: Colibrí
Regulation Number: 21 CFR 866.3378
Regulation Name: Clinical Mass Spectrometry Microorganism Identification And Differentiation System
Regulatory Class: Class II
Product Code: QQV, QBN, LON
Dated: December 21, 2022
Received: December 21, 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,

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)*
K223245

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 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 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.

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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
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

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

III. Legally Marketed Predicate Device

Device Name	Colibrí System
510(K) Number	K220546

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 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 Colibrí 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 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, 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 System, 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, 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. Run-time 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 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 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.

The conjunction of Colibrí device with WASPLab device does not change, expand or limit the intended use of the Predicate Device and does not affect the safety and effectiveness of the predicate.

Both the Colibrí in conjunction with WASPLab device and the Predicate Device are intended for the preparation of target ID and AST microbial suspensions of colonies grown on culture media plates streaked with human specimens indicated as an aid in the diagnosis and treatment definition for the bacterial infections.

Similarities		
Item	**New Device**	**Predicate Device**
Device Name (K number)	**Colibrí**	**Colibrí System (K220546)**
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 or Bruker MALDI Biotyper CA mass spectrometry systems for qualitative identification and microbial suspensions for the bioMérieux VITEK 2	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

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

Similarities		
Item	**New Device**	**Predicate Device**
Device Name (K number)	**Colibrí**	**Colibrí System (K220546)**
	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 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.	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.
Method of testing	Direct testing from isolated colonies for ID purposes in conjunction with bioMérieux VITEK MS or Bruker MALDI Biotyper CA System. Direct testing from isolated colonies for AST purposes in conjunction with bioMérieux VITEK 2.	Same
Sample/Media Type	Isolated bacterial colonies from any patient source grown on plates included in K193138 and K220546.	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, 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.	Same

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Similarities		
Item	**New Device**	**Predicate Device**
Device Name (K number)	**Colibrí**	**Colibrí System (K220546)**
	When connected with MALDI Biotyper CA instrument, 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 instrument.	
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-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 must be tested in MANUAL MODE on the VITEK 2.	Same
Calibration	Colibrí requires four different calibrations, one on the nephelometer, three on the cameras. None of these calibration activities require user intervention.	Same
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 System (K220546)**
Plate management	Automatic plate loading for image capturing that is performed according to set image protocol.	Manual loading for image capturing and selection by the operator of media plate type.
Plate incubation	Automatic and managed by the WASPLab.	Manual.

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

VII. Performance Data

Colibrí uses equally designed and developed hardware and software modules as the Colibrí System. Therefore, the performance of the predicate device represents the performance of the new device. The results of the analytical studies were submitted to support the 510(k) Premarket Notifications K193138 and K220546 and showed that Colibrí technology allow the preparation of target slides for MALDI-TOF identifications and microbial suspension for AST with good performance regarding the:

- Accuracy of colony picking from culture plates
- Reproducibility of identification results
- Inclusivity of species and genera with different colony morphologies and characteristics and at various incubation times
- Absence of positional effect on the target slides
- Stability of the spots with and without the matrix
- Accuracy of the on-board nephelometer
- Accuracy of microbial content of the suspensions for AST
- Accuracy of AST results, including between-instruments and operators' reproducibility
- On-board reagent stability
- Absence of carry-over

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

Full workflow validation

This study aims to demonstrate the accuracy of Colibrí in picking designated colonies of different microbial species, selected by the laboratory technologist using WASPLab WebApp, for the preparation of target slides for MALDI-TOF identification and of microbial suspensions for AST.

Three Colibrí interfaced with three WASPLab were used to pick isolated colonies from mixed cultures prepared with gram-positive and gram-negative strains, to prepare target slides for microbial identification and microbial suspensions for AST. Strains were selected to be representative of different species of *Enterobacterales* (n=4), *Staphylococcus* (n=2), *Streptococcus* (n=1), *Enterococcus* (n=2) and non-fermenters (n=1), including "on-panel" species for VITEK MS exhibiting a range of on-scale MIC values toward at least 4 antibiotics representative for the major classes of drugs in VITEK 2 cards.

After the automatic preparation, the target slides were analysed by the mass spectrometer and microbial suspensions were associated to the appropriate card of antibiotics to perform susceptibility testing. Furthermore, processed plates were visually inspected by the operator in comparison to the colonies designated on the plate image in WASPLab WebApp to verify that were successfully picked by the Colibrí. For microbial identification, performance was calculated as percentage of spotted colonies matching the expected identity; for AST, the MICs obtained by bioMérieux VITEK 2 using Colibrí 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.

Colonies designated by the operator were 100% correctly picked without any event in which a wrong colony was picked, providing evidence that the picking coordinates defined by WASPLab software are correct and are successfully interpreted by Colibrí. For the VITEK MS, a total of 292 spots were prepared and 98.6% of designated colonies has been identified correctly with high confidence in comparison to the expected strain identity. Data show that no incorrect identification occurred on spots prepared by the Colibrí and that it was always able to accurately pick designated colonies.

The results are summarized in the tables below. Due to the high degree of agreement between MICs determined from samples prepared manually and samples prepared by the Colibrí with WASPLab (with both EA and CA ≥98% for each antimicrobial agent/organism group tested), the AST accuracy was deemed acceptable. In addition, and since this is a method-to-method comparison, the cumulative results for all antimicrobial agents and species combined were evaluated. For all species and antimicrobial agents, 100% (1315/1315) of on-scale MIC results were in EA and 99.4% (2703/2720) were in CA with the comparator result. No very major or major errors occurred.

Identification results of the Colibrí obtained with the bioMérieux VITEK MS stratified per gram-negative species.

Expected Organism Identity	Culture Medium	Strains Tested	Colonies Picked	VITEK MS Identification Result			% Agreement*	
				Good Confidence	Low Discrimination	No ID	Culture Medium	Species/ Group
Citrobacter koseri	TSA	1	10	10	--	--	100%	100%
	MAC	1	11	11	--	--	100%	
Escherichia coli	TSA	1	14	14	--	--	100%	100%
	MAC	1	9	9	--	--	100%	
Klebsiella pneumoniae	TSA	1	7	7	--	--	100%	100%
	MAC	1	9	9	--	--	100%	
Proteus mirabiliis	TSA	1	7	7	--	--	100%	100%
	MAC	1	8	8	--	--	100%	
Pseudomonas aeruginosa	TSA	1	8	8	--	--	100%	100%
	MAC	1	9	9	--	--	100%	
TOTAL	**2**	**5**	**92**	**92**	**--**	**--**	**100%**	**100%**

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

Identification results of the Colibrí obtained with the bioMérieux VITEK MS stratified per gram-positive species.

Expected Organism Identity	Strains Tested	Colonies Picked	VITEK MS Identification Result			% Agreement*
			Good Confidence	Low Discrimination	No ID	
Enterococcus faecalis	1	40	39	--	1	97.5%
Enterococcus faecium	1	40	38	--	2	95.0%
Staphylococcus aureus	1	40	40	--	0	100%
Staphylococcus saprophyticus	1	40	40	--	0	100%
Streptococcus agalactiae	1	40	39	--	1	97.5%
TOTAL	**5**	**200**	**196**	**--**	**4**	**98.0%**

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

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AST 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*	80	80	100.0%	80	80	100.0%	80	80	100.0%	80	0	0	0	0
	Non-fermenters	20	20	100.0%	20	20	100.0%	20	20	100.0%	20	0	0	0	0
Ampicillin	*Enterococcus*	40	40	100.0%	20	20	100.0%	40	40	100.0%	20	20	0	0	0
	Streptococcus	20	20	100.0%	0	0	N/A	20	20	100.0%	20	0	0	0	0
Ampicillin / Sulbactam	*Enterobacterales*	60	60	100.0%	20	20	100.0%	60	59	98.3%	20	40	0	0	1
Aztreonam	*Enterobacterales*	80	80	100.0%	40	40	100.0%	80	80	100.0%	20	60	0	0	0
Cefazolin	*Enterobacterales*	60	60	100.0%	0	0	N/A	60	60	100.0%	0	60	0	0	0
Cefepime	*Enterobacterales*	80	80	100.0%	80	80	100.0%	80	76	95.0%	40	0	0	0	4
	Non-fermenters	20	20	100.0%	20	20	100.0%	20	20	100.0%	20	0	0	0	0
Cefotaxime	*Streptococcus*	20	20	100.0%	0	0	N/A	20	20	100.0%	20	0	0	0	0
Cefoxitin	*Enterobacterales*	80	80	100.0%	38	38	100.0%	80	80	100.0%	20	60	0	0	0
Ceftazidime	*Enterobacterales*	80	80	100.0%	80	80	100.0%	80	76	95.0%	0	40	0	0	4
	Non-fermenters	20	20	100.0%	20	20	100.0%	20	20	100.0%	20	0	0	0	0
Ceftriaxone	*Enterobacterales*	80	80	100.0%	20	20	100.0%	80	80	100.0%	0	80	0	0	0
	Streptococcus	20	20	100.0%	0	0	N/A	20	20	100.0%	20	0	0	0	0
Ciprofloxacin	Non-fermenters	20	20	100.0%	0	0	N/A	20	20	100.0%	20	0	0	0	0
	Staphylococcus	40	40	100.0%	20	20	100.0%	40	40	100.0%	20	0	0	0	0
	Enterococcus	40	40	100.0%	40	40	100.0%	40	40	100.0%	20	0	0	0	0
Clindamycin	*Staphylococcus*	40	40	100.0%	0	0	N/A	40	40	100.0%	20	20	0	0	0
	Streptococcus	20	20	100.0%	0	0	N/A	20	20	100.0%	20	0	0	0	0
Ertapenem	*Enterobacterales*	80	80	100.0%	0	0	N/A	80	80	100.0%	60	20	0	0	0
Erythromycin	*Staphylococcus*	40	40	100.0%	0	0	N/A	40	40	100.0%	20	20	0	0	0
	Enterococcus	40	40	100.0%	20	20	100.0%	40	40	100.0%	0	20	0	0	0
	Streptococcus	20	20	100.0%	19	19	100.0%	20	20	100.0%	0	20	0	0	0

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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*	80	80	100.0%	20	20	100.0%	80	80	100.0%	60	20	0	0	0
	Non-fermenters	20	20	100.0%	20	20	100.0%	20	20	100.0%	20	0	0	0	0
	Staphylococcus	40	40	100.0%	0	0	N/A	40	40	100.0%	20	20	0	0	0
Imipenem	Non-fermenters	20	20	100.0%	20	20	100.0%	20	20	100.0%	20	0	0	0	0
Levofloxacin	*Enterobacterales*	80	80	100.0%	20	20	100.0%	80	80	100.0%	0	60	0	0	0
	Non-fermenters	20	20	100.0%	20	20	100.0%	20	19	95.0%	20	0	0	0	1
	Staphylococcus	20	20	100.0%	20	20	100.0%	20	20	100.0%	20	0	0	0	0
	Enterococcus	40	40	100.0%	40	40	100.0%	40	40	100.0%	20	0	0	0	0
	Streptococcus	20	20	100.0%	20	20	100.0%	20	20	100.0%	20	0	0	0	0
Linezolid	*Staphylococcus*	40	40	100.0%	40	40	100.0%	40	40	100.0%	40	0	0	0	0
	Enterococcus	40	40	100.0%	40	40	100.0%	40	40	100.0%	40	0	0	0	0
	Streptococcus	20	20	100.0%	0	0	N/A	20	20	100.0%	20	0	0	0	0
Meropenem	*Enterobacterales*	80	80	100.0%	20	20	100.0%	80	80	100.0%	60	20	0	0	0
	Non-fermenters	20	20	100.0%	20	20	100.0%	20	20	100.0%	20	0	0	0	0
Moxifloxacin	*Staphylococcus*	40	40	100.0%	0	0	N/A	40	40	100.0%	40	0	0	0	0
Nitrofurantoin	*Enterobacterales*	80	80	100.0%	80	80	100.0%	80	77	96.3%	0	40	0	0	3
	Staphylococcus	40	40	100.0%	0	0	N/A	40	40	100.0%	40	0	0	0	0
	Enterococcus	40	40	100.0%	20	20	100.0%	40	40	100.0%	20	20	0	0	0
Oxacillin	*Staphylococcus*	40	40	100.0%	20	20	100.0%	40	40	100.0%	0	40	0	0	0
Penicillin (Benzyl-penicillin)	*Enterococcus*	40	40	100.0%	39	39	100.0%	40	40	100.0%	20	20	0	0	0
	Streptococcus	20	20	100.0%	20	20	100.0%	20	20	100.0%	20	0	0	0	0
	Staphylococcus	40	40	100.0%	19	19	100.0%	40	40	100.0%	0	40	0	0	0
Piperacillin / Tazobactam	*Enterobacterales*	80	80	100.0%	40	40	100.0%	80	76	95.0%	60	20	0	0	4
	Non-fermenters	20	20	100.0%	20	20	100.0%	20	20	100.0%	20	0	0	0	0
Quinupristin / Dalfopristin	*Staphylococcus*	40	40	100.0%	40	40	100.0%	40	40	100.0%	40	0	0	0	0
Tetracycline	*Enterobacterales*	80	80	100.0%	40	40	100.0%	80	80	100.0%	40	40	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
	Staphylococcus	40	40	100.0%	0	0	N/A	40	40	100.0%	20	20	0	0	0
	Enterococcus	40	40	100.0%	0	0	N/A	40	40	100.0%	0	40	0	0	0
	Streptococcus	20	20	100.0%	0	0	N/A	20	20	100.0%	0	20	0	0	0
Tigecycline	*Enterobacterales*	80	80	100.0%	40	40	100.0%	80	80	100.0%	60	20	0	0	0
	Staphylococcus	20	20	100.0%	0	0	N/A	20	20	100.0%	20	0	0	0	0
	Enterococcus	20	20	100.0%	0	0	N/A	20	20	100.0%	20	0	0	0	0
	Streptococcus	20	20	100.0%	0	0	N/A	20	20	100.0%	20	0	0	0	0
Tobramycin	*Enterobacterales*	80	80	100.0%	20	20	100.0%	80	80	100.0%	0	60	0	0	0
	Non-fermenters	20	20	100.0%	0	0	N/A	20	20	100.0%	20	0	0	0	0
Trimethoprim / Sulfamethoxazole	*Enterobacterales*	80	80	100.0%	0	0	N/A	80	80	100.0%	0	80	0	0	0
Vancomycin	*Staphylococcus*	40	40	100.0%	20	20	100.0%	40	40	100.0%	40	0	0	0	0
	Enterococcus	40	40	100.0%	40	40	100.0%	40	40	100.0%	40	0	0	0	0
	Streptococcus	20	20	100.0%	20	20	100.0%	20	20	100.0%	20	0	0	0	0

AST summary of results, organism group

Group	Total tested	# EA	% EA	Total Evaluable	# EA of Evaluable	% EA of Evaluable	Total categ.	# CA	% CA	# S	# R	# vmj	# maj	# min
Enterobacterales	1400	1400	100.0%	638	638	100.0%	1400	1384	98.9%	520	720	0	0	16
Non-fermenters	200	200	100.0%	160	160	100.0%	200	199	99.5%	200	0	0	0	1
Staphylococci	520	520	100.0%	179	179	100.0%	520	520	100.0%	340	160	0	0	0
Enterococci	380	380	100.0%	259	259	100.0%	380	380	100.0%	200	120	0	0	0

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

510(k) Summary

Group	Total tested	# EA	% EA	Total Evaluable	# EA of Evaluable	% EA of Evaluable	Total categ.	# CA	% CA	# S	# R	# vmj	# maj	# min
Streptococci	220	220	100.0%	79	79	100.0%	220	220	100.0%	180	40	0	0	0

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

Conclusions:

The predicate device, Colibrí System and the new device, Colibrí both utilize the same technology for the preparation of the MALDI-TOF targets and the AST microbial suspensions. The minor differences between the devices do not adversely affect safety and effectiveness. The submitted documentation demonstrates that the subject device is substantially equivalent to the predicate device.